

Data quality assessment of the Major Trauma Registry of Navarra and comparison of its results with TraumaRegistry DGU[®] of the German Trauma Society

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“Have patience. Allah does not deny the rewards of the righteous.”

(The Holy Quran 11: 115)

**To my mother, my father, my wife,
my brothers, my sister and my niece
To family and friends who believe in me**

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1 ABSTRACT

Background: Trauma registries are useful tools to assess and improve trauma care through benchmarking. In Spain, data are limited at national level, while most of the well-established trauma registries are at regional or provincial level, such as the Major Trauma Registry of Navarra (MTR-N) in Navarra, a region in northern Spain. The effectiveness of trauma registries in improving patient outcomes depends on data quality. Therefore, the aim of this thesis was to study the data quality of the MTR-N and to evaluate the treatment and outcome of the severely injured patients in Navarra through internal and external comparison (Germany).

Methods: We assessed the data quality of MTR-N in terms of completeness of cases, completeness of data and concordance of MTR-N data by evaluating patient's medical records. Regarding completeness of cases, the Standardized Mortality Ratio (SMR), the ratio between observed and expected mortality, was calculated using Trauma and Injury Severity Score (TRISS). We also evaluated the influence of prehospital response times with regard to survival of trauma patients in Navarra. For internal benchmarking, the mortality prediction model of Navarra (MPMN) was internally validated and compared to the Revised Injury Severity Classification Score II (RISC II), a prediction model developed by the German Trauma Registry (TraumaRegister DGU[®] (TR-DGU[®])). The performance of the models was evaluated by assessing model discrimination (Area under the Receiver Operating Characteristic (AUROC) and model calibration (Hosmer-Lemeshow test (H-L)). For international benchmarking, we compared data collected in the MTR-N and the TR-DGU[®] and we calculated the SMR using the RISC II. Thirty-day-mortality was used for the trauma scoring system.

Results: Different populations were used to meet the objectives of the study. Regarding the completeness of the cases, we defined the characteristic profiles of missing patients and found that the hospital RTS and the number of injuries are independent predictors to be missing in the MTR-N with an adjusted odds ratio of 1.844 (95% CI 1.092-3.114) and 0.574 (0.428-0.770), respectively. They are usually elderly patients with a single head injury. The difference between the observed and expected mortality for missing patients was -1.5% (SMR 0.83) and 0.5% (SMR 0.98) for included patients. The overall average completeness and correctness rate for all variables was 92.8% (95% CI, 92.0–93.8) and 98.0% (97.5–98.5),

respectively. No significant association was found in the multivariate analysis between the different response times and mortality: arrival at the scene (OR 1.0; 95% CI, 0.99-1.01), in the scenario (1.00, 0.98-1.02) and total time (1.00; 0.99-1.01).

The AUROC for the MPMN model was 0.92 (95% CI 0.90-0.95) and for the RISC II model was 0.94 (0.92-0.96), with no statistical difference between the models (DeLong $p = 0.269$). Both models displayed good calibration with no statistical difference between observed and predicted mortality ($p=0.09$ for MPMN and $p=0.35$ for RISC II).

For the epidemiological comparison between both systems, 646 patients from Navarra and 43,110 from Germany were statistically processed. The number of traffic accidents was higher in the TR-DGU[®] compared to the MTR-N (55.6% vs. 36.3%), while in the hospitals in Navarra, more low-height falls were observed in comparison with German hospitals (34.5% vs. 20.0%). Prehospital intubation rates were higher in Germany than in Navarra (36.6% vs. 11.8%, respectively). Patients with Glasgow <9 on the scene were intubated more frequently by German prehospital teams compared to prehospital emergency teams in Navarra. The difference between observed and expected mortality was -0.4% (SMR 0.97; 95% CI 0.93–1.04) in Germany and 1.6% (1.08; 1.02–1.14) in Navarra.

Conclusions: The evaluation of the data quality of the MTR-N in terms of completeness of data and concordance of the cases shows that it contains reliable and high-quality data although there is a non-negligible number of patients not included. Excluded patients displayed a specific injury profile, despite fulfilling inclusion criteria. These were often elderly patients (often women) with associated comorbidities and isolated head injury. The MPMN and RISC II models have shown good discrimination and calibration for 30-day mortality prediction in severe trauma patients documented in MTR-N. While the RISC II is applicable for external benchmarking, in the case of internal benchmarking, the MPMN is suitable for Navarra's trauma system as it is easier to obtain given the lower number of variables needed for its calculation. The overall adjusted outcome of severely injured patients treated in Navarra is comparable to that of Germany. However, improvements are necessary at prehospital and hospital level to increase trauma quality care in Navarra. There were less young adults with severe injuries in Navarra than in Germany.

Regularly reviews of the management of severe trauma patients are necessary to detect areas for improvement.

Keywords: severe trauma, prediction models, data quality, quality of trauma care, mortality, epidemiology, trauma registries.

RESUMEN

Antecedentes: Los registros de trauma son herramientas útiles para evaluar y mejorar la atención de los pacientes a través de la comparación con otros. En España los datos son limitados a nivel nacional y la mayoría de los registros de traumatismos establecidos son regionales o provinciales, como el Registro de Trauma Grave de Navarra (RTG-N). Es evidente que la efectividad de los registros de trauma para mejorar los resultados depende de la calidad de los datos. Por lo tanto, el objetivo de este estudio fue conocer la fiabilidad de los datos del RTG-N y evaluar el tratamiento y resultado del paciente gravemente herido en Navarra mediante la comparación interna y externa (Alemania).

Métodos: Evaluamos la calidad de los datos de RTG-N en términos de integridad de los casos, integridad de datos y concordancia del RTG-N con las historias clínicas de los pacientes. Se comprobó la integridad de los casos, el índice de mortalidad estandarizada (IME) y la relación entre la mortalidad observada y la esperada utilizando el *Trauma and Injury Severity Score* (TRISS). También evaluamos la influencia de los tiempos de respuesta prehospitalarios con respecto a la supervivencia de dichos pacientes. Para la comparación interna, el modelo de Predicción de Mortalidad de Navarra (MPMN) fue validado y comparado con el *Revised Injury Severity Classification Score II* (RISC II), un modelo de predicción desarrollado por el registro alemán. El rendimiento de los modelos se evaluó con la característica operativa del receptor (COR) y el área bajo la curva (ABC), la precisión con la mortalidad observada y predicha, y la calibración con la prueba *Hosmer-Lemeshow* (H-L). Los datos de los pacientes del RTG-N se compararon con los del registro alemán, *TraumaRegister DGU*[®] (TR-DGU[®]) and el IME se calculó utilizando el RISC II.

Resultados: Para cumplir los objetivos del estudio se utilizaron diferentes poblaciones. En cuanto a la integridad de los casos, definimos los perfiles característicos de los pacientes desaparecidos y encontramos que el RTS hospitalario y el número de lesiones son predictores independientes de los pacientes que faltan en el RTG-N con un *odds-ratio* ajustado de 1.844 (IC 95% 1.092- 3.114) y 0.574 (0.428-0.770), respectivamente. Por lo general, son mujeres de edad avanzada con una sola lesión en la cabeza. La diferencia entre la mortalidad observada y la esperada para los pacientes no incluidos fue de -1.5% (IME 0.83) y 0.5% (IME 0.98) para los

pacientes incluidos. El promedio general de integridad y la tasa de corrección para todas las variables fue de 92.8% (IC 95%, 92.0-93.8) y 98.0% (97.5-98.5), respectivamente. No se encontró asociación significativa en el análisis multivariado entre los diferentes tiempos de respuesta y la mortalidad: llegada al lugar (OR 1.0, IC 95%, 0.99-1.01), en el escenario (1.00, 0.98-1.02) y tiempo total (1.00; 0.99-1.01).

El ABC de la curva COR para el modelo MPMN fue 0.925 (IC 95% 0.902-0.952) y para el modelo RISC II fue 0.941 (IC 95% = 0.921-0.962) (p DeLong = 0.269). Ambos modelos mostraron una buena calibración sin diferencia significativa entre la mortalidad observada y la esperada (p = 0.09 para el modelo MPMN y p = 0.35 para el modelo RISC II).

Para la comparación epidemiológica entre ambos sistemas, se procesaron estadísticamente 646 pacientes de Navarra y 43.110 de Alemania. El número de accidentes de tráfico fue mayor en el TR-DGU® en comparación con el RTG-N (55,6% frente al 36,3%), mientras que en los hospitales de Navarra se observaron más caídas de baja altura en comparación con los hospitales alemanes (34,5%. vs. 20.0%). Las tasas de intubación prehospitalaria fueron más altas en Alemania que en Navarra (36,6% frente a 11,8%, respectivamente). Los pacientes con Glasgow <9 en escena fueron más intubados por los equipos sanitarios prehospitalarios alemanes que sus homólogos de Navarra. La diferencia entre la mortalidad observada y la esperada fue de -0.4% (IME 0.97, IC 95% 0.93-1.04) en Alemania y 1.6% (1.08; 95%; 1.02-1.14) en Navarra.

Conclusiones: La evaluación de la calidad de los datos del RTG-N en términos de integridad de datos y concordancia de los casos demuestra que contiene datos fiables y de alta calidad si bien hay un número no despreciable de pacientes no incluidos con un perfil muy concreto. A menudo se trataba de pacientes de edad avanzada (mujeres) con comorbilidades asociadas y lesión craneal aislada. Los modelos MPMN y RISC II han demostrado una buena discriminación para predicción de la mortalidad a 30 días en pacientes con trauma severo documentados en RTG-N. Mientras que el RISC II es aplicable para la evaluación comparativa externa, en el caso de la evaluación comparativa interna, el MPMN es adecuado para el sistema traumatológico de Navarra, ya que es más fácil de obtener dado el menor número de variables necesarias para su cálculo. El resultado global ajustado de los pacientes con

lesiones graves tratados en Navarra es comparable al de Alemania. Sin embargo, se necesitan mejoras a nivel prehospitalario y hospitalario para aumentar la calidad de la atención traumatológica en Navarra. Hubo menos adultos jóvenes con lesiones graves en Navarra que en Alemania. Es necesario revisar continuamente el manejo del paciente traumatizado para detectar puntos de mejora en su asistencia.

Palabras clave: trauma severo, modelos de predicción, calidad de los datos, calidad de la atención traumatológica, mortalidad, epidemiología, registros de trauma.

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3 LIST OF ABBREVIATIONS

Abbreviated Injury Scale	AIS
Accident and Emergency Department	A & E
American College of Surgeons Committee on Trauma	ACS-COT
American Society of Anaesthesiologists Physical Status	ASA-PS
Area Under Curve	AUC
<i>Complejo Hospitalario de Navarra</i>	CHN
Computerized Tomography	CT
Confidence Interval	CI
European Union	EU
Glasgow Coma Scale	GCS
Global Burden Disease Study	GBD
Hosmer-Lemeshow test	H-L
Injury Severity Score	ISS
Intensive Care Unit	ICU
International Classification of Diseases Injury Severity Score	ICISS
International Classification of Diseases-ninth-Clinical Modification	ICD-9CM
International Normalized Ratio	INR
Major Trauma Outcome Study	MTOS
Major Trauma Registry of Navarra	MTR-N
Mortality Prediction Model of Navarra	MPMN
National Trauma Data Bank	NTDB
New Injury Severity Score	NISS
Odds Ratio	OR
Receiver Operating Characteristic	ROC
Respiratory Rate	RR
Revised Injury Severity Classification	RISC
Revised Injury Severity Classification, version II	RISC II
Revised Trauma Score	RTS
Structural Deformity Index	SDI
Survival Risk Rates	SRR
Systolic Blood Pressure	SBP
Trauma and Injury Severity Score	TRISS
Trauma Audit and Research Network	TARN
Traumatic Brain Injury	TBI
Triage-RTS	T-RTS

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5 LIST OF PUBLICATIONS

This thesis is based on the five publications shown below. The publications are referred to in the text by their roman numerals.

Paper I

Ali B, Fortún M, Belzunegui T, Ibañez B, Cambra K, Galbete A. Missing patients in “Major Trauma Registry” of Navarre: incidence and pattern. *Eur J Trauma Emerg Surg* 2017;43(5):671-83.

Paper II

Ali B, Lefering R, Belzunegui T. Quality assessment of Major Trauma Registry of Navarre: Completeness and correctness. Submitted to *International Journal of Injury Control and Safety Promotion*.

Paper III

Ali B, Fortun M, Belzunegui T, Teijeira R, Reyero D, Cabodevilla A. Influence of prehospital response times in the survival of trauma patients in Navarre. *An. Sist. Sanit. Navar.* 2015; 38:283-292.

Paper IV:

Ali B, Lefering R, Fortun M, Belzunegui T. Validation of the Revised Injury Severity Classification Score II and of the Mortality Prediction Model of Navarre. *Emergencias* (Accepted for publication).

Paper V

Ali B, Lefering R, Fortun M, Belzunegui T. Epidemiological comparison of severely injured patients between Navarre (Spain) and Germany. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine* 2017;25:107.

6 INTRODUCTION

Severe trauma is an important health problem that requires a multidisciplinary approach, including for example emergency medical service, trauma physicians and rehabilitation physicians (1). Any attempt to improve the quality of trauma care requires thorough monitoring (2). Monitoring is often done using trauma registries that can help us analyze the results of the given treatment (2).

The performance of a trauma system can be reviewed on a regular basis and compared with previous data from the same institution (internal benchmarking) (3,4). In addition, one can compare data from other institutions (external benchmarking) or against a recognized standard (3,4). A prerequisite for benchmarking is a statistically validated outcome prediction model (3).

In previous decades, several models have been developed to predict mortality or survival in trauma patients (5). A frequently used and cited model is the Trauma and Injury Severity Score (TRISS) (5). The heterogeneity of the trauma population makes it difficult to apply one accurate model for both minor and major injuries while also being applicable to all age groups (5). Therefore, many registries have developed their prediction models like PS06 in Trauma Audit and Research Network (TARN), Revised Injury Severity Classification version II (RISC II) in German Trauma Registry, etc. (6,7).

In Spain, however, no strict national guidelines for pre- or intra-hospital care of trauma patients exist, nor is there any nationwide trauma registry. Until 2014, Navarra, a region in the north of Spain, was the only province with a population based trauma registry following the recommendations of uniform Utstein style for documentation of severe trauma patients in Europe (8). To assess Navarra's trauma care, the Mortality Prediction Model of Navarra (MPMN) was developed in 2013 (9), although it has not been validated up until now.

Continuous measurement and evaluation of a trauma system's performance against other trauma systems is necessary to gain information about best available treatments. For this purpose, all benchmarking processes should start with internal benchmarking as it provides a baseline for comparison with others.

On the other hand, the effectiveness of trauma registries in improving patient outcomes depends on data quality (10,11). It has been shown that quality problems in clinical registries significantly affect quality-of-care evaluation results. Few studies have evaluated data quality in trauma registries, and studies that have done this have primarily focuses of data completeness (11). Trauma registries are subject to data quality issues in terms of completeness, accuracy, and consistency. Despite the critical importance of data quality for the validity of analyses based on trauma registries, our understanding of data quality in trauma registries is limited (10,11).

The principal objective of this thesis was to study the data quality of Major Trauma Registry of Navarra (MTR-N). Secondly, the thesis aimed to evaluate quality of Navarra's trauma care, through an internal benchmarking process (within Navarra's trauma system) and international comparison (between Navarra and Germany) through respective trauma registries.

7 REVIEW OF THE LITERATURE

7.1 Definitions: Trauma & Major Trauma

Trauma is defined as the acute physiological and structural change (injury) that occurs in a patient's body when an external source of energy dissipates faster than the body's ability to sustain and dissipate it (12). Trauma can therefore cross a spectrum from minor to major life-threatening events. Trauma and injury are often used interchangeably. Trauma (or injury) includes intentional and unintentional injury from motor vehicle crashes, penetrating or blunt violence, falls, firearms, poisoning, and burns (13).

The American College of Surgeons Committee on Trauma (ACS-COT) explains trauma as a bodily injury that may encompass a large range of severity (14). The current view of trauma, according to the ACS-COT, has focused primarily on those injuries that are life-threatening and could be life changing because it may result in long-term disability, also known as major trauma.

The definition of major trauma is fundamental as it provides the reference standard against which triage guidelines will be tested (15). There is a 40-year tradition of grading the severity of individual injuries using the Abbreviated Injury Scale (AIS) (16), and based on this scale, the Injury Severity Score (ISS) can be calculated as the sum of the squares of the highest AIS code in each of the three most severely injured ISS body regions (17). In the United States, Major Trauma Outcome Study (MTOS) an ISS of >15 was associated with a mortality risk of at least 10% and related to a distinct flex in the mortality curve (18). In addition, most trauma registries use the MTOS definition of major trauma as an ISS score of >15 (19–24).

Several limitations of the ISS have been highlighted (25,26), giving rise to the New Injury Severity Score (NISS) (25). The NISS is a simple modification of the ISS and is calculated the sum of the squares of the three most worst AIS injuries regardless of body region (25). In addition, NISS has shown better outcome prediction than ISS in several studies (27–29). The definition of Major Trauma is commonly based on anatomic injury alone, and both ISS >15 and NISS > 15 are recommended cut-off values (15). However, the increased number of included patients by choosing NISS >15

instead of ISS >15 should be seen as an increase in sensitivity without a loss of specificity, implying that NISS >15 is superior to ISS >15 as a definition of Major Trauma (8,15,27,28).

7.2 Epidemiology of Major Trauma

Severe or Major Trauma is a pandemic disease and one of the leading causes of death and disability (30,31). According to the Global Burden Disease Study (GBD) in 2010, the fraction of global deaths due to injuries (5.1 million deaths) was marginally higher in 2010 (9.6%) compared with two decades earlier (8.8%). This was driven by a 46% rise in deaths worldwide due to road traffic accidents (1.3 million in 2010) and a rise in deaths from falls (32). By 2030, the World Health Organization (WHO) has estimated that road traffic accidents will be the fourth leading cause of death (in the baseline scenario), and the third leading cause of death, ahead of ischaemic heart disease, in the optimistic scenario (33). It is well known that the burden of injuries on population health is not limited to mortality or short-term impact (34,35). According to the GBD, in the year of 2010, the global burden of disease was 2490 million disability-adjusted life years (361/1000 inhabitants), of which trauma accounted for 278.6 million disability-adjusted life years (11.2%) (31).

In the European Union (EU), injuries due to accidents and violence are a major public health problem, killing more than 230,000 people each year (annual average 2008-2010) and disabling many more (36). Suicides, road accidents and low falls are the three main causes of fatal injuries, together representing 58% of all injury deaths (36). Injuries are the leading cause of death for young people, from early childhood, until middle age. Between 1 and 14 years of age, injuries are responsible for 28% of all deaths of children (36). Of particular note, the death rates of children in poorer countries are higher than those in richest countries (36–38).

Annually, 123,000 people in the EU aged 60 and above die due to trauma, which represents 53% of all trauma deaths. Low falls are the main cause (28%) of fatal injuries among older people, particularly for women. There are considerable differences in the injury fatality rates of the senior population among the EU member states - e. g. the share of injury deaths compared to all deaths of people above 65 years of age ranges from 1% in Greece to 6% in Slovenia) (36).

Moreover, injuries are an important source of direct medical costs as well as indirect costs resulting from economic production losses; in the Netherlands for example, the direct costs of injury represents 5% of the health care budget whereas in Spain the total costs associated with road traffic accidents alone account for 1.35% of the gross national product (39).

The difference between and within countries indicate a high potential for reducing injury mortality in certain areas. To reduce mortality and morbidity due to trauma, in 2010, competent governmental authorities from 22 countries signed up for a Joint Action for Injury Monitoring in Europe aiming to have by 2015 one common hospital-based injury data collection system in their countries/ regions (40).

7.3 Trauma in Spain

In Spain, the National Statistics Institute (INE) registered the deaths of 390,419 people in the year 2013 (41). According to the distribution by chapters of the International Classification of Diseases-ninth-Clinical Modification (ICD-9CM) (42), deaths due to external causes were 14,678 (3.8% of the total), and represented the leading cause of mortality among individuals between 10 and 39 years of age (3.4 and 13.0 deaths per 100,000 inhabitants) (41). In 2013, 1,807 people died in Spain in traffic accidents. The annual decrease in the incidence of traffic accidents and the consequent morbidity and mortality can be attributed to a point penalty system, the gradual intensification of surveillance measures and sanctions, and the publicity given to road safety issues (43–45), and it has been reported by several trauma registries on regional level (46–49).

7.4 Overview of commonly used trauma-scoring systems

The observed variation in mortality and long-term morbidity among different centers and countries could reflect differences in the quality of trauma patient care, different severity of the injury and / or individual characteristics of the patients in the study populations (50). It is therefore important to generate instruments that allow the homogenization of its evaluation, management and vital forecasting. The trauma severity scores are a series of scales to evaluate the anatomical, physiological changes and probability of survival (51–54).

7.4.1 Anatomic injury scoring

The severity of trauma patient's anatomic injuries are based either on AIS (16) or Scales based on ICD-9CM codes (55).

7.4.1.1 Abbreviated Injury Scale

The Abbreviated Injury Scale (AIS) was designed by the Association for the Advancement of Automotive Medicine (16) and has been updated 8 times since its introduction in 1971, the most recent the 2015 update (56–59). It includes more than 2000 diagnosis in which each injury is assigned a number from 1 to 6, where 1 is a minor injury, 5 is critical injury and 6 is non-survivable injury (60). (See appendix A)

The AIS scale has been widely criticized (50,57,60–62). For example, it does not have biunique intervals (i.e., the relationship between AIS scores and mortality is not linear), the relationship between the survival rate and maximum AIS by the body region of the patients vary, and difference between AIS 1 and 2 is not the same as that between AIS 4 and 5 (60,63).

Although the greatest limitation is that since AIS is a value for each injury, and being injured by traffic accidents often are polytraumatized patients, this classification system does not offer solutions on how to measure the severity of injuries in an individual as a whole (64). With all its advantages and disadvantages, the fact is that the AIS is still at the moment the most widely disseminated classification in the world of research for the prevention of road traffic injuries and, more specifically, biomechanical research (65).

7.4.1.2 Injury Severity Score

The Injury Severity Score (ISS) was developed by Baker et al. in 1974 and is used as a standard measure to quantify the impact of anatomic injury (17). It classifies and quantifies the overall severity of injury across body regions and is calculated by summing the squares of the highest AIS severity codes in each of the three most severely injured of the six different body regions (See patient example in Appendix A). The score range is from 1 to 75, a grade 6 AIS in a body region automatically adds 75 points as it is a fatal injury (17).

The ISS has following limitations: an error in AIS scoring increases the ISS error by its square, many different injury patterns can yield

the same ISS score (50), and it underestimates injuries that occur in the same anatomical region, since only the major one is considered (22). Furthermore, mortality is not strictly an increasing function of the ISS. The mortality rate of a patient with an ISS of 25 could be higher than the mortality rate of a patient with an ISS of 27 due to different AIS score combinations that comprise the ISS score (50,63).

7.4.1.3 New Injury Severity Score

New Injury Severity Score (NISS) was introduced by Osler et al. in 1997 (66). This scale is a revised version of the ISS but is easier to calculate as the sum of squares of the three most severe AIS injuries regardless of body regions (see patients example in Appendix A).

Due to the similarity between the two ISS and NISS scales, a number of comparative studies have been carried out showing that NISS is a better predictor of outcome than ISS (27–29), especially in blunt trauma and among patients in critical condition (9,58,67), but it is not suitable for evaluating the injured in borderline condition (68). Although NISS avoids many of the acknowledged limitations of ISS, it only takes into account a maximum of three injuries and like ISS it is not linearly related to the mortality (63).

7.4.1.4 International Classification of Diseases Injury Severity Score

Osler et al and Rutledge et al. presented International Classification of Diseases Injury Severity Score (ICISS) based on ICD-9CM, which consists in calculating the survival risk rates (SRR) for each ICD-9CM code (69). In turn, SRR ratios are calculated by dividing the number of survivors by the total number of patients with this specific trauma (69,70). ICISS has some advantages over the ISS. First, it represents a true continuous variable that takes on values between 0 and 1. Second, it includes all injuries. Third, ICD-9CM codes are readily available and do not require special training or expertise to determine. Finally, initial observations suggest that ICD-9CM has better predictive power when compared to the ISS.

Despite the apparent advantage of the ICISS, however, it has not yet replaced other methods of outcome analysis. In addition, further validation is needed before it can be used widely.

7.4.1.5 Trauma Mortality Prediction Model

Trauma Mortality Prediction Model (TMPM) is based on empiric evaluation of five most severe injuries calculated using regression models with AIS or ICD-9CM terminology (71). Some studies have shown that the mortality prediction calculated by TMPM model were more accurate than ISS, AIS, NISS and ICISS systems (67,72,73).

However, the potential limitation of ICD-9CM based scoring systems is that they are based on administrative data that are designed for hospital billing for all diseases and not for prediction modeling involving injury. Besides, AIS terminology describes injuries more accurately than ICD-9CM codes (74). In a recent comparison with the ICD-9CM, prediction based on the AIS was found to be superior (67,75). Furthermore, the scoring of traumatic brain injury (TBI) severity may be particularly problematic with ICD-9CM based predictive models (76).

7.4.2 Physiological scores

7.4.2.1 Glasgow Coma Scale

The Glasgow coma scale (GCS) was developed in 1974 by Teasdale and Jannet (77). Its calculation consists of adding the score of the best motor response, the best verbal response and the best ocular response. Its value goes from 3 (worse) to 15 (best). It is a universal tool for evaluating level of consciousness in patients with TBI. Given its prognostic power it is part of many survival scales (3,9,18,78,79).

7.4.2.2 Revised Trauma Score

The Revised Trauma Score (RTS) is one of the more common physiologic scores in use (80). It combines 3 specifics, commonly assessed clinical parameters, as follows: GCS, systolic blood pressure (SBP), and respiratory rate (RR) (78). These parameters are coded from 0 to 4 based on the magnitude of physiological derangement (See Appendix A).

The RTS is calculated by adding together the coded values for each of these three physiological parameters. When used for field triage (Triage-RTS), the unweighted RTS determined by simply combining the coded values ranges from 0 to 12 and is calculated very easily

(81). A score of less than 11 is an indication for transfer to a dedicated trauma center (82). When used for quality assurance and outcome prediction, a coded form of the RTS is more often used. The coded RTS is calculated as shown next where SBPc, RRc and GCSc represent the coded (c) values of each variable (50):

$$\text{RTS} = 0.9368 \text{ GCSc} + 0.7326 \text{ SBPc} + 0.2908 \text{ RRc}.$$

This shows the importance of the level of consciousness to predict the evolution of patients, given the coefficient assigned to the variable GCS. Its value goes from 0 (worst) to 7.84 (best); If RTS < 4 the chance of survival is 50%. Different studies have used RTS as a tool for predicting outcomes in patients with severe trauma (8,50).

The major disadvantage of T-RTS and RTS is that both the GCS and RR components of both scales can be altered by consumption of drugs or drugs and / or orotracheal intubation (83). Another problem with the RTS is the rapidly changing physiological parameters since a well-resuscitated patient might present a lower score despite severe injury (84). The duration of any physiological derangement will also have a profound impact on outcome, but, this fact is not truly accounted for by the RTS or by any other method depending on it (50).

7.4.3 Combined scores

7.4.3.1 Trauma and Injury Severity Score

The physiological component represents the dynamic component after the trauma and has a significant influence on the prognosis of patients with severe trauma. Trauma and Injury Severity Score (TRISS), derived from MTOS, is considered the standard method for outcome assessment (5). It is a statistical model of logistic regression to calculate the probability of survival (Ps) based on mechanism of injury (blunt or penetrating), ISS, physiological parameters (RTS) and patient age as dichotomous variable.

The mathematical formula is:

$$P_s = 1 / (1 + e^{-b})$$

Where e is the logarithm neperian and

$$b = b_0 + b_1 (\text{RTS}) + b_2 (\text{ISS}) + b_3 (\text{age index})$$

The coefficients derived from the MTOS study (14) for the calculation of the TRISS model are as follows:

	b^0	b^1	b^2	b^3
Blunt	-0.4499	0.8085	-0.0835	-1.743
Penetrating	-2.5355	0.9934	-0.0651	-1.136

The age index if < 54 years = 0, if > 54 years = 1.

TRISS has been criticized in the scientific literature for being based on trauma patients in the United States and Canada, presenting regression coefficients related to the reality of these countries (54,85–92). These criticisms have led to the development of many studies in which regression coefficients were adjusted to the local reality, considering that, according to some investigators, the predictive value of this score may be maximized when using coefficients adjusted to the studied population (90,93–97). For example, The British trauma registry: TARN has developed its own prediction model, called PS06, PS07, and so on, in which updated coefficients are calculated every year (95). The actual model is available from the TARN website (<http://www.tarn.ac.uk>). In principle this model considers the same data as the TRISS; however, the ISS is included as a transformation, and interaction terms (age x sex) are also included.

7.4.3.2 Revised Injury Severity Classification & version II

Lefering developed the Revised Injury Severity Classification (RISC) in TraumaRegistry DGU® of the German Trauma Society (TR-DGU®), based upon 2,008 severely injured patients from the TR-DGU® during the years 1993 to 2000 (98). Over years it has seen that RISC has some important limitations (99). It uses 10 different variables for prediction, which makes it increasingly difficult to provide complete data in all patients (98). Furthermore, the RISC had been developed with data from 1993 to 2000, which led to an overestimation of risk of death in recent years.

These limitations led authors to update the RISC and in 2014, RISC II was published. It was developed using 30,000 cases and validated with new data from TR-DGU® (99). It combines 13 different components measured on hospital admission, including some laboratory values (98). One of its greatest advantage lies in the solution provided for the variables with missing values since it assigns them a 0 value and thus does not change the prognosis of

patients with severe trauma. With this model, it is possible to estimate the prognosis of all patients with severe trauma if at least the two variables are essential; Age and injury severity measured by the AIS scale (99).

RISC II predictive model involves the following predictors: two highest AIS scores, AIS score for head injury, age, gender, pupil reactivity and pupil size, motor function according to GCS, type of trauma (blunt or penetrating), the patient's condition assessment according to American Society of Anaesthesiologists Physical Status (ASA-PS), SBP, acidosis (base deficit), coagulopathy (International Normalized Ratio [INR]) and hemoglobin, the need for cardiopulmonary resuscitation. Considering the two highest AIS scores, AIS score for head injury in separate variables significantly improved the predictive power of the model. RISC II system has high prediction accuracy and outperforms TRISS scale (99).

The description of RISC II variables with their coefficients published by Lefering et al. (99) and an example of its calculation is shown in Appendix A.

7.4.4 Variability in injury severity scoring

It is generally accepted to take into account the anatomical criteria to determine the injury severity, and physiological parameters that characterize the response of the body functional systems to the damage. Age, sex, comorbidities, various clinical parameters (RR, SBP, etc.), indices of acidosis, coagulopathy, oxidative stress, inflammatory response, timely diagnosing and the quality of treatment, the need of rendering various types of emergency aid are considered as independent risk factors of fatal severe trauma outcome. Creating a universal scale is complicated by variety of injuries and disorders caused by severe trauma and insufficient study of injury outcome predictors (74). Furthermore, all scores are not intended to be used for outcome prediction/trauma registry benchmarking, e.g. The T-RTS is a physiologic trauma score designed for field triage of patients who are significantly injured and require trauma center transfer. Comparing ISS/NISS and physiological scores is not always justifiable, as they are intended for different purposes.

Scales that include anatomical parameters can neither be calculated until the diagnostic process is complete, nor can they be measured at the scene of the accident (100). The description of the injury

should be precise enough to reflect its true severity since combinations of various lesions in different anatomical regions can lead to the same ISS value and yet have very different mortality risks.

In addition, the ISS scale assesses all regions of the body equally, obviating the importance of TBI in the mortality of a severe trauma patient and thus underestimating them. NISS offers advantages over ISS in that it takes into account the lesions regardless of their anatomical location although it underestimates, like the ISS, the TBI injury severity (99). This is due to the limitations of the AIS scale on which both scales (ISS and NISS) are based. For example, an AIS injury of grade 5 in head has a higher mortality than an AIS injury of 5 in the thorax or the abdomen (101).

On the other hand, the physiological scores can be calculated both at the scene of the traumatic event and in the Accident and Emergency (A & E) department in order to classify patients according to severity and decide on consequent action. The TRISS method is considered the Gold Standard for evaluation of results and despite its limitations it has been adapted by many trauma registries (5,95).

The RISC II model offers certain advantages over all predictive models previously developed (99). As far as we know, neither the UK TARN nor the RISC II model has been validated in an external dataset. To compare generalisability of different prediction models, the existing models should be benchmarked on the same, external dataset (102).

The strength of a scale to assess a severe trauma patient depends greatly on the population under study. A model developed in one population will always better predict outcomes in that same population than another developed in another population (103). Differences in the basic characteristics of the population and the trauma care system can alter the results of the predictive models, so an external validation of the models to evaluate the results must be done in a similar population from which the original model was developed. In summary, it is difficult to predict the prognosis of patient with severe trauma with only an anatomical, physiological or metabolic scale, without considering the age, existing chronic diseases and genetic disposition (104–107), since they influence the mortality of these patients (50).

At present, there is a great variety of anatomical, physiological or combined scales for the evaluation of the trauma patient, each with advantages and disadvantages (5). The anatomical scales require complementary examinations (such as Computerized Tomography), not available in the extra-hospital setting and time for classification and scoring, which is why they are rarely used in the initial care. Physiological scales have been shown to be reliable in the prediction of mortality based on repercussion in different parameters (blood pressure, RR, level of consciousness, etc.) measurable from the first moment of patient care and without the need for any apparatus which makes them very useful in the prehospital context (108). Combined scales are often more comprehensive and reliable though their application is more complex. However they can be very useful in evaluating and comparing emergency systems (109).

Periodically new scales are introduced or improvements in existing ones appear to help assess severe trauma patients. Even though these scales incorporate most of the variables that influence prognosis, validation studies are lacking for their general use.

Until validated studies of the scales are available, we can only use the available scales bearing in mind their limitations. Current and future research will determine the true applicability and utility of trauma scales, as well as their ability to enable decision making in the individual patient (109).

7.5 Trauma Systems

The implementation of comprehensive regional trauma systems has led to substantial risk reduction of mortality and complications associated with severe injury (110). For instance, Germany has documented a reduction in mortality after regionalization of trauma care (trauma networks) (111,112). The management of critically ill patients with multiple injuries requires expert, multidisciplinary, high-cost, coordinated and timely interventions (113). The success of any trauma plan and resultant system depends on the ability to ensure that each injured patient will receive timely access to necessary resources and optimal care which will enable the patient to have the best possible outcome (114).

Although trauma care organization is crucial to optimizing the results (115), there is no international golden standard. Trauma systems are based on two fundamental pillars: the pre-hospital structure and

the hospital centre, as a definition of the trauma centre concept. There are two large models at both pre- and in-hospital level, and adscription to one model or the other is conditioned to socioeconomic (116), cultural and geographical factors (117–120) rather than to final outcomes (115).

Currently in the U.S., the prehospital systems are incorporated within other units, and are fundamentally staffed by paramedics with direct control, and a medical supervisor (121,122). Depending on their level, they are authorized or not to perform certain maneuvers (115).

In Europe, the pre-hospital systems may or may not depend upon the hospital, and their more advanced versions are staffed by a physician in each mobile unit, trained and authorized to apply advanced life support techniques, administer drugs, perform laboratory tests, and use focused abdominal sonography for trauma extended in thorax (e-FAST), etc.(115). The most effective systems are the inclusive kind, where all hospitals form part of the system, with different levels of certification depending on the capacity of each centre (123).

Two in-hospital systems have been developed: that introduced in the US, and the system implemented in Europe (115). In the US, the key element is the trauma centre, defined by levels and subjected to periodic evaluation. In this regard, such centres are required to meet a series of requirements or conditions ranging from a minimum volume of attended patients a year to teaching and research programs and specific initiatives such as gender-based violence or motivational secondary prevention interventions in trauma patients (alcohol, drugs of abuse, violence). Periodic recertification is required, and external audits can be performed (124).

In Europe it is more common for patients with severe trauma to be attended in high complexity centres, though these are often not of a monographic nature (115). According to one survey from 2005, the development of trauma systems seemed to be more advanced in the central states of Europe and less developed in others (125). Spain would occupy the penultimate place with a score of 2 out of 10. Several factors that might affect the implementation of a trauma system have been identified. Factors that facilitate the process include research documenting the need for changes in existing care, continuous surveillance and quality improvement, and broad based leadership (124,126). Factors inhibiting the process include lack of

financial resources and political will, and resistance against the centralization of healthcare services (126,127).

Germany has a multi-payer healthcare system with two main types of health insurance: obligatory health insurance for work-related accidents and general health insurance (128). In Germany, physician-operated emergency medical services manage most pre-hospital traumas. There are 52 physician-staffed helicopters, approximately 1000 physician-staffed ambulances and numerous paramedic staffed ambulances. A physician at scene sees almost all serious trauma cases. Doctors working pre-hospital and hospital are physicians with a post-graduate emergency medicine training and certification; usually they are anesthesiologists (112). In the UK, the recent development of London's trauma system gives reason to expect promising results in the future (129).

Better understanding of the benefits and limitations of different trauma care settings and systems requires the comparison of these organizations across regional and national systems (130). There are only a few comparative studies available and they are largely limited to North America, but research studies in Australia and Europe have recently increased the focus on this important aspect of quality improvement (130–132).

In summary, injury prevention, pre-hospital care, acute care facilities and post-hospital care are basic components of a trauma system. It is fundamental to monitor care and benchmarks through continuous quality improvement assessment (133). The performance of a trauma system requires measurement through data from a trauma registry, the only way to monitor compliance with best practice/evidence based guidelines (134).

7.6 Spanish Trauma System

Spain has universal public health care coverage, which is recognized and warranted by its Constitution and provided by the Spanish government (135).

Trauma care systems in Spain are provided by the National Health Service in a decentralized way by the seventeen autonomous communities whose process of decentralization was completed in January 2002 (136). It is a National Health Service defined in the 'Health National Law' as of public status and universal coverage, integrated in a number of 'Sanitary services' that cover the whole

population, financed from the general state budget. The system's providers are, mostly, the system's servants and the distribution of resources is managed by the system's political directors and/or non-professional managers (137). Much of the hospital chain is administered by the NHS (41%), accounting for 68% of the total national hospital beds (138).

Hospitals in Spain are classified as [1] basic general hospitals, which, among other services, offer general surgery, anesthesiology and resuscitation 24 h a day, 365 days a year; [2] general hospitals with the same services as well as ICU, besides other medical and surgical specialties; and [3] regional hospitals, which as well as the aforementioned services must also have departments of neurosurgery, thoracic and plastic surgery as well as other specialties. They are not categorized according to their trauma care capacity and there are no national guidelines that regulate the organization of the trauma team (136,139).

In 2003 Queipo de Llano et al. described the Spanish Trauma System (136). There is a single emergency telephone number where the first information is received and the most appropriate resource available is activated (136). The initial assistance of a trauma patient is performed by a pre-hospital emergency medical system responsible for the on-site care of the patients in coordination with other public services. They also recollect and elaborate the pre-hospital clinical history that provides valuable information for the teams that receive the patient in the A & E department.

On arrival at the hospital the patient is attended by emergency physicians supported by the hospital's on-call "trauma team". In the A & E department, all severe and multiple injured patients are treated when they are received by the emergency hospital doctors, first in the triage or resuscitation areas and then after stabilization, they are passed to the observation area or to the ICU or surgery. From there, the doctors call the appropriate specialists: unless the patient has no musculoskeletal lesions and only cerebral, thoracic, abdominal or vascular injuries, the first to attend the patient is usually the orthopedic surgeon, in the relevant cases patients are attended to by respective surgical specialists. There is close collaboration and coordination between the orthopedic surgeons, the emergency physicians and the other specialist surgeons to comply with treatment prioritization protocols (136,139).

Doctors working at pre-hospital level and emergency departments are usually family physicians with some qualification in trauma care since there is no medical emergency specialization in Spain (139).

7.7 Trauma registry

Trauma systems have data registries to describe and evaluate (the quality of) trauma care which is aimed at trauma system improvement (140). Monitoring trauma patients can help us to take information about types, grades, severity, incidence, prevalence, and other characteristics of trauma injuries (141). Trauma registries are designed to provide information useful to improve the efficiency and quality of trauma care, epidemiological and clinical research, and the evaluation of outcomes (142–145).

They generally include patient demographic data and information on the circumstances of the accident (mechanism and causes), pre-hospital care and transfer to hospital, the care received in the emergency service and during hospital admission, an anatomical description of the injuries, measures of the physiological consequences and severity, complications, outcomes and patient destination (2,146–151).

Trauma registries have facilitated data analysis over the short and long terms, resulting in changes in protocols and care guidelines, estimation of costs, optimization of services, and the formulation of hypotheses that promote research in this area (152). However, to improve quality in trauma care the great value of trauma registries lies in their potential to compare institutions—i.e., to compare different institutions, or to compare the same institution at different times (153–155).

7.7.1 Worldwide trauma registries

The first trauma registry in the modern era was a database implemented in Chicago (Cook County Hospital) in 1969 and the most well-known database is the US MTOS, started in 1975 in the United States of America (18). The MTOS cohort has been widely used as a benchmark for comparing outcomes in patients with trauma using the TRISS methodology (18). Retrospectively, the ACS-COT established the National Trauma Data Bank (NTDB), which is an aggregation of U.S. and Canadian trauma registry and is the largest existing trauma registry data bank (156). NTDB aims to

improve the care of injured patients through systematic efforts in prevention, care, and rehabilitation, and to inform the trauma community the public, and decision makers about a wide variety of issues that characterize the state of care for injured persons. Currently, it contains data of approximately five million injured patients from about 900 trauma centers.

In Europe, the UK Trauma Audit and Research Network (TARN), the German Trauma Registry (TR-DGU[®]), the Dutch trauma registry, the Norwegian Trauma Registry and the Swedish Trauma Registry are well established nationwide trauma registries. The TR-DGU[®] was established in 1993 by the German Society of Trauma Surgery (*Deutsche Gesellschaft für Unfallchirurgie*, DGU) (157,158). TR-DGU[®] aims to enroll all trauma patients that are admitted alive with subsequent need for intensive care, including patients who dies in the hospital before admission to the ICU.

Participation is voluntary, only hospitals certified as part of a local trauma network (*TraumaNetzwerk DGU[®]*) are obliged to participate. Approximately 90% of the participating hospitals are from Germany, but with a growing number of participants from abroad. Currently hospitals from Belgium, Finland, Luxembourg, The Netherlands, Austria, Switzerland, Slovenia and the United Arab Emirates submit data to TR-DGU[®]. To date, TR-DGU[®] contains more than 50,000 severely injured patients (157).

The TARN has been operating for the past 20 years and is located at the University of Manchester, UK. The TARN is concentrating trauma data collected from all hospitals in the UK, analyzing it and producing epidemiological, clinical and audit reports (158). TARN monitors the standards of trauma care set out by the Royal College of surgeons, British Orthopedic Association, and National for Health and Clinical excellences and provides each NHS Trust and Commissioner with case-mix-adjusted outcome analysis and comparisons of trauma care across institutions. The main goal of TARN is to facilitate the development and improvement of trauma services, thereby reducing the associated burden of death and disability (95).

In 1999, the Dutch government instructed the trauma centres to establish regional trauma registries to be able to measure the magnitude of the trauma problem and to evaluate and improve the trauma care. Comprehensive regional registries were established for

all admitted trauma patients, including both those patients admitted immediately, and those patients who were secondary referrals. Patients who died in the emergency department were also included (159). To get insight into the total Dutch trauma care, prehospital data are also collected, in addition to the MTOS hospital data (160). All categories of patients, such as short admissions and older patients with isolated hip fracture, were included in contrast to other trauma registries (161).

In Spain, there is no national trauma registry and most of the well-established trauma registries are either at regional (47) or provincial level (162,163).

7.7.2 Limitations of trauma registries

All available trauma records have limitations. The main limitation of a trauma registry is the substantial amount of resources, time and effort required for its implementation and maintenance (164). In spite of this, a trauma registry has to be flexible enough to include new variables in light of the results obtained or the changes produced over time (111). The registered data on trauma patients rarely represent a population-based trauma sample (31). In effect, registries are usually hospital-based and do not include less patients with minor trauma, patients not needing hospital admission, or the most critical cases where death occurs at the site of the accident or on the way to hospital (2). On the other hand, the voluntary participation of the centres in such registries can lead to sample representativeness problems, unless the setting of the registry is characterized by a single centre or a well-organized trauma system that can adequately control participation. Patient data should be processed confidentiality and anonymously without the need for individual informed consent for inclusion in the registry (2).

Interpretation of the results of studies derived from trauma registries requires caution, due to possible disparities in the registered data, inclusion criteria, number and type of variables, use and type of scales, or characteristics of the population included (2,8,111). Thus, the internal validity of trauma registries should be assessed in order to ensure data quality, since the results depend on the data quality (10,31).

There are significant differences between trauma registries, with no globally accepted and standardized definitions for documenting,

reporting and comparing data referred to severe trauma cases (8). As an example, consensus is lacking in aspects as basic as the definition of severe or major trauma. This is because different taxonomic systems are used in application to trauma, and even when the same system is employed, different defining cut-off points are used (2,8). This lack of uniformity poses substantial challenges to most initiatives seeking to assess the quality of healthcare systems across regions (8). There have been cooperative efforts to establish homogenization (Utstein) (8) though no general consensuses have been established to date.

7.7.3 Measurements of trauma outcome

To measure the quality of trauma care, outcome parameters should be defined. Outcome after hospitalisation is a function of patient characteristics on admission, quality of care, and random events (3,165). In-hospital mortality is a principal outcome measure in worldwide trauma registries (140). Several outcome variables are currently applied in Europe and worldwide such as in-hospital mortality, 30-day mortality, 30-day in-hospital mortality, etc. It is well known that hospital mortality underestimates mortality in older people after trauma (166). Thirty-day mortality analysis can miss some late deaths in hospital, while the focus on hospital deaths alone will miss some deaths in step-down units (like rehabilitation units or other hospitals).

Comparison of crude mortality rates were previously used as indicators of quality of trauma care but comparison of crude mortality rates without adjusting for the risk profile of the patients is of limited value, (167) as this approach will cause trauma centers treating high-risk patients to appear to have low performance compared with other centers. The rationale of risk adjustment is to remove sources of variation that are institution-independent. The goal is that the residual differences reflect actual differences in quality of care (168).

This adjustment removes case-mix variations that may affect the outcome independent of quality of care. Outcome prediction models are commonly used to identify “unexpected deaths,” and to benchmark system or hospital performance (19). A statistical prediction model can be a powerful tool for evaluating trauma care, but inappropriately applied, it may result in misleading evaluations (3). Risk stratification models attempt to increase the reliability of predicting the relationship between patient and injury characteristics to observed outcomes (169).

Various trauma scores have been developed to assist in the prediction of outcomes (mostly death) for patients, depending on a combination of demographic, anatomical, and physiologic parameters (19,95). These trauma scores have been applied to databases to compare predicted (e.g., predicted number of deaths) versus actual outcomes (19,95,98), enabling comparison of trauma systems (hospital, state, national, and international). However, the external validity of such models may be limited by differences between trauma systems and imprecise data field definitions (5).

The assessment of the performance of trauma systems is necessary to identify areas for improvement and increase the quality of care (170,171). The performance of a trauma system can be analyzed on a regular basis and compared with previous data from the same institution (internal benchmarking) as well as with data from other institutions (external benchmarking) or against a recognized standard (4,172).

7.7.4 Outcome prediction models

An outcome prediction model is a statistical model, or a mathematical equation, that includes two or more prognostic factors, or variables, to calculate the probability of a predefined outcome. In trauma, the outcome is usually mortality at a certain time point. Outcome prediction models can be used to calculate individual survival probabilities, to compare survival between different hospitals and to compare actual survival with predicted survival based on the reference database (3).

Predictive models include variables that influence the prognosis of severely injured patients and thus can determine the probability of survival or identify unexpected deaths, among other things (19). They can inform about the future course of the patients after injury or evaluate the observed outcome against the expected outcome in a benchmarking procedure against a recognized standard or versus other hospitals (173).

7.7.5 Performance of outcome prediction models

Performance evaluation of a prognostic model is necessary before its results can be used. The general point is that evidence is needed to show it does what it is intended to. (103). The idea of validating a prognostic or diagnostic model is generally taken to mean

establishing that it works satisfactorily for patients other than those from whose data the model was derived (103). A good model may allow the reasonably reliable classification of patients into risk groups with different prognoses. However, to show that a prognostic model is valuable it is not sufficient to show that it successfully predicts outcome in the initial development data (103,174). It is well known that all prognostic models should be at least internally validated before introduction in order to adjust for optimism (174), which is the term applied when the model performs worse than expected in a new dataset (175).

The main ways to assess or validate the performance of a prognostic model on a new dataset include comparing observed and predicted event rates for groups of patients (calibration) and quantifying the model's ability to distinguish between patients who do or do not experience the event of interest (discrimination) (103,175). Calibration is usually measured by the Hosmer-Lemeshow test (H-L), which evaluates the precision in different subgroups (99,176). The most frequently used measure for discrimination is the area under the receiver operating characteristic curve (AUROC), a summary measure of using all possible score values for prediction of survival (or death) (99,176). Precision or the extent to which a prognostic score (i.e. a score which provides a risk of death estimate for each case) is able to closely predict the observed mortality rate (99,176) should also be considered.

To be useful, a risk score should be clinically credible, accurate (well calibrated with good discriminative ability), have generality (be externally validated), and, ideally, be shown to be clinically effective that is, provide useful additional information to clinicians that improves therapeutic decision making (effectiveness) and thus patient outcome (46,47). External validation is essential to support the generalizability of prognostic models and to provide evidence that the model does in fact accurately predict outcomes (103,177). As the goal of validation is to demonstrate satisfactory performance for patients from a population different from the original, it is clearly desirable to evaluate a model on new data collected from an appropriate patient population in a different center (174).

The external validation of outcome prediction models is limited by differences based on epidemiology and type of trauma care. A prognostic model may not be extrapolated to other systems with a different case-mix unless it includes all of the important prognostic

variables and the variables are appropriately modeled (103,178). The difficulty is to know whether a model actually includes all important variables (103). However, one way of reducing case mix variation would be to define a set of patient inclusion and exclusion criteria for a registry or a prognostic study (178). Furthermore an evaluation of the dissimilarity among patients in different centers (known as variation in case-mix) and of the selection criteria must be undertaken by transporting a prognostic model to a different trauma system or trauma population (103).

7.8 The Trauma System in Navarra

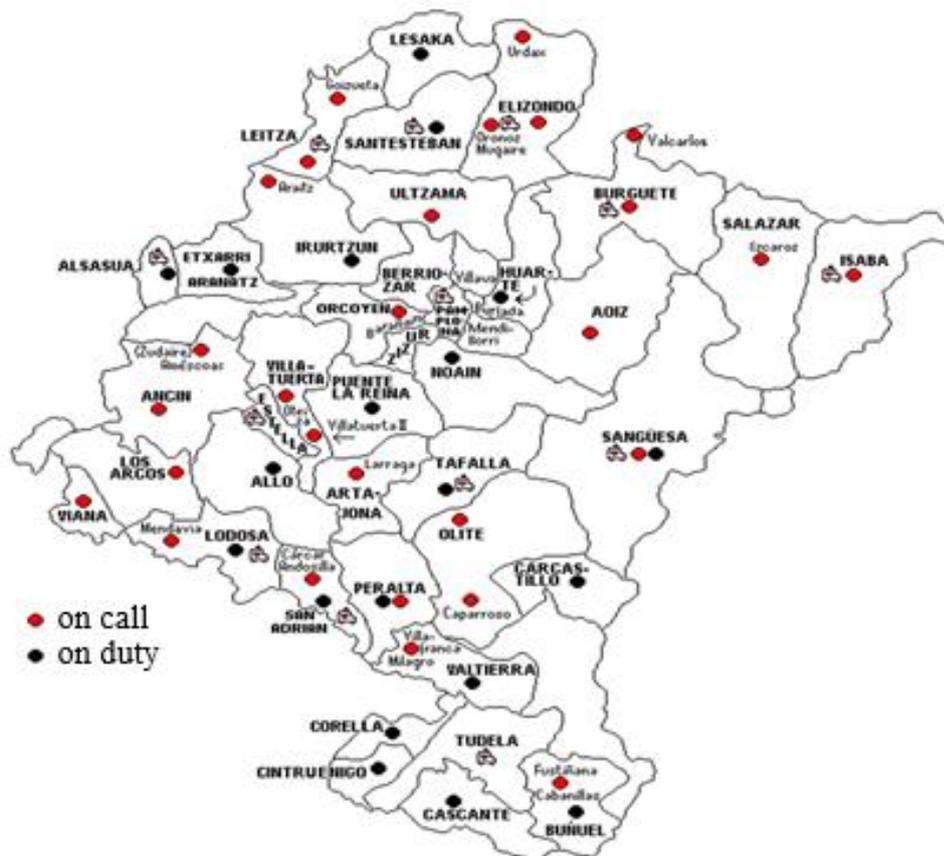
Navarra is an autonomous province in Northern Spain with an area of 10,421 km² and a population of 637,000 inhabitants. The emergency care system of Navarra is publicly funded, providing coverage to the entire population. The system is divided in three areas: Pamplona, Tudela and Estella.



Graphic, courtesy of Dr. Mariano Fortun
Figure 1. Areas of Navarra.

7.8.1 Prehospital trauma care

Due to the division into three large areas of health in Navarra, with its hospitals, another link in the chain of care of severe trauma patients is the Continuous Care Points. Some are rural, and others are urban (Pamplona, Tafalla, Estela, Tudela). They are within the primary care system. They all have two things in common: one of them is the team that forms it; and the other is the availability of care. The emergency health care team in the rural areas is comprised of a doctor and a nurse who use personal vehicles. In some places, especially the urban ones, medical teams have official vehicles including a driver, although he/she does not have any health assistance responsibilities. The availability of care is 24 hours a day, 7 days a week, every week of the year. As shown in the map at some points the team is either physically located at health centers or located on-call at their homes.



Graphic, courtesy of Dr. Mariano Fortun

Figure 2. Continuous Care Points in Navarra.

7.8.2 Transportation

In Navarra, both paramedic and/or physician-staffed resources are activated by the coordination center-SOS Navarra (112) according to the seriousness of victims. Paramedic resources (basic life support ambulances) consist of certified auxiliary ambulance technicians. Physician-staffed resources (ambulances and helicopters with advanced life support) responsible for medical assistance include physicians, registered nurses and auxiliary certified technicians. In Pamplona, there are two physician-staffed ambulances strategically positioned to give medical assistance to the whole area. The areas of Tudela and Estella are covered by one physician-staffed ambulance each, located in the corresponding hospitals.

They also elaborate the prehospital clinical history that is going to be a valuable piece of information for the teams that receive the patient in the A & E department. Trauma care in Navarra is performed according to the Advanced Trauma Life Support guidelines at both prehospital and hospital level. The physicians working pre-hospitally and in A & E are usually family doctors with post-graduate emergency medicine training.

7.8.3 Coordination center-SOS Navarra

The prehospital management is performed by a coordination center-SOS Navarra, which mobilizes resources for outpatient care (physicians or paramedics) according to the seriousness of the victim's condition that carry patients to the appropriate hospital emergency services. The coordination center-SOS Navarra is accessed through a free call number, 112. Several people work there including operators who receive multiple calls; one of their duties is to filter calls and derive health related and emergency issues to the coordinating physician, while other issues are issued to corresponding professionals (firefighters, police, etc.), as the case may be.

7.8.4 Trauma Code in Navarra

It is well known that severe trauma is a time-dependent disease and therefore early identification of a patient with severe trauma is fundamental at the site of the traumatic event. This classification is based on anatomical and physiological criteria, mechanism of injury,

availability of resources, time and distance to the hospital. The level of care available at the destination hospital has a significant impact on the outcome of the patient with severe trauma.

Efficient communication between the Coordination Centre-SOS Navarra, the prehospital and hospital teams is fundamental to improve the overall care of patients with severe trauma. Therefore, prior knowledge of the arrival of a patient with severe trauma is essential because it would activate the protocol for the reception and care of the patient by the trauma team according to the information received.

Activation of the "trauma code" is only possible after the identification of a patient with severe trauma (see Navarra's Trauma Code in Appendix B). This requires establishing a series of criteria for identification based on the patient's own characteristics (age, previous comorbidity, etc.), vital signs (RR, SBP, etc.), injury mechanism (penetrating injuries, etc.), anatomical injuries (fracture of 2 or more long bones) and evidence of high energy trauma. These criteria diminish the under triage of patients with severe trauma, improves the performance of emergency physicians who must initially assess the trauma patient and establishes management priorities, from collaboration requests to specialists to coordinate the necessary interventions according to established procedures (with adequate time).

The minimum data required by the coordination center-SOS Navarra once the code trauma is activated and depending on the professional that activates it for transmitting to the receiving hospital center include:

- Alarm call date and time. Crash site. Difficulty of access.
- Number of victims affected and possible subsequent transfers or the possibility of arrival of uncontrolled patients by means not coordinated by Coordination center-SOS Navarra.
- Sex, age, comorbidities and previous treatments (oral anticoagulants, antiplatelet agents) if possible.
- Activation criteria: priority 0,1, 2 or 3 (lower number referring to higher priority).
- Significant vital signs (such as SBP, pulse, sat O₂, etc.)

- Type of accident: traffic, fall, fire, etc.
- Injury mechanism: blunt, penetrating, etc.
- Affected area/s: head, face, chest, abdomen, extremities.
- Estimated time of arrival and means of transportation used.
- Resuscitation measures performed and their effectiveness.
- Current state of consciousness, breathing and circulatory.
- Need for ventilator support.
- Hemodynamic stability and the initiation of permissive hypotension or hemostatic resuscitation.
- In children: the presence of hypotension, indicating a loss of a 20% of the total volume. In children, no permissive hypotension is recommended if there is associated TBI, although it may be considered in the case of perforating wounds without associated TBI.
- Prehospital care: yes/no.
- Life support treatment:
 - Measures to stop bleeding
 - Airway; Endotracheal tube, laryngeal mask
 - Oxygenation / ventilation: mask, mask with reservoir, etc.
 - Circulatory support: liquids, drugs (adrenaline, Noradrenaline, amiodarone, dopamine, etc.).

Note: it is proposed to use the M.I.S.T method (below) to transmit messages to the hospital / coordination center-SOS Navarra.

M: mechanism of injury.

I: injuries found or suspected.

S: symptoms and signs presented by the patient.

T: treatments applied and response to them.

7.8.5 Hospitals in Navarra

There are three hospitals that treat severe trauma patients in the region. Navarra's first recognized Major Trauma Centre (comparable to a level 1 trauma center), the Complejo Hospitalario of Navarra (CHN) located in the regions capital Pamplona, constitutes the only tertiary referral hospital. When necessary, two local hospitals (Hospital Reina Sofia in Tudela and Hospital Garcia Orcoyen in Estella) can provide initial trauma care while awaiting the proper timing for transportation to the CHN. Table 1 shows the basic features of Navarra's hospital.

In the hospital A & E departments, the severe and multiple injured patients are treated by the emergency physicians. Patients are assessed and stabilized in the resuscitation areas. Diagnostic procedures are performed at the same time and from there the emergency physicians call the appropriate specialists. There is a close collaboration and coordination between the orthopedic surgeons, emergency physicians and the other specialist's surgeons to comply with treatment prioritization protocols.

Table 1. Hospitals in Navarra.

Hospital García Orcoyen u Hospital of Estella (90 beds)	
Hospital	Local hospital
Function	Urgent care, stabilization and referral to CHN.
Services related to trauma care	A & E General surgery 24 h Laboratory 24 h Orthopedic surgeon 24 h Gynecologist 24 h Pediatrician 24 h Anesthetist 24h Conventional radiology with CT scan 24h. ICU with limited beds.
Hospital Reina Sofía of Tudela (120 beds)	
Hospital	Local hospital
Function	Urgent care, stabilization and referral to CHN.
Services related to trauma care	A & E General surgery 24h

	Orthopedic surgeon 24 h Gynecologist 24 h Anesthetist 24h Pediatrician 24 h Conventional radiology with CT scan 24h. ICU with limited beds.
Complejo Hospitalario of Navarra (1100 beds)	
Hospital	Tertiary referral hospital
Function	Urgent care, stabilization, admission and specialized care. Experienced and organized trauma team to provide trauma care 24 h.
Services related to trauma care	A & E ICU Radiology 24 h Interventional Radiology on call Neurosurgeon 24 h General Surgery 24 h Cardiac, Vascular, Thoracic on call Plastic surgeon 24 h Orthopedic surgeon 24 h Maxillofacial surgeon 24 h Anesthetist 24 h Hematologist 24 h Laboratory 24 h

7.9 Major Trauma Registry of Navarra

In 2010, the Navarra Health Service established the Major Trauma Registry of Navarra (MTR-N) with three main goals:

- To know the epidemiological characteristics of the major trauma in Navarra.
- To assess the trauma system of Navarra.
- To establish comparisons with other trauma records to improve trauma care.

MTR-N is a comprehensive population registry strictly tailored to the variables and categories defined by Utstein Trauma Template (European Core Dataset) for trauma documentation (8). The registry

is formally owned by the Navarra Health Services and is governed by order 53/2010, of May 27, in the Minister of Health.

7.9.1 Inclusion and exclusion criteria

Database inclusion criteria were patients injured by external agents of any kind with a NISS >15. Exclusion criteria were: patients admitted in hospital more than 24 h after injury; patients declared dead before arrival at hospital or with no signs of life on hospital arrival and no response to hospital resuscitation; asphyxia; drowning; or burnt patients with no other trauma injuries (8).

7.9.2 Mode of access

Each service (prehospital, hospital, forensic, Coordination center-SOS Navarra, police) is involved in the collection of data and is assigned a role depending on the data they provide and each person a username with his password. To register patients, the application enables the cooperation of various users in data collection. The users of this application are all doctors from the Hospital and Prehospital Emergency Care Departments and those of the ICU of the Public Health System of Navarra, with an approximate total of 150 users. Users name, and password are provided by the Navarra Health System and they are unique and non-transferable. In Table 2 we can see the different users and their functions.

Table 2. Users of MTR-N and their functions.

<p>Hospital user</p> <p>It represents the emergency doctor who belongs to a hospital. It manages hospital and prehospital data of patients with severe trauma. He/she can register, modify and delete information of any case of trauma. He/she can view all data of a registered patient. He/she can exploit (Excel files, Pdf reports, graphs) all the data that is in the system (also those of the other roles), except those that are exclusive to the administrator.</p>
<p>Prehospital user</p> <p>It represents the user who travels in a physician-staffed resource (ambulance, helicopter, etc.). He/she can register and modify the prehospital data of trauma cases. He/she can delete trauma cases with only prehospital information. He/she can view the following data for a patient: Identification information, prehospital and response</p>

times.
<p>Forensic user</p> <p>Represents the forensic user of the Institute of Legal Medicine. He/she can register, modify and delete information of any case of trauma with forensic information. She/he can view the following data for a patient: Identification, hospital records, response times, police data, and forensic data, if available.</p>
<p>Coordination center-SOS Navarra user</p> <p>Represents the user of coordination center-SOS Navarra, that manages the SOS response times. He/she can upload an Excel file that automatically updates the SOS information of the trauma cases that already exist in the system. They can only view the information on response times of trauma patients.</p>
<p>Police user</p> <p>It represents the police, who manages the data of Structural Deformity Index (SDI). They can upload an Excel file that automatically updates the SDI information for trauma cases that already exist in the system. They can only view SDI data.</p>
<p>Manager Role</p> <p>Represents the user who is in charge of maintaining the system. He/she can register and modify the users of the system. He/she can register and modify the medical variables that are used in the system. These variables appear in the drop-down boxes that the user can select. He/she can be logged like any other role, inheriting its same modification privileges. She/he can be logged like any other role, inheriting its own exploitation privileges.</p>

7.9.3 Data incorporation

To obtain all the information that constitutes a case of trauma, the following entities are involved:

- CHN, Hospital of Garcia Orcoyen, Hospital of Reina Sofia.
- Prehospital services (physician-staffed ambulances).
- Coordination center - SOS Navarra.
- Anatomical Forensic Institute
- Police.

A new case can be identified by the following users: hospital, prehospital or forensic. If the patient has been transported by ambulance, the prehospital user usually identifies the trauma case.

However, if a patient is transferred directly to the Forensic Anatomical Institute a forensic user will introduce patient data to the registry. The hospital user tries to identify the patient when it arrives at A & E department. Once the trauma case has been identified, all users can enter their respective data set in collaboratively and asynchronously. The hospital user can access and exploit all the available data.

When a patient arrives alive at the hospital, a typical scenario of collaboration works in the following manner: a prehospital user identifies a possible case of trauma (personal data, date, and receiving center) and prehospital information: RTS, prehospital GCS, injury mechanism, and intent of the injury, etc. Then, a hospital user diagnoses the patient and completes the patient's records: ISS, NISS, RTS, and previous comorbidity. After this the data manager supervises the inclusion criteria and either maintains or removes the patient from the database, checks the variables, and closes the case when the patient is discharged or dies.

The injuries suffered by each patient are entered using a computer application based on an adapted list of 152 injuries according to the revised AIS-85 version (163). Note that in this list, most of injuries have the same injury severity level, for instance: grade 3 for femur fractures, etc. Therefore, MTR-N reports the injury severity level instead the full AIS code.

Response times are registered by the software applications of the Emergency System that manages all time periods since a call is received by the Emergency System up to hospital arrival at the hospital (100). The different intervals are obtained on the basis: time of call, time of arrival at scene, time of departure from the scene and time of arrival at hospital (100). In MTR-N, response times are calculated automatically matching both databases by patient's name (unique identifier between both sources).

Since a patient can be treated in different hospitals, the system supports the collaboration of several hospitals, enabling the possible management of transfers (163,179). Thus, a case of trauma may consist of several hospital records (one for each hospital) in which the system summarizes according to a predefined algorithm after analyzing the different hospital records (163,179).

7.9.4 Registry structure

7.9.4.1 Log in

Plataforma
MAJOR TRAUMA
Proyecto del Servicio Navarro de Salud
en colaboración con la Universidad Pública de Navarra

El proyecto | Quienes somos | Contacto

Por favor, inicie sesión

Usuario

Contraseña

5 0 6 1 7 9 4 2 8 3
~ \ ! @ # \$ % ^ & * ()
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Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M

trauma.navarra.comunicacion@gmail.com v1.3

Figure 3. Log In.

To enter the online application, you need a username and a password as explained in the Table 2.

7.9.4.2 Main page

The screenshot displays the main interface of the MAJOR TRAUMA platform. At the top, the header features the platform's name and project details. Below this, a user navigation bar shows the current user and session options. The main content area is a table listing patient cases, with a 'New' button for adding entries and a 'Search' button for finding existing ones. The table is sorted by last name. At the bottom of the interface, there are several utility buttons for generating reports and understanding variables. Two callout boxes highlight specific features: 'Meaning of variables' and 'Automatic reports on completeness'.

Figure 4. Start window.

This window appears after log in. It shows the latest entries in MTR-N. It allows users to edit, delete and search for an existing case or to register a new patient.

7.9.4.3 Search

You can use advanced search options to select a subset of the system cases. This way you can search for cases by variables such

as the following: Name and / or surname, Sex, Age range, Period (dates) in which you have been registered, Range of ISS values, Range of RTS values, Injuries, Mechanism, intentionality of injury, etc.

7.9.4.4 New case at hospital

It has four parts:

- Identification information
- Prehospital data
 - Information on injury
 - Prehospital care
 - RTS, T-RTS calculation
- Hospital data
 - ISS, NISS calculation
 - RTS, T-RTS calculation
 - Hospital care data
 - Discharge information
- Submit data.

7.9.4.4.1 Identification data

To register a new patient, the compulsory data are name, first surname, date and time of entry to the hospital. Every case of trauma should include at least: 1)-

- Date and time of entry to the first receiving health center.
- Patient's name and surname: with flexibility in writing.

The screenshot displays the 'Plataforma MAJOR TRAUMA' web interface. The header includes the project name and navigation links. The user is logged in as 'Admin Bismilnawazish'. The main form is titled '1. Identificación' and contains the following fields:

- Nombre*** (Name)
- Primer apellido*** (First surname)
- Segundo apellido** (Second surname)
- Edad** (Age)
- Sexo** (Sex): Radio buttons for V (Woman) and M (Man).
- Exitus prehospitalario** (Prehospital death): Radio buttons for Sí (Yes) and No (No).
- Datos de entrada al centro receptor** (Data of entry to the receiving center):
 - Centro receptor*** (Receiving centre): Dropdown menu showing 'Hospital de Navarra'.
 - Fecha*** (Date of accident): Date selection fields (day, month, year).
 - Hora*** (Time of accident): Time selection fields (hour, minute).

A 'Validar identificación' button is located at the bottom of the form. The footer shows the email 'trauma.navarra.comunicacion@gmail.com' and the version 'v1.3'.

Figure 5. New patient: Identification data.

By pressing the 'Validate Identification' button the system will automatically check if the trauma case already existed previously. If the case existed previously, users will be warned, and offered the possibility to modify the data that already exist. This allows you to modify the existing case data. If the case did not exist, we can continue to enter new data (prehospital and hospital).

7.9.4.4.2 Prehospital data

Plataforma MAJOR TRAUMA
 Proyecto del Servicio Navarro de Salud
 en colaboración con la Universidad Pública de Navarra

Admin Bismilnawazish Cerrar sesión Buscar

Prehospitalario Prehospital data

Traumatismo

Tipo de traumatismo predominante: Contuso (Type of trauma)

Mecanismo de la lesión: Caída gran altura (Injury mechanism)

Intencionalidad de la lesión: Accidental (Injury intention)

Parada cardíaca prehospitalaria: No (CPR)

Atención prehospitalaria

Aviso prehospitalario al centro receptor: No (Prehospital alert)

Tipo de transporte: Vehículo privado (Type of transport)

Cuidados prehospitalarios: Nivel 1: No (Prehospital care)

Intubación prehospitalaria: No (Intubation)

Tipo de intubación: (Type of intubation)

Inmovilización prehospitalaria: (Prehospital immobilization)

Oxigenoterapia prehospitalaria: No (Oxygenation)

Acceso venoso prehospitalario: No (Fluid therapy)

Fluidoterapia prehospitalaria: (Fluid therapy)

Calculadora RTS

Escala del coma de Glasgow

Apertura ocular: Espontánea (4) (Eye response)

Respuesta verbal: Orientado (5) (Verbal response)

Respuesta motora: Cumple órdenes expresadas por voz (6) (Motor response)

Otras variables

Frecuencia respiratoria: (Respiratory rate)

Tensión arterial sistólica: (Systolic blood pressure)

RTS (Respiratory Trauma Score)

T-RTS (Trauma-Respiratory Trauma Score)

Calcular RTS/T-RTS Prehosp.

Modificar datos prehospitalarios Salir sin guardar

trauma.navarra.comunicacion@gmail.com v1.3

Figure 6. Prehospital data.

7.9.4.4.3 Hospital data

ISS, NISS calculation: For the introduction of a hospital record for our hospital, simply click on the tab 'Hospital'.

Plataforma MAJOR TRAUMA
 Proyecto del Servicio Navarro de Salud en colaboración con la Universidad Pública de Navarra

Admin Bismilnawazish | Cerrar sesión | Buscar

MODIFICAR UNA FICHA HOSPITALARIA | Salir sin guardar

Modificar ficha hospitalaria

Entrada | **ISS** | RTS | Cuidados | Alta/Traslado

1. Cabeza (Head)

Grado 1

- Cefalea/Mareos secundarios al TCE
- Rigidez cervical sin fractura ni luxación
- Laceración cuero cabelludo

Grado 2

- Amnesia del accidente
- Letargia, estupor, obnubilación. Puede ser despertado con estímulo verbal
- Incontinencia < 1 hora

2. Cara (Face)

Grado 1

- Abrasión corneal
- Laceración de lengua
- Fractura nasal o de rama mandibular
- Fractura dental, avulsión o dislocación

Grado 2

- Fractura cigomática, orbitaria, cuerpo mandibular o subcondilar
- Fractura tipo LeFort I

3. Tórax (Thorax)

Grado 1

- Fractura costal
- Rigidez columna dorsal
- Contusión de caja torácica
- Contusión esternal

Grado 2

- Fractura de 2-3 costillas
- Fractura esternal

4. Abdomen

Grado 1

- Abrasión/cont. superficial/ laceración de escroto, vagina, vulva, periné
- Rigidez de espina lumbar
- Hematuria

Grado 2

- Contusión superficial/laceración estómago, mesenterio, vejiga, ureter, uretra.
- Contusión menor/laceración de riñón, hígado

5. EE/anillo pélvico (Extremities/pelvic ring)

Grado 1

- Contusión de codo, hombro, rodilla, tobillo
- Fractura/luxación de dedos
- Esguinces

Grado 2

- Fractura de húmero, radio, cúbito, rótula, tibia, clavícula, escápula, carpo, metacar., calcáneo, tarso, metatar., rama púbica o fract. pélvica

6. Externo (External)

Grado 1

- Abrasión/contusiones < 26 cm en cara, manos < 51 cm en cuerpo
- Laceraciones superficiales < 6 cm en cara, manos < 11 cm en cuerpo
- Quemadura de 1º grado
- Quemaduras de 2º o 3º grado < 10%

Grado 2

- Abrasión/contusiones < 25 cm en cara, manos < 51 cm en cuerpo

Patient's injuries

Lesiones del paciente

- Cabeza (1) Laceración cuero cabelludo
- Cabeza (2) Fractura simple de bóveda
- Cabeza (3) Contusión cerebral/HSA
- Cabeza (4) Hematoma intracraneal subdural o epidural < 50 ml

Calcular ISS y NISS

ISS

NISS

Calcular ISS/NISS

Modificar ficha hospitalaria | Salir sin guardar

Figure 7. AIS scale sorted by six ISS regions.

Calculation of ISS, NISS Clicking on the tab 'ISS' we can introduce the different personal injuries. The lesions are organized into six zones (head, face, thorax, abdomen, EE / pelvic ring, External). In each of these zones the lesions are classified from lower to higher severity (with an index of 1 to 6). Once the lesions are entered, we will click on the 'Calculate ISS / NISS' button.

The screenshot shows a web application interface for calculating RTS and T-RTS. At the top, there is a navigation bar with tabs: 'Entrada', 'ISS', 'RTS' (selected), 'Cuidados', and 'Alta/Traslado'. Below the navigation bar is a header 'Calculadora RTS / T-RTS'. The main content area is divided into two sections: 'Escala del coma de Glasgow' and 'Otras variables'. In the 'Escala del coma de Glasgow' section, there are three dropdown menus: 'Apertura ocular' (set to 'Espontánea (4)'), 'Respuesta verbal' (set to 'Orientado (5)'), and 'Respuesta motora' (set to 'Cumple órdenes expresadas por voz (6)'). In the 'Otras variables' section, there are two input fields: 'Frecuencia respiratoria' (set to 20) and 'Tensión arterial sistólica' (set to 180). Below these fields, there are two output boxes: 'RTS' (set to 7.84) and 'T-RTS' (set to 12). A 'Calcular RTS/T-RTS' button is located at the bottom of the form. At the very bottom of the page, there are two buttons: 'Modificar ficha hospitalaria' and 'Salir sin guardar'.

Figure 8. Calculation of hospital RTS & T-RTS.

Introduction of hospital care

By clicking on the tab 'Care' we can introduce the various hospital care that has been done to the patient

The image shows a screenshot of a web-based form for 'Modificar ficha hospitalaria' (Modify hospital record). The form is divided into several sections, each with a title and a set of input fields. Annotations with lines pointing to specific fields are provided in boxes on the right side of the form.

- Comorbilidad previa** (Previous comorbidity): A dropdown menu is set to 'Enfermedad sistémica moderada'. An annotation box labeled 'Comorbidity' points to this dropdown.
- Valores obtenidos de analítica** (Laboratory values obtained):
 - 'Primera medición EB' (First EB measurement): A text input field. An annotation box labeled 'Base excess' points to it.
 - 'Fecha normalización EB' (EB normalization date): A date selector (month, day, year). An annotation box labeled 'Date until normal arterial base excess' points to it.
 - 'Hora normalización EB' (EB normalization time): A time selector (hour, minute). An annotation box labeled 'Date until normal arterial base excess' also points to it.
 - 'Primera medición INR' (First INR measurement): A text input field. An annotation box labeled 'INR' points to it.
- Primer TC** (First CT scan):
 - 'Fecha' (Date): A date selector (day, month, year). An annotation box labeled 'Date to first CT scan' points to it.
 - 'Hora' (Time): A time selector (hour, minute). An annotation box labeled 'Time to first CT scan' points to it.
- Primera intervención quirúrgica "key"** (First key surgical intervention):
 - 'Tipo de primera intervención quirúrgica urgente' (Type of first key emergency intervention): A dropdown menu. An annotation box labeled 'Type of first key emergency interventions' points to it.
 - 'Fecha' (Date): A date selector (day, month, year). An annotation box labeled 'Data of first key emergency interventions' points to it.
 - 'Hora' (Time): A time selector (hour, minute). An annotation box labeled 'Time of first key emergency interventions' points to it.

At the bottom of the form, there are two buttons: 'Modificar ficha hospitalaria' and 'Salir sin guardar'.

Figure 9. Data about hospital care: laboratory values, CT scan and surgical intervention.

Discharge or transfer

Entering the discharge or transfer data. By clicking on the 'Upload / transfer' tab you can enter the patient's discharge or transfer to another hospital

The image shows a web form titled 'Alta hospitalaria/Traslado' (Discharge/Transfer) within a system for modifying hospital records. The form includes the following fields and callouts:

- Fecha de alta:** A date picker showing '18' of 'Septiembre' of '2017'. Callout: 'Discharge date'.
- Destino al alta:** A dropdown menu with 'Casa' selected. Callout: 'Discharge destination'.
- Estado neurológico al alta:** A dropdown menu with 'BUENA recuperación' selected. Callout: 'Glasgow Outcome Scale - at discharge from main hospital'.
- Supervivencia:** Radio buttons for 'Sí', 'No', and 'Desconocido'. Callout: 'Survival'.
- Máximo nivel de cuidados en el hospital:** A dropdown menu with 'Observación/ Urgencias' selected. Callout: 'Maximam level of hospital care'.
- GRD:** A text input field.

At the bottom of the form are buttons for 'Modificar ficha hospitalaria' and 'Salir sin guardar'.

Figure 10. Discharge information.

All Variables of MTR-N, adjusted to the Utstein Trauma Template, with their corresponding categories are explained in APPENDIX B.

7.9.4.4.4 Send data

At any time (having filled in the mandatory fields of identification) we can create the new case of trauma simply by clicking on the button 'Send data'. Prehospital and hospital data are optional, and can be introduced later if desired.

In summary, the MTR-N offers the following possibilities:

1. Identify a new case of trauma: the hospital record.
2. Enter and change hospital information.
3. Introduce and modify prehospital information.
4. Find cases of trauma.

7.9.5 Visualization of data provided by Coordination centre-SOS Navarra

We can view the information provided by Coordination center- SOS Navarra for a specific case of trauma, by clicking on the icon  in the list of initial trauma cases. The information shown will be as follows: time from alarm to resource activation, time from resource activation to resource immobilization, time at scene and time from alarm to hospital arrival

7.9.6 Forensic data

The MTR-N also includes information about trauma patients who died on scene or during transportation to the hospital (163,180). These patients are brought to Forensic Anatomic Institute where an autopsy is carried out to register their lesions. Once a patient is admitted to the Forensic Anatomic Institute, a forensic user is responsible to introduce the patient's data into the MTR-N. We can visualize the information provided by the Forensic anatomical Institute for a particular case of trauma, by clicking on the icon  in the list of initial trauma cases.

7.9.7 Structural Deformity Index Data

We can visualize the information provided by Foral Police for a particular case of trauma, by clicking on the icon  in the list of cases of initial trauma. It contains information about injury severity at the scene of a motor vehicle crash calculated by Structural Deformity Index (SDI) (152). The use of the SDI may assist prehospital and hospital health care providers to suspect the presence of particular serious injuries when anatomical and physiological criteria are not definitive.

7.9.8 Data protection

The data protection law 15/1999 and RD 1720/2007 have been complied and the project was approved by the Ethics Committee of the Navarra Health Service. The legislation in force on safety and confidentiality of personal data were particularly taken into account for software development, and security measures classified as high level (data backup was performed in a different place to the server residence and encryption of the media containing this information) were implemented (181). Confidentiality was guaranteed using SSL

3.0/TLS 1.0 encryption. The system records access date and time and if access has been possible. As for authentication, each user received a signature file (provided by the system administrator) to enter the system and ensure their identity (181).

7.9.9 Data quality control

A data manager was responsible for the general supervision and administration of the system, as well as for verifying the compliance of the inclusion criteria and of the introduction of patient data. Data were checked for completeness and plausibility; inconsistencies and missing data were solved by queries to the hospital. However automatically generated reports on completeness of data are available at any time. All patients documented in MTR-N have a clinical identification number that can link that case to its hospital medical file.

7.9.10 Evaluation of Navarra's trauma system

Belzunegui et al. introduced the Mortality Prediction Model of Navarra (MPMN) that contains variables that predicts mortality in Navarra (9). This model is used to assess the Navarra's trauma system and to compare its performance with internationally accepted standards (9). It was developed using the data from 378 patients treated in Navarra and documented in MTR-N between 2010 and 2012 (9). The likelihood of survival based on the MPMN model developed by Belzunegui et al. is calculated from the following logistic regression equation:

$$\text{Logit}(p) = -5.72 + 0.074 \cdot \text{Age} + 0.133 \cdot \text{NISS} + 0.922 \cdot \text{Comorbidity (if Healthy/mild systemic disease (value 0) or Moderate/severe systemic disease (value 1), according to the pre-injury ASA-PS-0.726} \cdot \text{Hospital RTS}.$$

Where Age, NISS and RTS are continuous variables and comorbidity is divided into Healthy/mild systemic disease (value 0) or Moderate/severe systemic disease (value 1), measured by the pre-injury ASA-PS.

7.9.11 Quality of data

Trauma registries underlying these outcome prediction models need to be accurate, complete and consistent. The quality of trauma registries is challenged by various factors, e.g. missing patients

despite fulfilling inclusion criteria (182), high rates of missing values (183,184), inter-observer reliability of injury coding (182,184), lack of consensus on definitions, and inadequate data control.

The capacity of a trauma registry to inform improvements in the quality of trauma care depends upon the quality of its data (141,185,186). Incomplete and erroneous data are a threat to the use of trauma registries for comparing and benchmarking systems of trauma care (187). If the quality of data in a trauma registry is unknown, questionable or poor, it will be less valuable as a tool for improving the quality of trauma care.

As Lefering et al. mentioned, the data quality of trauma registries should be evaluated in three dimensions: 1) completeness of cases, 2) completeness of data and 3) correctness of data (153).

The first refers to the adherence to the inclusion and exclusion criteria as systemic non-documentation of cases would bias the results. Failure to meet the inclusion criteria would ultimately lead biased and incorrect results (186). Therefore, adherence to the inclusion and exclusion criteria is critical for the consistency of the records of trauma (186). The number of patients incorrectly included (i.e., those who do not meet the criteria of severity and have been included) is relatively important, as they may be excluded when analyzing. However, the number of patients who should have been included in the database and are not (missing) should be minimized, and their characteristics known, so that we can determine whether there is a specific pattern of systematic error occurring or it happens randomly (182,188).

The second criterion is the completeness of the data. It has been shown that all trauma registries have some variables with incomplete values (10,188) and this may limit a meaningful analysis of the data (189). For instance in practice, obtaining comprehensive data on response times, physiological data such as RR, GCS (188) or base excess may be difficult (99). In any case the number of missing values should be minimized, especially those variables necessary for the used prediction model.

Finally, the third dimension of data quality is the correctness of data, or accuracy. The accuracy or correctness of data is the degree of concordance of registered data with the “true” studies that have evaluated the correctness of national registries using hospital files or

death registries (190). Errors in data coding and in retrieving data from the hospital records have been reported previously, with error rates as high as 28% (191). Other authors such as Heinänen et al. have reported an excellent accuracy of diagnoses for the trauma registry of the Helsinki University Hospital's Trauma Unit (192). The information provided by a trauma record is as valid as the data entered into it. Strategies for controlling the validity of data are essential (11). The usefulness of these registers depends on the quality of the collected data, and so an effort should be made to achieve the highest possible quality of data given the available resources. The recorded data therefore must be accurate, reliable and complete.

8 HYPOTHESIS AND AIMS OF THE PhD PROJECT

The MTR-N follows the recommendations of the uniform Utstein style for documentation of severe trauma in Europe and provides good quality data needed to study the epidemiological characteristics and trauma care of major trauma in Navarra.

Trauma care in Navarra is comparable to some European countries such as Germany in terms of epidemiology, trauma registry system, approach and results.

8.1 Main Goal

The purpose of this thesis study was to evaluate quality of data of MTR-N and to assess outcomes of patients with severe trauma treated in Navarra by conducting both internal and international trauma-registry comparisons.

8.2 Specific goals

- To assess the completeness of cases, i.e. missing patients in MTR-N despite fulfilling inclusion criteria (I).
- To study the completeness of data and detect specific variables with missing values (II).
- To assess the correctness of data, i.e. to study the concordance between MTR-N and patient's medical records (II).
- To assess the accuracy of ISS and NISS score (II).
- To determine variables related to mortality in severe trauma patients in Navarra and the influence of response times of the Emergency Medical Services in this mortality (III).
- To assess Navarra's trauma system and compare its performance with the German's trauma system through outcome prediction models (IV).
- To compare the injury profile, treatment, and outcome of severely injured patients in Germany and Navarra (V).

9 Methods

9.1 Study setting and population

9.1.1 PAPER I

The required sample size (consisting of patients included and missing patients) is calculated with the formula:

$$n = z^2 (p.q) / e^2$$

n = required sample size; z = 1.96 (confidence level of 95 %); p estimated percentage of missing patients; q = 100 – p and e = sampling error accepted. The size of the sample was calculated with under the hypothesis of 20 % of missing patients with a confidence interval between 0.15 and 0.25 and a 95 % of reliability.

The required sample size was 198 patients. Since each month 20 patients were included in MTR-N, random checks in the three hospitals were required for a period of 10 months (from 2010 to 2014). A review was made of medical records of all patients assisted in the emergency room of any hospital in Navarra for any trauma through the *Historia Clínica Informatizada* computer software.

Patients meeting the inclusion criteria of the trauma registry and not included in the database were assigned to the “missing” group. The patients already included in the trauma registry were assigned to the “included” group. In both groups, the following data were collected: Age, sex, type of accident, mechanism of injury, physiological parameters, characteristics of injuries, injury severity, length of hospital stay, highest level of hospital care, previous comorbidity, and hospital mortality. The probability of survival was calculated with TRISS methodology.

9.1.2 PAPER II

A retrospective review of all MTR-N cases documented in the months of June and July of 2014 and 2015 was performed. For each case, we extracted values of 42 parameters according to Utstein style from the MTR-N (Table 3). Clinical identification numbers of patients registered in MTR-N were extracted to identify patient’s medical files through *Historia Clínica Informatizada* (computerized software of patient’s medical files). To assess concordance between MTR-N and medical files, values of the same variables (Table 1)

were recorded again by another doctor not involved in the regular work of the MTR-N and who was blinded for the registry data. For each parameter, we defined a tolerable deviation from the value found in the hospital records in advance (see Paper II, Table 1).

Comparing registry data with what is found in the patient file could have 6 different outcomes (see Paper II, Table 2). In order to check the accuracy of ISS and NISS score, patient's injuries were retrieved again from the hospital files, and ISS and NISS were calculated again. We determined accuracy for these two scores as well as for the number of injuries.

9.1.3 PAPER III

We evaluated a retrospective cohort of severe trauma patients documented in MTR-N and attended to in the Navarre Health Service for a four-year period between 2010 and 2013. The following data were collected: age, sex, type of accident, mechanism of injury, physiological parameters, characteristics of injuries, injury severity, length of hospital stay, response times, previous comorbidity, discharge destination, GOS at discharge and 30-day mortality (for categories of each variable please see section).

Response times were registered by the software applications of Emergency System that manage all specific times since a call is received by the Emergency System up to hospital arrival. Different intervals are obtained on the following basis: time of call, time of arrival at scene, time of departure from the scene and time of arrival at hospital.

9.1.4 PAPER IV

A retrospective cohort study of severe trauma patients documented in MTR-N was analyzed between 2013-2015. MPMN (see section 7.15) and RISC II (see APPENDIX A and section 7.4.3.2) risk models were calculated. To document mortality from any cause follow-up 30 days after the traumatic event was carried out by either calling or consulting the unique computerized patient medical records of the Community of Navarra.

The collected data included: demographic data (age and sex), comorbidity, type of accident, injury mechanism, transport, prehospital intubation, prehospital CPR, anatomical and physiological scores, and head, face, thoracic, abdominal, limb and

pelvic rings with [AIS]> 2 points), laboratory data (hemoglobin, INR, base deficit), length of hospital stay and 30-day mortality.

9.1.5 PAPER V

Paper V compared data from MTR-N and TR-DGU[®] in a period from 2010 until 2013. Adult patients (≥ 16 years) with a NISS >15 were included. Patients who had been admitted to the hospital more than 24 hours after the trauma, or had been declared dead before hospital arrival, or had been injured by hanging, drowning or burns, were excluded. From TR-DGU[®], only patients treated in German hospitals were considered.

The compared parameters were age, sex, pre-injury ASA-PS, injury scoring, injury pattern, mechanism of injury, injury distribution, pre-hospital timings, transportation method, prehospital intubation, treatment at hospital, discharge destination, hospital and 30-day mortality.

9.2 Statistical methods

The Statistical Package for the Social Sciences (SPSS, IBM Inc., Armonk NY, USA) was employed for statistical management.

In study I, III, IV and V, the qualitative variables were described with the frequency distribution of each category. Categorical data were expressed as proportions and percentages. Quantitative variables were described using the mean and standard deviation (SD) if following a normal distribution, and the median and interquartile range (IQR) otherwise.

In study I, III and IV, the study of the association among qualitative variables was performed using the Chi-square test. The Mann–Whitney test and mean comparison for independent samples were used for continuous variables (not normally distributed and normally distributed, respectively). A value of $p < 0.05$ was considered statistically significant.

In study I, multivariate statistics were performed to estimate the risk of not being included. The odds ratio (OR) was presented with a 95 % confidence interval.

In study II, data completeness was calculated for all cases and data correctness for those cases with documentation data in MTR-N, separately for each variable. The overall completeness and correctness rates were given with 95% confidence interval.

In study III, logistic regression was used to evaluate the association between response times and mortality with control of the variables that influence it. The dependent variable was survival or not and the independent variables were those that were significant in the bivariate analysis and the prehospital care response times.

In study IV, the quality of MPMN and RISC II in predicting 30-day mortality was analyzed and presented in terms of discrimination, precision and calibration. Discrimination measures the ability of a scoring system to separate survivors from non-survivors. This was measured with the area under the receiver operating characteristic curves (AUROC). The AUROC summarizes the trade-off between sensitivity and specificity of a predictive score by using all score values as potential cut-off values. Its value varies between 0.5 (no discrimination) and 1.0 (perfect discrimination). The AUROC values were presented with their 95% confidence interval. The AUROC values were compared with the DeLong test (193). Precision describes the agreement of observed mortality rate and score-based prognosis. Calibration refers to the concordance between predicted and observed outcome over the entire risk spectrum. To assess calibration, we used the H-L. For this statistic, the whole population is split in deciles of approximately equal size. Observed and expected number of deaths is determined in each subgroup and then combined to give a chi-squared distributed statistic. A p-value < 0.05 (statistical significant deviation between the observed and predicted outcome) is considered poor calibration and $p > 0.05$ as a good calibration. Finally, a plot of predicted probabilities from MPMN and RISC II regarding to observed 30-day mortality has been provided.

In study V, all parameters from MTR-N and TR-DGU[®] were checked for comparability, and for some variables transformations had to be done before the analysis. All comparisons are based on real measurements; no imputations for patients with missing data were performed. For reasons of comparability patients who died beyond day 30 were considered survivors in this analysis. Regarding injury coding, in TR-DGU[®] injuries were graded according to reduced (450 codes) version of AIS-08. This reduction was possible due to

numerous detailed injury descriptions (codes) with the same severity level. Such codes were merged into a single code, conserving the appropriate severity descriptor. On the other hand, according to the revised AIS-85 version, a list of 152 injuries was used in the MTR-N. Note that in this list, most of injuries have the same injury severity level, for instance: grade 3 for femur fractures, etc. So, MTR-N reported the injury severity level instead the full AIS code. A few injuries thus had a different severity level as in the actual version of AIS used in TR-DGU®.

Expected mortality was defined as the average value of individual prognosis derived from the Revised Injury Severity Classification II (RISC II), a prognostic score developed from the TR-DGU® data.

10 Results

10.1 PAPER I

Seventy-nine (79) cases of patients, who met inclusion criteria (NISS > 15) were not included in our trauma registry (39.5%), and were identified. The main differences between the profiles of missing vs. included patients are shown in Table 3.

Table 3. Main differences between the profiles of missing vs. included patients

	Included patients n = 121	Missing patients n = 79
mean Age:	56	63
Gender: Female	24%	42%
Blunt mechanism	96%	100%
Injury mechanism: traffic accidents	54%	37%
Injury mechanism: falls < 3m	21%	48%
Mean NISS:	25	18
Median Hospital RTS:	6.9	7.7
ASA-PS 3 or 4	35%	48%
Median number of injured areas	2	1
Median global number of AIS coded per patient	4	2
Probability of survival (TRISS):	0.78 (0.99–0.72)	0.91 (0.99–0.77)

Furthermore, the profile of missing patients by the age group in years (≤ 50 , 51-64 ≥ 65) showed that most patients (46) were over 65 years. Of these, (70%) were women: (80%) had previous comorbidity of moderate-to-severe systemic disease, (81%) with an injury mechanism of low height fall, (48%) arrival to hospital in a conventional ambulance, NISS median [IQR] and Hospital RTS median [IQR] 7.8 [7.8,7.8]), characteristics of injuries (number of injured area's median [IQR] 1 [1, 2]), whose highest level of medical care was hospital admission, and/ or observation (89%) and (83%) discharged home with good recovery (83%). The difference between the observed and expected mortality for missing patients was -1.5% (SMR 0.83) and 0.5% (SMR 0.98) for included patients.

The multivariate logistic regression has shown that having a high hospital RTS and lower number of coded injuries are significant predictors for being missing with an OR of 1.84 (1.09–3.11) and 0.57 (0.43–0.77), respectively.

10.2 PAPER II

The results were based on the source data verification of 87 patients with 42 data points each (3,696 comparisons) data sets selected from MTR-N. 30-day mortality was 23% (n=18). The mean age was 57 years; 68% were males, and the average ISS and NISS was 18.2 and 25.7 points, respectively. The percentage of patients by means of transportation, with physician (ground or helicopter), paramedic ambulance and private vehicle were 67.0%, 27.0% and 6.0%, respectively. The percentage of relevant injuries (AIS ≥ 3) regarding to head, thorax, abdomen and injuries of extremities and pelvic ring were 57.0%, 40.0%, 9.7% and 12.3%, respectively.

The overall average completeness rate for all variables was 92.8% (CI 95 %, 92.0 – 93.8). The percentages of missing data in MTR-N ranged from 0% (29 variables) to 76.8% (first base excess). Figure 14 only shows variables with missing values in MTR-N and/or variables with values in medical files but not in MTR-N.

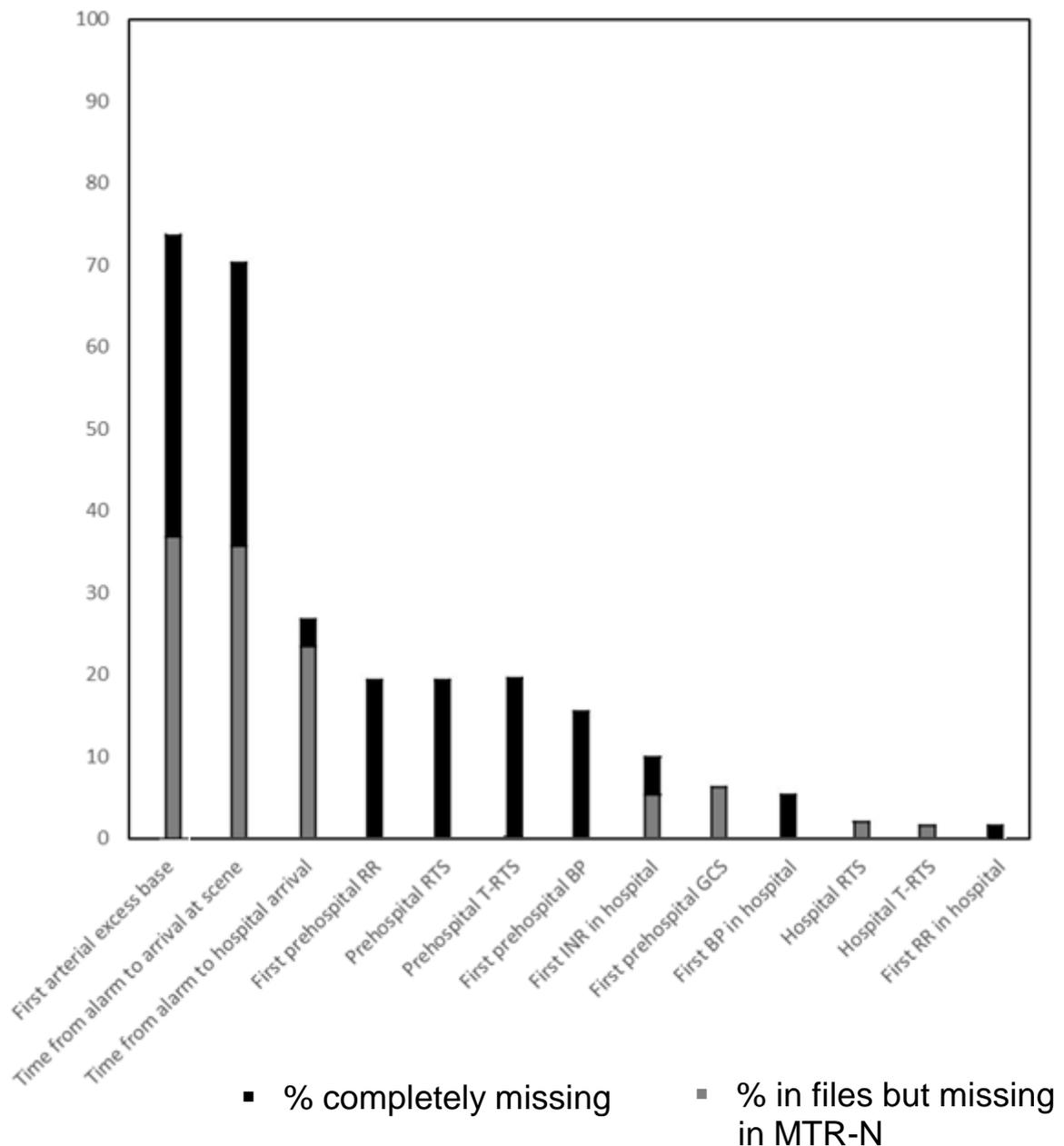


Figure 11. Completeness of data (variables with missing values in MTR-N and/or in medical files)

There was a considerable range of data correctness rates for different variables. Exact concordance ranged from 100% (22 variables) to 93.0% (7 variables). Paper II, Figure 2 shows the

respective values for all parameters, ordered by the decreasing rate of exact concordance.

10.3 PAPER III

Of the 217 cases available for analysis, 42 (19%) died. Of the total injuries, 206 (94%) were blunt, 42 deaths (20%) and 11 (5%) were penetrating, without any deaths. The mean age and sex of the injured were 50 ± 21 years (69% males) with a range between 1 and 93 years.

Response times disaggregated by patients who survive, or die are reflected in Paper III, Figure 2. Logistic regression analysis including the predictor variables that were significant in the bivariate analysis and response times show that no significant association was found in the multivariate analysis between the different response times and mortality: arrival at the scene (odds ratio (OR) 1.0; 95% confidence interval (CI) from 0.99 to 1.01), in the scenario (OR 1.00; 95% CI from 0.98 to 1.02) and total time (OR 1.00; 95% CI from 0.99 to 1.01).

Table 4. Characteristics of patients included in the Paper III.

	Dead	Alive	P
Total no. of patients	42	175	
Age, mean (SD)	66.3 (18.1)	46.1 (20.2)	<0.01
Male Gender (%)	27 (18)	123 (82)	<0.01
Road traffic accidents (%)	17 (16)	90 (84)	<0.01
Low fall (<3 m) (%)	16 (33)	33 (67)	<0.01
Prehospital RTS	5.8 (1.8)	7.4 (0.8)	<0.01
Prehospital intubation (yes, %)	18 (51)	17 (49)	<0.01
ISS, mean (SD)	29.2 (9,8)	19.9 (8.6)	<0.01
NISS, mean (SD)	39.4 (12.2)	26.6 (8.8)	<0.01
Response times			<0.01
Time form alarm to scene (SD)	00:21 (00:15)	00:23 (00:22)	
On scene time (SD)	00:22 (00:15)	00:23 (00:18)	
Time from alarm to hospital (SD)	01:08 (00:28)	01:05 (00:44)	

10.4 PAPER IV

In this study, 516 patients were included with a mean age of 56 ± 22.8 years, of which 363 (70%) were males. Ninety patients (17.4% [95% CI 14.2-20.7]) died within 30 days. The average ISS and NISS was 19.5 and 26.7 points, respectively. The AUROC for RISC II was 0.941 (95% CI 0.921-0.962) and the AUROC for MPMN was 0.927 (0.902-0.952), the differences were not statistically significant (p deLong = 0.269). The predicted mortality, establishing a cut-off point of 0.5, for the MPMN and RISC II model was 16.4% and 15.4%, respectively. The H-L calibration statistic revealed good calibration for RISC II (8.9, $P=0.35$) and MPMN (13.6, $P=0.09$).

Table 5. Profile of injury-related patients with NISS >15 included in Paper IV.

	Dead	Alive
Total no. of patients	90	426
Age, mean (SD)	72.2 (18.7)	52.4 (22.1)
Male Gender	54 (60%)	309 (73%)
ASA-PS (3 or 4)	56 (61%)	133 (31%)
Blunt mechanism	87 (97%)	407 (96%)
Road traffic accidents	19 (21%)	163 (38%)
Low fall (< 3 m) (%)	54 (60%)	140 (33%)
Brain injury (AIS head ≥ 3)	78 (87%)	220 (52%)
Relevant thorax trauma (AIS ≥ 3)	34 (38%)	220 (52%)
Relevant abdominal trauma (AIS ≥ 3)	8 (10%)	50 (12%)
Relevant injuries of the extremities (AIS ≥ 3)	6 (9%)	43 (10%)
ISS, mean (SD)	26.5 (11.7)	18.3 (7.4)
NISS, mean (SD)	35.6 (13.7)	25.2 (7.5)

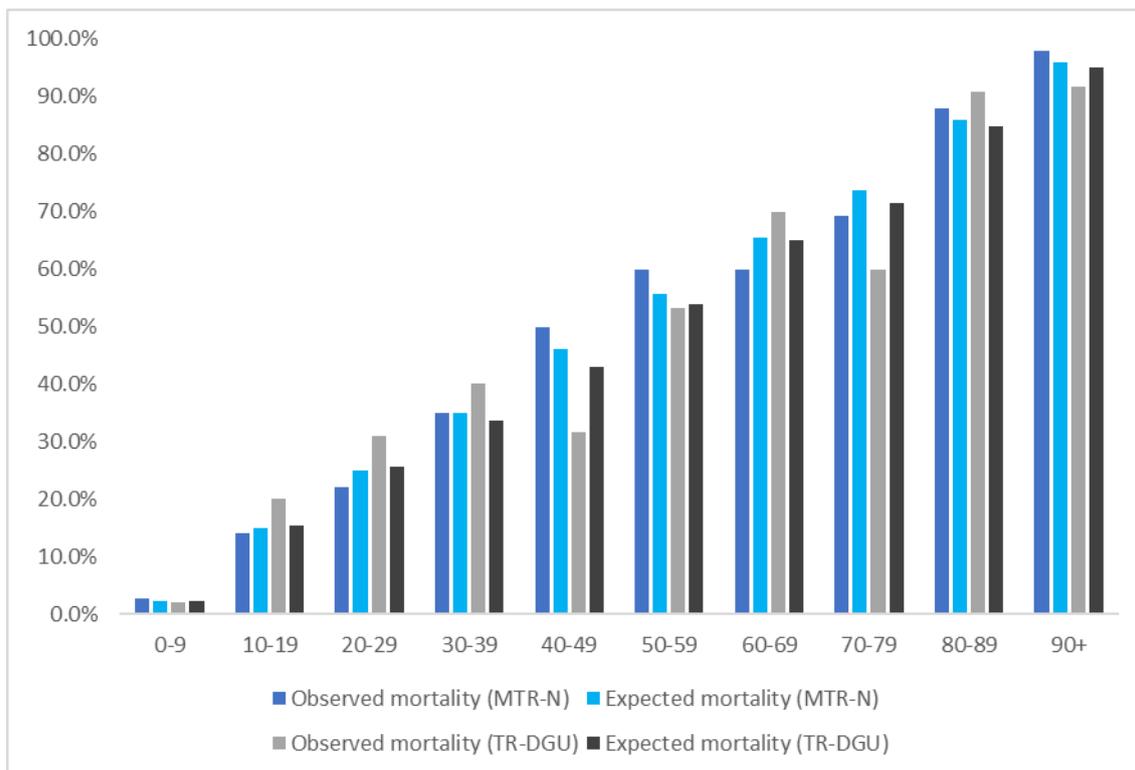


Figure 12. The observed and expected mortality according to MPMN and RISC II models.

10.5 PAPER V

10.5.1 Patient characteristics

For descriptive analysis, the study included the data of 646 patients from MTR-N attended to in three hospitals of Navarra and the data of 48,799 patients attended to in 611 hospitals with documentation from the TR-DGU®.

The average age at the time of injury was 57.9 ± 21.9 in Navarra and 51.6 ± 20.7 in Germany. The percentage of trauma patients by age grouping between both regions is shown in Paper V, Figure 1. More traffic accidents were included in TR-DGU® compared to MTR-N (55.6% vs. 36.3%) while more falls from low height were attended in hospitals in Navarra compared to German hospitals (34.5% vs. 20.0%).

There was a higher rate of chest, extremities, abdominal trauma in Germany than in Navarra (53.1% vs 42.5%, 31.4% vs 12.0 and 13.6% vs 8.2%, respectively). The prevalence of head injuries was higher in MTR-N than TR-DGU® (61.5% vs. 47.0%). However,

isolated head injuries (e.g. AIS-code ≥ 3 in the head region, all other AIS-codes < 2) were slightly more common in German hospitals compared to Navarra's hospitals (15.0% vs 13.9%, respectively).

Table 6. Main differences between the profiles, characteristics, information on injury mechanism and relevant injuries sustained and outcome of German vs. Navarra trauma patients.

	MTR-N	TR-DGU®
Total no. of patients	646	48,799
Age, mean (SD)	57.9 \pm 21.9	51.6 \pm 20.7
Male Gender	441 (68.3%)	34,919 (71.9%)
ASA-PS (3 or 4)	55 (8.5%)	6,627 (15.8%)
ISS, mean (SD)	20.4 \pm 9.7	24.1 \pm 11.9
NISS, mean (SD)	26.5 \pm 9.6	30.7 \pm 13.7
Low fall (<3m)	250 (34.5%)	9,472 (20.0%)
Road traffic accidents	231 (36.3%)	24,988 (55.6%)
Bran injury (AIS head ≥ 3)	397 (61.5%)	22,927 (47.0%)
Relevant thorax trauma (AIS ≥ 3)	274 (42.5%)	25,916 (53.1%)
Relevant abdominal trauma (AIS ≥ 3)	53 (8.2%)	6,648 (13.6%)
Relevant injuries of the extremities (AIS ≥ 3)	77 (12.0%)	15,327 (31.4%)
Observed mortality (30 days)	140 (21.6%)	6423 (14.9%)
Expected mortality (RISC II)	129 (20.0%)	6595 (15.3%)

10.5.2 Prehospital setting

In Germany, more patients were treated by physician-staffed ambulances than in Navarra (67.4% vs. 58.1%, respectively). Helicopters were used more frequently to transport trauma patients in Germany (25.8%) than Navarra (4.3%). More unconscious patients were observed in Germany (24.2%) than in Navarra (14.6%). Intubation rates were higher in Germany than in Navarra (36.6% vs. 11.8%, respectively) even in patients with GCS < 9 (see Paper V Table 4)

In prehospital setting, German patients receive more volume than in Navarra patients (88.6% with a median of 1000ml vs. 62.3% with a median of 500ml).

10.5.3 Diagnostic procedures and treatment at hospitals

More CT scans were performed in Navarra's hospitals than in German ones (96.2% vs. 88.4%, respectively). However, more whole-body CT scans were carried out in Germany than in Navarra

(77.1% vs. 44.4%, respectively). It took more time to perform the first CT scan and first surgical intervention after admission in Navarra than in Germany (0:43 and 1:52 vs. 0:23 and 1:23, respectively).

Patients were more likely to be admitted to ICU in German hospitals than in Navarra's hospitals (91.4% vs. 36.0%, respectively). A higher percentage of ventilated patients (52.5% vs. 23.2%) and more days on ventilator (8.8 ± 11.5 vs. 5.8 ± 8.5) were observed in Germany than in Navarra. Furthermore, patients were admitted for longer periods in German hospitals than in Navarra (21.0 ± 20.9 vs. 12.1 ± 14.0 days).

10.5.4 Outcomes

Both the 30-day mortality and the hospital mortality rate were higher in MTR-N than in TR-DGU[®] (21.6% and 23.2% vs. 14.9% and 15.5%, respectively). Paper V, Figure 5 shows the mortality rate of trauma patients by age group in both regions.

11 DISCUSSION

Trauma systems have data registries to describe and evaluate (the quality of) trauma care (194). Internal and external benchmarking intend to assess and improve trauma quality care to reduce morbidity and mortality related to trauma (195). Appreciable quality improvements rely on valid evaluations that use accurate data (11).

Thus, the present study assessed the data quality of a comprehensive population based trauma registry in Navarra, (MTR-N) in terms of completeness of cases, completeness of data and correctness of data.

Continuous measurement and evaluation of a trauma system's performance against other trauma systems is necessary to gain information about best available treatments.

Therefore, in this study, we have performed the epidemiological comparison between Navarra (Spain) and Germany. To do so all benchmarking processes should start by dealing with internal benchmarking because this requires an organization to examine itself, and this provides a baseline for comparison with others.

MPMN developed in MTR-N has been internally validated and its performance has been compared to RISC II introduced by Lefering et al. (IV). Results showed that RISC II has performed slightly superior to MPMN in terms of discrimination and calibration and it is suitable for external benchmarking. However, for internal benchmarking MPMN has proved good prediction in terms of discrimination, precision and calibration.

The comparison between Navarra's and German's trauma system was performed through respective trauma registries (MTR-N vs. TR-DGU®). Differences in the characteristics of trauma patients and trauma systems between both regions were noted (see below).

11.1 PAPER I

Patients not included in the MTR-N displayed a specific injury profile. They are usually elder women, undergoing no specific treatment and admitted for observation and/or hospitalization with conservative treatment until death or until being discharged home with their baseline status.

This profile sometimes implies that the doctors treating these patients do not consider them as major multiple trauma patients as there is no physiological effect (“increased RTS”, GCS 15 points, “normal blood pressures”) and they do not require surgery or admission in intensive care units.

This raises an issue worth considering: should we include elderly patients with accidental low falls, resulting in severe brain injury and with limited therapeutic efforts? These findings do not mean that such patients are treated inappropriately but simply that therapeutic efforts are limited due to their fragile conditions. This is because aggressive interventions would not improve their quality of life. Perhaps similar cases are found in other databases and therefore should not necessarily be considered bad management of trauma registries, but steps should be taken towards creating specific records for these fragile patients. This would also help to improve the comprehensive care of these patients.

The aging population in developed countries changes the profile of trauma patient's and this may in turn alter the inclusion criteria of patients in the registries or build specific registries (geriatric trauma, hip fractures in the elderly). If the purpose is to check to what extent early medical interventions improve survival of patient, then efforts should be focused on creating specific registries segmenting the databases for these patients and analyzing them specifically. Thus, in the future, it may prove wise to exclude these patients when comparing trauma registries.

11.2 PAPER II

We noted a significant percentage of missing rates with regard to the recording of base excess, response times, RR, SBP and GCS in MTR-N. In the case of base excess, hectic situations contribute to prevent routine measurement. Furthermore, doctors do not consider necessary its request in elderly patients with “normal” physiological measurements and with isolated head injury after low falls. Lefering et al. also reported missing values of base excess in TR-DGU® (99).

In our system, response times are registered by the software applications of Emergency System that manages all specific points in time since a call is received by the Emergency System up to the arrival of patients at the hospital. The different intervals include: time

of call, time of arrival at scene, time of departure from the scene and time of arrival at hospital. In our trauma registry, response times are calculated automatically matching both databases by patient's name (unique identifier between both sources). Due to the stressful conditions of emergency situations in many occasions the given name and the name recorded does not match and so the system discards both. This results in a loss of a significant number of response time's values. Soon we will be able to manually enter the response times through an update of the software and we expect raise completion in 75-80% of cases.

In the literature, different approaches to measuring correctness of data have been considered, from the relatively simple methods of consistency and domain checks to monitoring of coding reliability and agreement with other databases, and to source data verification (11). For source data verification, the patient medical record remains the best source, or "gold standard", for evaluating correctness of data. However we are aware that hospital records themselves may not have 100% validity (196). An overall correctness of 98% found in this study, is significantly higher or in the same range as the results reported in similar studies in the past. Whereas some investigators reported poor identified error rates as high as 28%, others reported same correctness rates of 98%. However, one may argue that study designs differ significantly in some cases to detect data correctness.

Relevant deviation in coding of AIS and derived scores (NISS, ISS) was found in this study but fortunately it was a low percentage (< 10%). Coding variability of the AIS has flow-on effects for the overall utility of AIS-coded trauma databases. The MTR-N is based on the inclusion criteria (NISS >15) according to Utstein recommendations (8), so variability in AIS coding produce wrong calculations of NISS, and consequently influences the completeness of cases. It is well known that injury coding using the AIS is subject to variation between observers (61). Therefore, agreement on AIS severity codes must be improved through training and education to prevent wrong calculations of ISS and NISS

Deficient rates of completion and correctness of data may lead to bias when evaluating trauma systems. This is especially important if missing data did not occur randomly. Consequently, rigorous attention to data quality in trauma registries is critical for valid benchmarking of trauma systems. Further improvement of the completeness of the trauma registry will occur if the process of

inclusion was automated with computer systems that link the label 'trauma patient' (e.g. receptionist enters a mark upon entrance of the patient in the hospital) to information about length of stay (e.g. when the discharge letter is put into the system) (182).

The great value of trauma registries is to help design intervention strategies that reduce morbidity and mortality related to trauma. The usefulness of trauma registries for benchmarking purposes is largely dependent upon the quality of the collected data. Thus, efforts should be made to ensure that the data introduced in the trauma registries are precise, reliable, complete, and concordant with the medical record of patient.

11.3 PAPER III

Several studies have demonstrated the influence of response times on patient outcome. Given the high missing rates of these values we studied its influence on patient's prognosis in our community. The study concluded that the 30-day all-cause mortality of polytrauma patients attended to by the emergency system in our region is influenced by age and by the injury severity determined by the prehospital T-RTS and by the NISS. The response times within the hospital did not show a significant influence. Different studies carried out in developed countries reproduce this model, but this does not mean that the response times are not important. In our context however, the response at the site of accident by highly qualified physician led emergency teams and an adequate hospital management showed that response times did not have a relevant weight in case of death. On the other hand, severity of the injuries and the fragility of the patient related to age and associated comorbidity played a significant role (8,171).

11.4 PAPER IV

The MPMN risk model has not been validated, which is a limitation to its implementation in clinical practice, nor has it been compared with other standardized models, such as RISC II in severe trauma patients.

The present study has shown that RISC II and MPMN are two predictive models that have a good discriminative capacity to predict global mortality of severe trauma patients at 30 days both in the

internal validation cohort from MTR-N and in the external validation cohort from TR-DGU®.

The MPMN showed a good discrimination capacity with an AUROC of 0.92, which is similar to that observed by Belzunegui et al. in the original study (AUROC 0.93). The accuracy of this model documented an observed mortality of 17.4% versus the predicted 16.4%, and an acceptable calibration (H-L p-value = 0.09). In this sense, the MPMN model may be considered a valid risk model that could serve as a comparison to see the evolution of our trauma care system. The accuracy of RISC II showed an observed mortality of 17.4% compared to the predicted 15.4% and a good calibration (H-L p-value = 0.35).

When interpreting these results, we should consider several aspects. The inclusion of laboratory values (base excess and INR) and indirect signs of bleeding (hypotension and hemoglobin) has been shown to influence the prognosis of severe trauma patients. The GCS in the RISC II is replaced by its motor component since it has been shown to be a better predictor than the total GCS score (79), while in the MPMN the total GCS score is still used to calculate of the RTS. Other variables such as reactivity and pupillary size were also added to the RISC II model based on their prognostic relevance in patients with TBI. In addition, there is a high prevalence of severe TBI in our series, 58% with AIS >2 at the head in the present study. Another important aspect is that the MPMN model underestimates the TBI, thus having a significant impact on the prognosis of severe trauma patients due to its high prevalence. It is shown that a grade 5 AIS lesion in the head has a higher mortality than an AIS lesion of 5 in the thorax or abdomen (101) and in the NISS-based MPMN model that is calculated with the AIS lesions this is not account. On the other hand, the RISC II model considers the two worst injuries with the highest AIS since they have been shown to predict the outcome of the trauma better than the ISS or NISS and they also consider the severity of the TBI, measured using AIS scale. This is an important factor that influences the prognosis of severe trauma patients. In addition, Lefering et al. used hospital mortality for their calculations, while our team used mortality rates at 30 days as recommended by Utstein's template (8).

As we have already mentioned, the calculation of RISC II for a severe trauma patient requires two essential variables, age and injury measured by the AIS scale but logically its predictive capacity increases as the values of the other remaining eleven variables are

added (99). On the other hand, the calculation of the MPMN model only requires 4 variables (age, hospital RTS, NISS and comorbidity according to ASA-PS) (9) and the values of these variables are present in almost all occasions (in this study, 98.5%). Given that both models have a good predictive capacity and are not statistically different and as it is easier to complete 4 variables than 13. Thus, MPMN is more likely to be implemented clinical practice due to its simplicity.

11.5 PAPER V

The overall results of this study showed that the adjusted mortality rates of severely injured patients in Navarra and Germany were comparable. The observed differences (0.04 difference in SMR) might be due to the difference in the trauma care systems and/or different populations in both registries.

There are some striking differences regarding the profile of injured patients between Germany and Navarra. The high percentage of young injured people in Germany compared to Navarra may be due to the traffic culture and the relatively liberal speed limits on the highways in Germany. In Navarra, the speed limit on highways and motorways is 100 km/h and 120 km/h respectively.

A high rate of low falls was found in both registries especially in the age group >60 years. As the proportion of elderly people increases, low falls with severe head trauma are also increasing. For example, in this study elder patients and a high percentage of head traumas were documented in MTR-N compared to TR-DGU®.

After having identified some differences in the two trauma populations, it is of highest interest whether the treatment of trauma patients and the organization of trauma care also would show some differences between Germany and Spain, or not.

In Navarra, paramedic resources for patient transport are used more frequently than in Germany. This is due to the Navarra's prehospital organization. A significant percentage of patients were transferred from the villages (periphery) in Navarra. In some cases, doctors sent patients in an ambulance accompanied by a paramedic, after attending them at the scene of the accident. In other cases, doctors attended the patient at the scene of the accident and the patient transferred to another ambulance team. Furthermore, changes in

trauma patient profiles have led to modifications of the resource activation protocols by Navarra's coordination center. For example, transfer of conscious elderly patients with isolated head injury after low fall to hospitals is delivered by paramedic ambulances. In the past, these patients were also attended to by physician-staffed resources but only for transfer. Given the limited number of physician-staffed ambulances in Navarra, and cost effectiveness requirements, protocols have been updated to adjust better to trauma needs and the seriousness of the case.

MTR-N has shown lower prehospital intubation rates in patients with GCS ≤ 8 . On the one hand, the use of supraglottic airway devices may be one of the reasons for not intubating these patients in the prehospital settings. Another reason could be the presence at the scene of the accident of an emergency physician. As previously reported about 5.6% of trauma patients from Navarra are transferred to the hospital in private vehicles. Other factors that may have influenced these results include the training of prehospital emergency medical services or the time taken to transfer the patients. However, further critical evaluation is required in this subgroup of patients, since the prehospital guidelines of Navarra recommend endotracheal intubation of all patients with GCS ≤ 8 and it is considered as one of the quality indicators of Navarra prehospital trauma organization.

More CT scans were performed in Navarra than in German hospitals. However, the percentage of whole body CT scans was lower in Navarra than in Germany. This is explained because in our hospitals doctors are still using selective CT scan rather than whole body CT scan. On one hand, there is a lack of solid scientific evidence in favor of whole body CT scan (197,198). Several retrospective and prospective studies agreed on a time benefit in favor of whole body CT scanning, but no consensus was obtained regarding a possible survival benefit (198–201). On the other hand, despite the favorable characteristics of CT scanning, it is still associated with a high radiation dose and might affect health care costs (202). It has been shown that whole body CT in high-energy trauma does not affect patient care if the patient is mentally alert, not intoxicated or shows signs of other than minor injuries when evaluated by a trauma-team. The risk of missing important traumatic findings in these patients is very low. Observation of the patient with reexamination instead of imaging may be considered in this group of often young patients where radiation dose is an issue (203).

This comparison between MTR-N and TR-DGU[®] has demonstrated areas for further improvement in both systems. Actions like massive publicity campaigns, a tightening of the penal code, speed limits, especially on high ways may reduce the vehicle accidents in Germany with the consequent reduction in the percentage of young injured population as seen in our region (24). Modifications at hospital and prehospital level are necessary in both systems to improve trauma quality care in both countries. Strategies to reduce the rate and severity of low falls may translate into positive results for trauma patients' survival in both countries.

11.6 Limitations of the study

11.6.1 Data quality

One limitation of the study is relatively small sample of patients when compared with large international databases. These aspects may limit the generalisability of the results. Unfortunately, there is no clear consensus in the literature on adequate sample size. Another limitation is the low number of published studies to evaluate the quality of a trauma registry (11), and therefore, there is no standard method for quality control (Study I & II).

Regarding completeness and correctness of cases of a trauma registry, no clear statement was found in the literature as to how many parameters are needed to perform a good data quality control for a medical registry. Most studies tend to investigate certain aspects such as the coding quality in a particular registry (204). Study II included all variables adjusted to Utstein recommendations and to our knowledge it was the first approach that gives a best possible overview about the data quality of these types of registries.

11.6.2 Validation of the MPMN and the RISC II in severe trauma patients documented in MTR-N

Firstly, it is a retrospective design, and therefore not initially intended to calculate the RISC II, which in some cases cannot be applied to all the independent predictive variables of the result. Some variables such as base excess was routinely measured but frequently not documented.

The H-L statistics test revealed good calibration for both models. However, the H-L tests have been criticized for relying heavily on sample size (205), i.e. the smaller the sample size the higher probability of a p-value >0.05 (i.e. good probability).

In addition, a prognostic model will always have better results in the population in which it was developed rather than in a different one (103). In this sense, it should be considered that RISC II is an index that comes from a population of trauma patients treated mainly in Germany and therefore the observed differences could be due to the different systems of trauma care in both countries.

11.6.3 TR-DGU[®] and MTR-N differences

Both the Navarra registry and TR-DGU[®] have different data collection procedures, inclusion criteria and coding methods.

In MTR-N, patients are included into the database thanks to the collaboration of users at different levels and a supervisor who is responsible for verifying completeness of data, adherence to the inclusion and exclusion criteria, and compliance with the Utstein style variables of each registered patient. TR-DGU[®] contains data from many different hospitals coded by multiple people. Despite multiple plausibility checks, the TR-DGU[®] may have more errors in its data input (206,207). Definitions were carefully checked to minimize bias due to the limitations mentioned above, and data were transformed into comparable variables where necessary. Some variables like ventilation days were redefined for this analysis as the Utstein template is unclear (8).

The different AIS versions used by both registries is a major limitation of this study and it may have affected the results. Specifically, the outcome prediction is affected in this comparison and requires a careful interpretation. For the majority of injuries, the severity levels were not changed during the AIS revisions. It has been shown that different AIS versions (e.g. AIS-98 vs. AIS-08) are not always comparable (208). However, a systematic assessment of AIS-85 versus AIS-08 was lacking. Nevertheless, it has previously been shown that a comparison of survival for trauma registries that use different AIS editions is possible (209). For trauma registries, a more contemporary AIS version should be adopted in order to enhance comparability with other registries. MTR-N will update its

AIS severity levels according to the recommendations by the Utstein template (8).

In study V, we excluded the early transfer out patients (<48h) from the descriptive analysis from the TR-DGU[®] because there was a risk of double counting; these patients may have been documented as “transfer in” patients from the receiving hospital; furthermore, outcome was missing in these cases, so they were also excluded for the RISC II calculation. In addition, patients who were transferred in from another hospital were also excluded because the RISC II score and initial status on admission were not available for these patients (99). In MTR-N, since a patient can be treated at different hospitals, the system supports the collaboration of several hospitals, enabling the possible management of transfers. Thus, a case of trauma may consist of several hospital records (one for each hospital) in which the system summarizes according to a predefined algorithm after analyzing the different hospital records (163). Consequently, information regarding the initial status on admission as well as outcome of a trauma case is always available.

Data on prehospital deaths are routinely documented in MTR-N (180) while no information about prehospital deaths is documented in TR-DGU[®]. It is useful to assess the effectiveness of care of the whole trauma system and the burden of trauma for society.

The outcome measure was 30-day all-cause mortality. It is well known that hospital mortality underestimates mortality in elderly people after trauma (166). The approach to consider 30-days mortality would miss some late deaths in hospital, while the focus on hospital deaths alone would miss some deaths in step-down units (like rehabilitation units or other hospitals).

While function and quality of life have been identified as important factors to measure trauma populations, a standardized protocol has not been established (210). Recently suggestions for a standardized approach to functional evaluation have been proposed (211). In these guidelines on evaluation of injury related disability, the authors advise to use a combination of EuroQol-5D and Health Utilities Mark III, along with the injury specific evaluation.

11.6.4 Differences between trauma systems in Navarra and Germany

Differences in trauma systems and hospitals – including prehospital treatment and hospital profiles – between Navarra and Germany are evident.

In Germany, physicians treated most of the trauma patients at the accident sites. Usually they are anesthetists with additional certification in emergency medicine.

In contrast, in Navarra doctors can attend a trauma patient at the scene and transfer them in a paramedic ambulance. In other cases, doctors attend a patient on scene and accompany the patient to the next hospital. Patients could also have been transferred to another ambulance team. Doctors working at prehospital and hospital level are family doctors with postgraduate emergency training.

Differences across the trauma systems and hospitals offer an opportunity to compare the different ways of treating trauma patients. In this study the analysis of large versus small trauma centers between both regions could not be carried out. On the one hand, choosing only larger trauma centers would result in a biased selection of cases. On the other hand, the number of hospitals in Navarra were too small to justify a subgroup analysis regarding size of hospital.

11.7 FUTURE IMPLICATIONS

11.7.1 Injury prevention

The proportion of elderly people continues its upward trend (210). The increasing elderly population is more active and longer-living than previous generation. Incidence of trauma in the elderly population, thus, has increased (211). Likelihood of falls increases with age associated with multiple factors (such as hearing problems, poor vision, muscle weakness, slow reactions, cognitive impairment and previous disabilities) as does the probability of significant injury as a consequence, while physiological reserve and the ability to recover is diminished (31). Accordingly, falls are the leading cause of injury deaths and disabilities among persons aged > 65 years and a major cause of pain, disability, loss of independence and premature death.

Steps should be taken to reduce falls from low-height and prevent therefore the consequent injuries (212). For this purpose, a risk assessment is necessary including the following:

- History of falls and patient's assessment of his/her functional ability.

- Medications and medical history.

- Perform gait assessment; physical examination (especially neurologic, cardiac); assessment of orthostatic vital signs; visual acuity examination; cognitive evaluation; examination of feet and footwear; home safety evaluation (213,214).

The exercise/physical therapy programs aimed at improving balance, gait, and strength has shown to reduce the frailty of the elderly (215), improve the cognitive function and strength muscle and increase quality of life (216–220).

Withdrawing or minimizing psycho-active medications (214), management of orthostatic hypotension (221), reduction of sarcopenia (220,222), management of foot problems, changes in footwear, modification of home environment (223), patient and caregiver education (213).

11.7.2 Future of the MTR-N

The MTR-N has now been functioning for seven years. Without the collaboration of different users and the supervision of a data manager, the registry would not exist. In addition, continuous work by the computer engineers in the development and maintenance of the registry, and the enthusiasm of the doctors involved with the MTR-N is essential.

Data from the MTR-N are increasingly useful for analysis of scientific questions for generating and testing hypotheses. As mentioned earlier, the MTR-N uses a self-created list of injuries which is based on AIS-85. Our injury coding in trauma registries should regard AIS updates. In order to be well in line with other trauma registries for international or national benchmarking, MTR-N will update its AIS version switching to AIS-08 version.

Other steps to improve the MTR-N must include the creation of an application in the patients' medical record to send the basic form (See Appendix C) to the data manager with the patient's clinical

history whenever a patient has an NISS >15, so that the case may be analysed and entered in the database.

Furthermore, to increase the completion rates of its variable, it will be necessary to implement the automation in the transfer of some variables such as base excess.

Future projects will cover conducting a long-term outcome study on severely injured patients in Navarra as well as cost-analysis of severe trauma.

12 CONCLUSIONS

1) Regarding the completeness of cases, there is a non-negligible number of patients not included despite fulfilling the inclusion criteria. These were often elderly patients (often women) with associated comorbidities and isolated head injury (I). Although the percentage of patients not included despite meeting the inclusion criteria in the MTR-N is relatively high (I), it represents a higher percentage of the casuistry compared to other records of injuries such as the German registry (V). This phenomenon may occur in other trauma registries, so steps must be taken towards the creation of specific registers to evaluate of these patients (I).

2) The evaluation of the data quality of the MTR-N in terms of completeness of data and concordance of the cases shows that it contains reliable and high-quality data (II).

3) The mortality of severe trauma patients attended to by the emergency system in our region is influenced by age and by the intensity of the aggression suffered, determined by the prehospital T-RTS and by the NISS. The prehospital response times do not have a significant influence (III).

4) The MPMN and RISC II models showed good discrimination and calibration to predict 30-day mortality in patients with severe trauma documented in MTR-N. The RISC II is applicable to the external comparative evaluation while in the case of internal comparison, the MPMN is suitable for the Navarra trauma system, since it is easier to calculate due to a smaller number of necessary variables (IV).

5) By using standardized records, it is possible to compare data of severely injured patients between Navarra and Germany. The overall adjusted outcome of severely injured patients treated in Navarra is comparable to that of Germany. Intubation rates were higher in Germany compared to Navarra even in trauma patients with GCS<9. Improvements are necessary at prehospital and hospital level to increase trauma quality care in Navarra. The

number of traffic accidents was higher in the TR-DGU[®] compared to the MTR-N, while in the Navarra hospitals there were more low-height falls compared to the German hospitals Regularly reviews of the management of severe trauma patients are necessary to detect areas for improvement (V).

CONCLUSIONES

1) En cuanto a la integridad de los casos, existe un número no despreciable de pacientes no incluidos a pesar de cumplir los criterios. La mayoría de pacientes no incluidos son de edad avanzada (a menudo mujeres) con comorbilidades asociadas y una única lesión craneal aislada (I). Aunque el porcentaje de pacientes no incluidos a pesar de cumplir los criterios de inclusión en el RTG-N es relativamente alto (I), representa un porcentaje mayor de la casuística en comparación con otros registros de trauma, como el registro de trauma alemán (V). Este fenómeno puede estar ocurriendo en otros registros de trauma, por lo que se deben tomar medidas para la creación de registros específicos para evaluar a estos pacientes (I).

2) La evaluación de la calidad de los datos del RTG-N en términos de integridad y concordancia de los casos muestra que estos son fiables y de alta calidad (II).

3) La mortalidad de los pacientes con trauma grave atendidos por el sistema de emergencias en nuestra región está influida por la edad, y por la intensidad de la agresión sufrida determinada por el T-RTS prehospitalario y por el NISS. Los tiempos de respuesta prehospitalaria no tienen una influencia significativa (III).

4)- Los modelos MPMN y RISC II han demostrado buena discriminación para predecir la mortalidad a 30 días en pacientes con trauma severo documentados en RTG-N. El RISC II es aplicable a la evaluación comparativa externa mientras que, para la evaluación comparativa interna, la MPMN es adecuada para el sistema traumatológico de Navarra, ya que es más fácil de calcular debido a un menor número de variables necesarias (IV).

5)- Al utilizar registros estandarizados, es posible comparar los datos de pacientes gravemente heridos entre Navarra y Alemania. El resultado global ajustado de los pacientes con lesiones graves tratados en Navarra es comparable al de Alemania. Las tasas de

intubación fueron más elevadas en Alemania que en Navarra, incluso en pacientes con GCS <9. Se necesitan mejoras a nivel prehospitalario y hospitalario para aumentar la calidad de la atención traumatológica en Navarra. El número de accidentes de tráfico fue mayor en el TR-DGU® en comparación con el MTR-N, mientras que en los hospitales de Navarra se atendieron más caídas de baja altura en comparación con los hospitales alemanes. Es necesario revisar continuamente el manejo del paciente traumatizado para detectar puntos de mejora en su asistencia (V).

13 FINAL CONCLUSIONS

MTR-N is precise, reliable, complete, and concordant with the medical record of patients. It contains reliable data, which is useful to improve trauma care and research in our community.

The Navarra trauma system provides good quality of care to severe trauma patients and its performance, in terms of short-term mortality, is comparable to Germany.

CONCLUSIONES FINALES

El RTG-N es preciso, fiable, completo y concordante con el registro médico de los pacientes. Contiene datos fiables que se pueden usar para la mejora de la calidad de la atención sanitaria y la investigación en nuestra comunidad.

El sistema traumatológico de Navarra brinda una buena atención a los pacientes con traumatismos graves en nuestra comunidad y su rendimiento es comparable al de los sistemas traumáticos más desarrollados de Europa, como Alemania.

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15 APPENDIX

15.1 APPENDIX A

AIS

With approximately 2000 entries, it scores individual injuries and classifies them from AIS 1 (Minor) to AIS 6 (Mortal) (16).

1. Minor injury
2. Moderate injury
3. Severe injury, with no vital commitment
4. Severe injury with vital commitment, probable survival
5. Critical Injury, Uncertain Survival
6. Incompatible injury to life

The ISS regions

These regions are as follows: head and neck including cervical spine, face; thorax includes diaphragm and dorsal spine; abdomen includes lumbar spine; extremities include pelvic ring and finally external injuries (abrasions, burns, etc.).

Patient example: In the following example, we calculate the severity of the injuries in a patient with severe trauma according to ISS and NISS.

Body region	Injury	AIS	AIS ² (ISS)	AIS ² (NISS)
Head	Accident amnesia	2	4	
Face	Nasal fracture	1		
Chest	Unilateral pleural effusion	3	9	9
Chest	Fractures of 5 ribs	3		9
Abdomen	Hepatic laceration	3	9	9
Extremities	Fracture of the distal phalanx of the first finger of the right hand	1		
Sum			ISS=22	NISS=27

The RTS score

Glasgow Coma Scale (GCS)	Systolic Blood Pressure (SBP)	Respiratory Rate (RR)	Coded Value
13-15	>89	10-29	4
9-12	76-89	>29	3
6-8	50-75	6-9	2
4-5	1-49	1-5	1
3	0	0	0

Coefficients of RISC II variables with their corresponding descriptions.

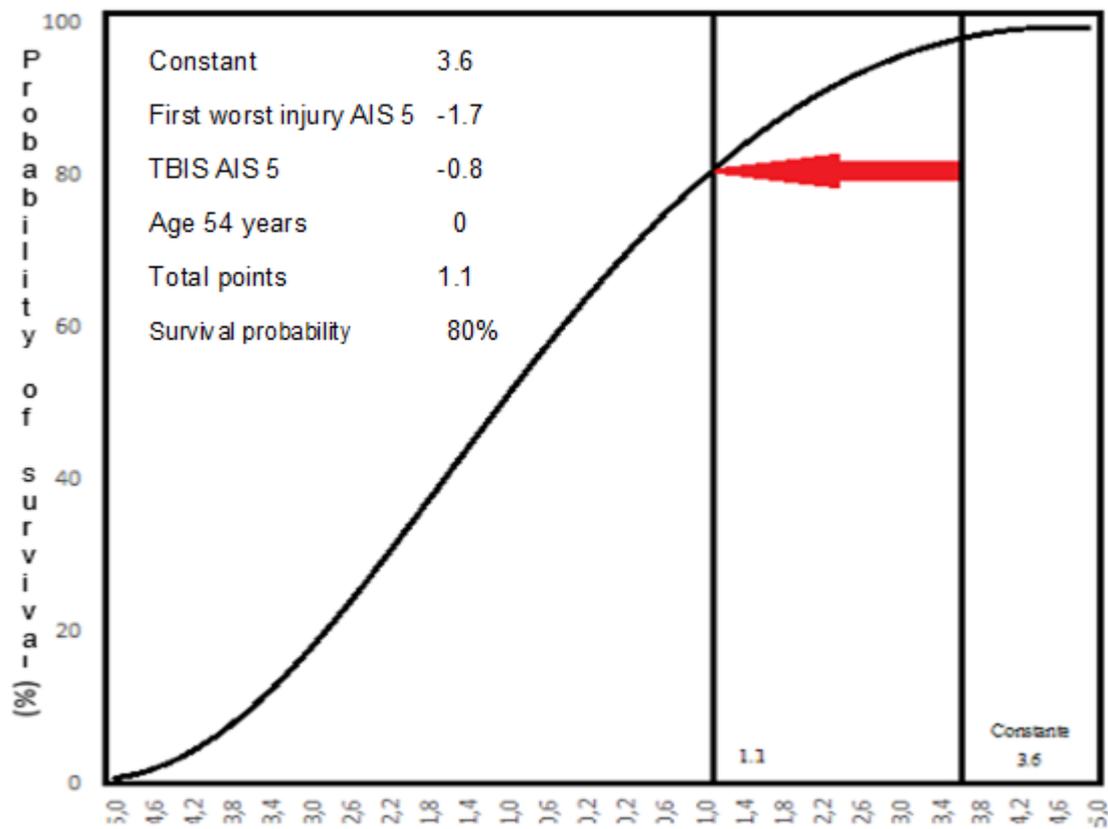
RISC II model variables	Variable description	Coefficient
Constant		3.6
Sex	Males/females	
	Male	0
	Female	+0.2
Injury Severity	Severity of the injury according to the AIS scale. If there is only one coded injury, the value of the second worst injury will be 0.	
Worst injury		
	AIS 3	-0.5
	AIS 4	-1.3
	AIS 5	-1.7
	AIS 6	-2.9
Second-worst injury		
	AIS 0-2	+0.2
	AIS 3	0
	AIS 4	-0.6
	AIS 5-6	-1.4
Head injury	Severity of the head injury according to the ISS scale	
	AIS 0-2	0
	AIS 3-4	-0.2
	AIS 5-6	-0.8
ASA	Pre-trauma ASA-PS as defined in the Utstein core dataset	
	1-2	+0.3
	3	0
	4	-1.3
Coagulation: INR	INR: The first value upon the patient's admission to the hospital. Divided into 4 categories.	
	<1.20	+0.6
	1.20-1.39	+0.2
	1.40-2.39, or missing	0
	≥ 2.40	-0.4
Acidosis: base deficit	Base deficit (mEq/L), the first value upon the patient's admission to the hospital. Divided into 4 categories.	
	<6.0	+0.3
	6.0-8.9, or missing	0
	9.0-14.9	-0.4
	≥ 15.0	-1.5
Mechanism	Divided into 2 categories: penetrating and blunt	
	Penetrating	-0.6
	Blunt	0
Systolic Blood Pressure	First value upon the patient's admission to the hospital. If no value is obtained, the prehospital Systolic blood pressure value can also be used, divided into 4 categories.	
	<90	-0.7
	90-110	0
	111-150	+0.3
	>150	0
Pupil reactivity	Pre-hospital data. If missing, assessment on admission was used. Divided into 3 categories according to the Eppendorf-Cologne Scale	

	(212).	
	Fixed	-1
	Sluggish, or missing	0
	Brisk	+0.2
Pupil size	Pre-hospital data. If missing assessment on admission was used. Divided into 3 categories according to the Eppendorf-Cologne Scale (212).	
	Both dilated	-0.5
	Anisocoria, or missing	0
	Normal	+0.2
Hemoglobin	Value upon the patient's admission to the hospital (mg/dl).	
	<7.0	-0.5
	7.0-11.9, or missing	0
	≥ 12.0	+0.4
CPR	Pre-hospital CPR, yes/no	
	Yes	-1.8
	No	0
Motor function	Use G assessment on admission in non-intubated cases; if missing, or patient was intubated, use prehospital assessment. Divided into 4 categories (212) according to the Eppendorf-Cologne Scale (Normal=6; Directed=4-5; Non-directed=2-3; None=1).	
	Normal	+0.6
	Directed	0
	Non-directed	-0.4
	None	-0.8
Age	Age in years at the time of accident, 10 categories	
	1-5	+1.4
	6-10	+0.6
	11-54	0
	55-59	-0.5
	60-64	-0.8
	65-69	-0.9
	70-74	-1.2
	75-79	-1.9
	80-84	-2.4
	≥ 85	-2.7

AIS, Abbreviated Injury Scale, ASA-PS, pre-injury American Society of Anesthesiologists Physical Status Classification, INR, International Normalized Ratio, CPR, Cardiopulmonary resuscitation, G, Glasgow coma scale.

An example of RISC II calculation

54 year old male with TBI



15.2 APPENDIX B

Criteria to activate the trauma code

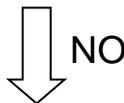
PHYSIOLOGICAL CRITERIA					
	Pediatric				Adults
	<1 year	>1 year			
RR/minute	<10 or >30	<10 or >30			<10 or >30
	Absence of pulses, capillary refill>3"				Pulse oximeter>90%
	<1 year	1 to 5 years	6 to 15 years		
HR/minute	<80 or >180	<80 or >180	<80 or >130		
	<1 month	1 month to 1 year	1 to 10 years	11 to 15 years	
P mmHg	<80	<70	<70 + age (years) x 2	<90	<90, absence of peripheral pulses
G	≤ 13				
	<12 years		13 to 15 years		Recovered CPR
Scores	ITP<9		RTS>12		



ANATOMICAL CRITERIA. (PRIORITY 1)

(The code will be activated with the presence of one of them).

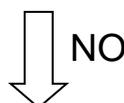
- Any penetrating injury in any anatomical location (firearm, weapon, bull horn, etc.).
- Massive closed trauma (entrapment / crushing).
- Suspicion of: Unstable thorax, flail chest, massive hemothorax, open pneumothorax.
- Suspected abdominal injury, (eFast +)
- Burns> 20% in adults or> 10% in children or inhalation or immersion injuries combined with trauma.
- TBI with neurological disorder, open fracture or sinking / deformity of skull, signs of skull base fracture.
- Proximal amputation by hand or ankle, catastrophic limb, crushing, entrapment.
- Paralysis or paresis of one or more extremities.
- Acute limb ischemia.
- Injuries to two or more body regions.
- Fracture of two or more long bones (proximal third), or fracture of the pelvis.
- Suspicion of spinal cord injury.



EVIDENCE OF A HIGH TRAUMA ENERGY. (PRIORITY 2)

(The code will be activated with the presence of one of them).

- Ejection from a vehicle (total or partial).
- Outrage.
- Impact with motor vehicle or bicycle at speed> 30 km / h.
- Precipitation of more than 3 meters.
- Explosion.
- Severe deceleration: Speed> 60-70 km / h.
- Difficult or prolonged extrication> 20 minutes.
- Crushing / Trapping.
- Structural deformity index (SDI)> 4.
- Overall evaluation of the traumatic event (dead passenger/s in the same vehicle, driver/motorist not wearing a helmet, occupants of the vehicle not wearing a seatbelt, significant deformity of the vehicle, accident with rollover).



SPECIAL CONSIDERATIONS* (PRIORITY 3)

(The code will be activated with the presence of one of them)

- Age ≥ 65 years.
- Pregnancy.
- Significant comorbidity (cardiorespiratory disease, diabetes mellitus, patients with anticoagulated and / or antiplatelet therapy, liver cirrhosis, morbid obesity, immunosuppression, chronic renal disease).

- Professional criteria *.

The patients under the section of Special Considerations should not be considered as solely as serious trauma, but for code activation when necessary, they will have to present some clinical alteration to be assessed by using the prehospital medical teams or the medical-coordinator (SOS Navarra).

* For example, after an analysis of our trauma registry, an increase in the number of TBI was observed in patients with anticoagulant therapy. These patients fall from their own height with “normal” normal vital signs. These patients are not considered severe trauma patients unless they present some warning signs such as impaired consciousness, or post-traumatic symptoms (headache, dizziness, nausea or vomiting, etc.).

** Due to difficult environmental conditions in pre-hospital settings, the level of evidence is low, however, the diversity of experience and knowledge of the prehospital staff is considerable, so the professional approach will be of great importance when considering a patient as serious trauma.

Variables of MTR-N adjusted to the Utstein style.

Identification variables	
Age	Number
Sex	1. Male; 2. Female; 3 = Unknown
Date and hour of admission	Date and hour
Hospital	1. Complejo Hospitalario of Pamplona; 2. Hospital Reina Sofia in Tudela; 3. Hospital Garcia Orcoyen in Estella
Prehospital data	
Dominant type of injury	1 = Blunt; 2 = Penetrating; 3 = Unknown
Mechanism of injury	1 = Motor vehicle injury; 2 = Motorcycle injury; 3 = Bicycle injury; 4 = Pedestrian; 5 = Traffic: other; 6 = Shot by handgun, shotgun, rifle, other firearm of any dimension; 7 = Stabbed by knife, sword, dagger, other pointed or sharp object; 8 = Struck or hit by blunt object; 9 = Low-energy fall; 10 = High-energy fall; 11 = Unknown
Intention of injury	1 = Accident (unintentional); 2 = Self-inflicted (suspected suicide, incomplete suicide attempt, or injury attempt); 3 = Assault; 4 = Other
CPR, G, RR, P, RTS	Number
Intubation	No; 2. Yes;1
Type of intubation	Orotracheal; 2. Supraglottic airway; 3. Others
Highest level of pre-hospital care provider	1 = Level I. No field care; 2 = Level II. Basic life support; 3 = Level III. Advanced life support, no physician present; 4 = Level IV. Advanced life support on-scene, physician field care
Type of transportation	1. Medicalized ambulance &/or helicopter; 2. None medicalized ambulance &/or helicopter 3. Private vehicle; 4. Others
Time from alarm to arrival at scene	The time from when the emergency call is answered (at the emergency call center) until the first medical provider arrives at the patient
Time from alarm to hospital arrival	The time between when the alarm call is answered (at the emergency call center) and when the patient arrives at the reporting hospital
Hospital variables	
Pre-injury ASA-PS Classification System	1 = A normal healthy patient/ a patient with mid systemic disease; 2 = A patient with moderate systemic disease; 3 = A patient with severe systemic disease
All Injuries according to AIS in each of the 6 anatomic regions	Number (1 to 6)
ISS, NISS, RR, G, SBP, RTS, Coagulation: INR, Arterial base excess, Time until normal arterial base excess, Hb, (upon arrival at ED/hospital) Time to first Computerized Tomography (CT) scan	Number
Type of first key emergency intervention	1 = Damage control thoracotomy; 2 = Damage control laparotomy; 3 = Extraperitoneal pelvic packing; 4 = Limb revascularization; 5 = Interventional radiology; 6 = Craniotomy; 7 = Intracranial pressure (ICP) device
Highest level of care	1. A & E, 2. Hospitalization; 3. Operating theatre, 4. ICU
Outcomes	
Discharge destination	1 = Home; 2 = Rehabilitation; 3 = Morgue; 4 = Another ICU (higher treatment level); 5 = Another intermediate or low care somatic hospital ward
Glasgow Outcome Scale – at discharge from main hospital	1 = Good recovery; 2 = Moderate disability (disabled but independent); 3 = Severe disability (conscious but disabled; depends on others); 4 = Persistent vegetative state (unresponsive); 5 = Death
Survival status	1 = Dead; 2 = Alive (4-week follow up after injury)
Length of stay and mechanical ventilation	Number

CPR, cardiopulmonary resuscitation, G, Glasgow coma scale, RR, Respiratory Rate, SBP, systolic blood Pressure, RTS, Revised Trauma Score, ISS, Injury Severity Score, NISS, New Injury Severity Score, INR, International Normalized Ratio, Hb, Hemoglobin, A & E, Accident and Emergency ICU, Intensive Care Unit.

15.3 APPENDIX C

Basic form

Basic form for trauma patient

Hospital Clinical record

Date of event

Name First family name Second family name

Age Sex Male or Female Mechanism of injury

- 1- traffic
- 2- fall
- 3- weapon
- 4- other: work accidents, etc

Type of injury 1- Blunt
2- Penetrating

Data on anatomical and physiological indicators to fill out

Anatomical index

Head	Face
Grade 1	Grade 1
Headache/ dizziness secondary to head trauma <input type="checkbox"/>	Corneal abrasion <input type="checkbox"/>
Neck stiffness without fracture or dislocation <input type="checkbox"/>	Tongue abrasion <input type="checkbox"/>
Scalp laceration <input type="checkbox"/>	Nose fracture or jaw branch <input type="checkbox"/>
Thorax	Abdomen
Grade 1	Grade 1
Rib fracture <input type="checkbox"/>	Abrasion/ laceration of the vagina, vulva, penis, scrotum or perineum <input type="checkbox"/>
Rigid dorsal spine <input type="checkbox"/>	
Ribcage contusion <input type="checkbox"/>	
Grade 2	
Extremities	Extrenal
Grade 1	Grade 1
Contusion elbow, shoulder, knee <input type="checkbox"/>	Less than 26 cm abrasion in face, hand within 51 cm of the body <input type="checkbox"/>
Phalangeal fracture or contusion <input type="checkbox"/>	
Patient's injuries	Calculation ISS and NISS
	ISS <input type="text"/>
	NISS <input type="text"/>

Physiological index

Revised Trauma Score (Calculator)

Systolic Blood Pressure (mmHg)

Respiratory Rate (breaths per minute)

Glasgow Coma Score

Calculate

15.4 APPENDIX D: PUBLISHED PAPERS



Missing patients in “Major Trauma Registry” of Navarre: incidence and pattern

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Abstract

Background Trauma registries (TR) collect information about trauma patients according to inclusion criteria, and it helps to establish protocols to improve care. However, all TR deal with incompleteness. The aim of this study is to assess the number of patients not included despite fulfilling inclusion criteria in our regional TR and identifying the predictors for being missing.

Methods The sample was randomly selected. Two months of each year from 2010 to 2014 (5 years) were selected, and medical files of all patients attended in the emergency department room during those months were studied. Patients who were already correctly included in the TR were assigned to the ‘included’ group, and patients who should have been but were not to the ‘missing’ group. The multivariable logistic regression analysis was performed to identify predictors for being missed from the TR.

Results Of a total of 200, 79 (40 % approximately) were identified as missing. We defined the characteristic profiles of missing patients and found that the hospital RTS and the number of injuries are independent predictors to be missing

in our trauma registry, with an adjusted odds ratio of 1844 [95 % (1092–3114) and 0.574 (95 % CI 0.428–0.770)], respectively.

Conclusions Overall, 40 % of the patients who met the inclusion criteria of the TR were not included in the registry. Our results can be generalized to other trauma records based on Utstein style, because we think probably that this fact is also happening in other databases.

Keywords Humans · Missing patients · Trauma registries · Utstein style

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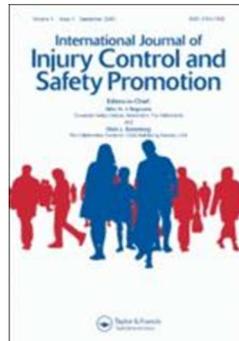
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Quality assessment of Major Trauma Registry of Navarra: Completeness and correctness

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Manuscript ID	NICS-2017-0031.R1
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Keywords:	data quality, missing values, correctness, completeness, base excess

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Manuscripts

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Influencia de los tiempos de respuesta prehospitalarios en la supervivencia de los pacientes politraumatizados en Navarra

Influence of prehospital response times in the survival of trauma patients in Navarra

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RESUMEN

La relación entre los tiempos de respuesta y la mortalidad de los pacientes politraumatizados en la denominada "hora de oro" sigue siendo tema de debate.

El objetivo del presente estudio es determinar las variables relacionadas con la mortalidad en dichos pacientes y la influencia de los tiempos de respuesta de los Servicios Médicos de Emergencia en dicha mortalidad.

Para ello se analizaron los datos del Registro "Major Trauma de Navarra" (cohorte retrospectiva de pacientes politraumatizados atendidos por el sistema sanitario de Navarra) durante los cuatro años comprendidos entre 2010 y 2013.

De los 217 casos de trauma disponibles para el análisis, fallecieron 42 (19%). En el análisis multivariante no se encontró asociación significativa entre los diferentes tiempos de respuesta y la mortalidad: llegada a la escena (odds ratio (OR) 1,0; intervalo de confianza al 95% (IC) de 0,99 a 1,01), en el escenario (OR 1,00; IC 95% de 0,98 a 1,02) y tiempo total (OR 1,00; IC 95% de 0,99 a 1,01). Las variables que influyen en la mortalidad son la edad del paciente y la gravedad de las lesiones medidas por el Triage-Revised Trauma Score (T-RTS) prehospitalario y el New Injury Severity Score (NISS).

La mortalidad de los pacientes politraumatizados atendidos por el sistema de emergencias en nuestra región está influida por la edad, y por la intensidad de la agresión sufrida determinada por el T-RTS prehospitalario y por el NISS. Los tiempos de respuesta prehospitalarios no influyen significativamente.

Palabras clave. Mortalidad del politraumatizado. "Hora de oro". Tiempos de respuesta prehospitalarios.

ABSTRACT

The relation between response times and mortality of polytrauma patients in the so-called "golden hour" continues to be a subject of debate.

The purpose of this study is to determine the variables related to mortality in these patients and the influence of response times of the Emergency Medical Services in this mortality.

To this end, the data in the "Major Trauma of Navarra" Register (retrospective cohort of polytrauma patients attended to by the Navarre Health Service) were analyzed for the four year period between 2010 and 2013.

Of the 217 trauma cases available for the analysis, 42 (19%) died. No significant association was found in the multivariate analysis between the different response times and mortality: arrival at the scene (odds ratio (OR) 1.0; 95% confidence interval (CI) from 0.99 to 1.01), in the scenario (OR 1.00; 95% CI from 0.98 to 1.02) and total time (OR 1.00; 95% CI from 0.99 to 1.01). The variables that influenced mortality are patient age and severity of injuries measured by the prehospital Triage-Revised Trauma Score (T-RTS) and the New Injury Severity Score (NISS).

The mortality of polytrauma patients attended to by the emergency system in our region is influenced by age and by the intensity of the aggression suffered, determined by the prehospital T-RTS and by the NISS. The response times of the hospital do not have a significant influence.

Keywords. Polytrauma mortality. "Golden hour". Pre-hospital response times.

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INTRODUCCIÓN

Hoy en día continúa el debate sobre qué estrategia de actuación prehospitalaria es mejor en el tratamiento del paciente politraumatizado (PPT) si “cargar y correr” o “quedarse y estabilizar”, y en este sentido siguen publicándose artículos que dan argumentos en uno u otro sentido¹⁻⁶. La clave de este tema es conocer si el valor añadido que da la actuación *in situ* de los Servicios Médicos de Emergencia (cateterizar una vía en la escena del accidente o actuar sobre la vía aérea, inmovilizar o realizar cualquier otra acción sobre el PPT) a pesar de alargar los tiempos en escena se ve recompensado con una mayor supervivencia.

El objetivo del presente estudio es determinar las variables relacionadas con la mortalidad en dichos pacientes y la influencia de los tiempos de respuesta de los Servicios Médicos de Emergencia en dicha mortalidad.

PACIENTES Y MÉTODO

Este estudio se llevó a cabo en Navarra, región situada al norte de España y que limita con Francia, con una superficie de 10.421 Km² y 637.000 habitantes. El sistema de emergencias es gestionado por un Centro de Coordinación que moviliza los recursos prehospitalarios según la gravedad de las víctimas (ambulancias medicalizadas y no medicalizadas) que trasladan a los PPT a los correspondientes servicios de urgencias hospitalarios. La comunidad cuenta con un hospital terciario y dos hospitales generales comarcales.

Desde 2010 nuestra comunidad cuenta con el *Major Trauma Registry de Navarra* (MTRN)⁷ que recoge retrospectivamente la cohorte de PPT gestionados por el sistema de emergencias con las variables definidas según el estilo normalizado Utstein y que se muestran en la tabla 1. Fueron incluidos todos los PPT lesionados por agentes externos de cualquier intencionalidad entre el 1 de enero de 2010 y el 31 de diciembre de 2013, con un *New Injuri Severity Score* (NISS) superior a 15 y atendidos por las

UVI-Móviles del Sistema de Emergencias de Navarra. Fueron excluidos aquellos cuya admisión en el hospital se produjo tras más de 24 horas de sufrir la lesión, lesionados por asfixia por inmersión, lesionados por ahorcamiento o pacientes quemados que no presentaban otras lesiones traumáticas⁸. El proceso utilizado para la recolección de datos ha sido descrito en detalle en una publicación previa⁹.

La protección de datos se garantizó con el uso de mecanismos de encriptación SSL 3.0/TLS 1.0 y registro de accesos. El Proyecto contó con el visto bueno del Comité ético de investigación clínica del Departamento de Salud del Gobierno de Navarra.

Los tiempos de respuesta fueron calculados automáticamente por la base de datos a través de las horas reflejadas en las aplicaciones informáticas del Sistema de Emergencias que gestiona los vehículos de atención prehospitalaria y la aplicación informática de los hospitales que gestiona los pacientes desde el momento que llegan al hospital. Los diferentes intervalos se obtuvieron en base a los tiempos: hora de llamada, hora de llegada a la escena, hora de salida de la escena y hora de llegada al hospital⁷.

Los datos categóricos se presentaron mediante el número absoluto y el porcentaje. Los datos cuantitativos se expresaron mediante la media y desviación estándar (SD) y la mediana y rango inter cuartil (IQR) cuando se consideró adecuado. Los datos categóricos se compararon mediante la prueba de χ^2 . Cuando no se cumplían las condiciones de aplicación, y en tablas 2x2, se utilizó el test exacto de Fisher. Las variables cuantitativas se compararon mediante el test de la t de Student y las pruebas no paramétricas mediante la prueba de la U de Mann-Whitney. Se utilizó la regresión logística para evaluar la asociación entre los tiempos de respuesta con la mortalidad con control de las variables que influyen en la misma. La variable dependiente fue la supervivencia o no y las variables independientes aquellas que resultaron significativas en el análisis bivariante y los tiempos de respuesta de atención prehospitalaria, objeto del presente estudio.

Tabla 1. Variables de los pacientes incluidos en la base con sus correspondientes categorías

Variables relacionadas con la fragilidad del paciente	Categorías
Edad	Edad del paciente en el momento del accidente
Sexo	1 = hombre/ 2 = mujer
Morbilidad previa al accidente según el sistema de clasificación ASA-PS	1 = sin patología/ 2 = enfermedad sistémica moderada/ 3 = enfermedad sistémica grave
Variables relacionadas con el accidente	Categorías
Tipo predominante	1 = contuso/ 2 = penetrante
Mecanismo	1 = vehículo de motor / 2 = motocicleta/3 =bicicleta/ 4 = atropello/ 5 = otros relacionados con tráfico/ 6 = arma de fuego/ 7 = arma blanca/ 8 = objetos diversos/ 9 = caída de baja energía/ 10 = caída de alta energía
Intencionalidad	1 = accidental/ 2 = autoagresión / 3 = agresión/ 4 = Otros
Revised Trauma Score (RTS)	Recogido por los primeros intervinientes en el lugar del accidente
Abbreviated Injury Scale (AIS)	Códigos AIS que reflejan la severidad de las lesiones del paciente
Injury Severity Score (ISS) y New ISS (NISS)	Valores del ISS y NISS que reflejan la severidad de las lesiones
Variables relacionadas con la atención pre hospitalaria	Categorías
Tiempo desde la alarma a la llegada al escenario	Tiempo transcurrido entre la entrada de la llamada de socorro al 112 y la llegada a la escena de los recursos asistenciales extra hospitalarios
Tiempo en el escenario	Tiempo que transcurre desde la llegada del equipo al escenario hasta que sale hasta el hospital
Tiempo desde la alarma a la llegada al hospital	El tiempo entre la entrada de la llamada de alarma al 112 hasta que el paciente llega al hospital
Nivel de los primeros intervinientes	1 = nivel I/ sin cuidados/ 2 = nivel II/ Soporte Vital Básico/ 3 = nivel III/ soporte vita intermedio (presencia de recursos de Atención Primaria)/ 4 = nivel IV/ Soporte vital Avanzado (UVI-Móvil o helicóptero medicalizado)
Intubación pre hospitalaria	1 = si/ 2 = no
Resultado	Categorías
Destino al alta	1 = domicilio 2 = rehabilitación/ 3 = Fallecido/ 4 = Traslado a otro centro de mayor nivel/ 5 = hospital de larga estancia
Secuelas a su alta hospitalaria según escala de Glasgow	1 = sin secuelas/ 2 = secuelas moderadas/ 3 = grandes secuelas con gran dependencia/ 4 = estado vegetativo/ 5= muerte
Supervivencia	1 = fallecimiento/ 2 = supervivencia (a los 30 días)

RESULTADOS

Se incluyeron para el análisis los datos de 462 PPT que cumplieron los criterios de inclusión. De ellos fueron excluidos 215 casos por ausencia de alguno de los tiempos de respuesta (escena o tiempo de transporte); 8 por tiempos erróneos (tiempos me-

nores de cero o mayores de 300 minutos); 2 casos por ausencia de variable dependiente (supervivencia o exitus); 2 por ausencia de NISS; 15 por ausencia de T-RTS y 3 por no constar la edad. Después de todas las exclusiones se dispuso de 217 pacientes (Fig.1).

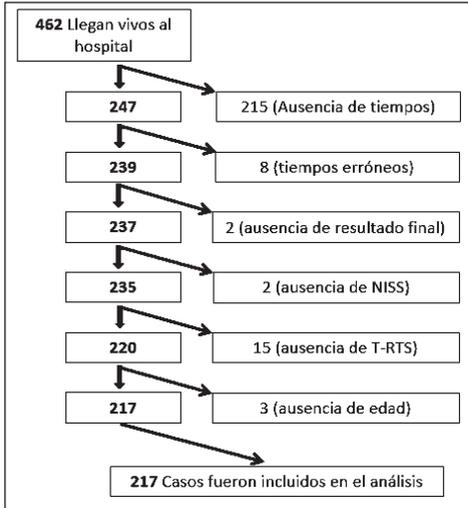


Figura 1. Diagrama de flujo. Pacientes incluidos en el estudio.

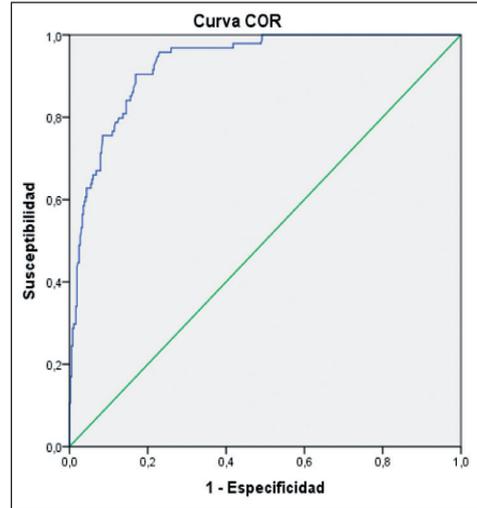


Figura 3. Curva ROC de los factores asociados a la mortalidad de los pacientes politraumatizados del Modelo 1, Área bajo la curva/ 0,931 IC 95% 0,873-0,964.

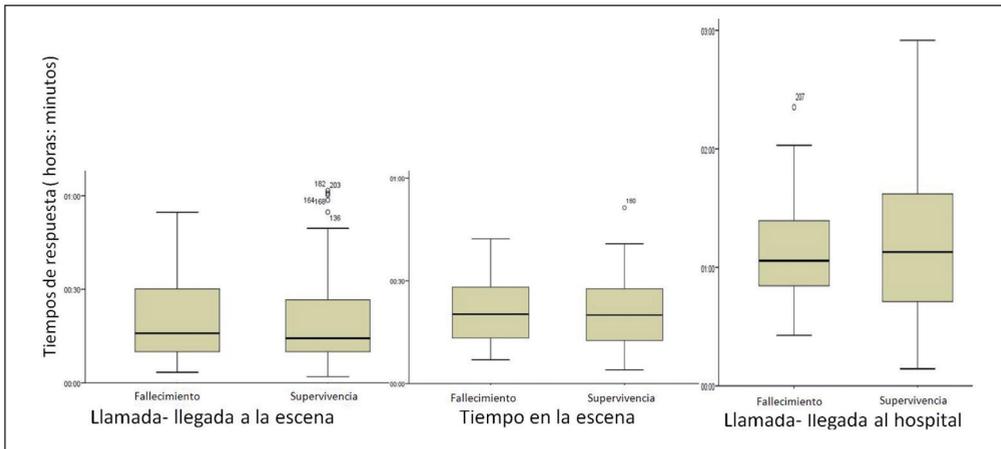


Figura 2. Diagramas de cajas en las que se observan los tiempos de respuesta de los equipos de emergencias desglosados en los grupos de pacientes que fallecieron y sobrevivieron,

De los 217 casos de PPT disponibles para el análisis, fallecieron 42 (19%). Del total de las lesiones 206 (94%) fueron contusas 42 fallecimientos (20%) y 11 (5%) fueron penetrantes, sin que se produjera ninguna defunción. La edad media y sexo de los accidentados fue de 50 ± 21 años (69% hombres) con un rango entre 1 y 93 años.

Fueron intubados 35 pacientes (16%), inmovilizados con diferentes métodos 141 (65%); a 137 (63%) se les cateterizó una vía periférica y a 145 (67%) se les administró oxígeno por diferentes dispositivos.

La puntuación media y su correspondiente desviación estándar en los diferentes parámetros de gravedad de las lesiones

Tabla 2. Distribución de los pacientes por las diferentes variables y resultado final

Variables	Valores	Fallecidos	Supervivientes	p
Total de pacientes	217	42 (19%)	175 (81%)	
Edad				
Media (desviación Estandar)	50 ± 21,3	66,3 ± 18,1	46,1 ± 20,2	<0,01
Sexo				
Varones	150 (69,1%)	27 (18%)	123 (82%)	0,46
Mujeres	67 (30,9%)	15 (22,4%)	52 (77,6%)	
Tipo de lesión				
Contusa	206 (94,1%)	42 (20,4%)	164 (79,6%)	0,08
Penetrante	11 (5,1%)	0 (0%)	11 (100%)	
Mecanismo				
Trafico	107 (49,3%)	17 (15,9%)	90 (84,1%)	0,03
Arma blanca o de fuego	8 (3,7%)	0 (0%)	8 (100%)	
Caída	49 (22,6%)	16 (32,7%)	33 (67,3%)	
Precipitación de altura	36 (16,6%)	8 (22,2%)	28 (77,8%)	
Otros	17 (7,8%)	1 (5,9%)	16 (94,1%)	
Intencionalidad				
Accidental	194 (89,4%)	36 (18,6%)	158 (81,4%)	0,56
Autoinflingida	13 (6%)	4 (30,8%)	9 (69,2%)	
Agresión	10 (4,6%)	2 (20%)	8 (80%)	
Índice fisiológico de gravedad				
RTS en el lugar del accidente, media (DS)	7 ± 1,3	5,8 ± 1,8	7,4 ± 0,8	<0,01
Índice anatómico de gravedad				
NISS, media (DS)	29,1 ± 10,8	39,4 ± 12,2	26,6 ± 8,8	<0,01
ISS	21,7 ± 9,5	29,2 ± 9,8	19,9 ± 8,6	<0,01
Intubación prehospitalaria				
No	182 (83,9%)	24(13,2%)	158 (86,8%)	<0,01
Sí	35(16,1%)	18 (51,4%)	17 (48,6%)	
Primer hospital de asistencia				
Centro de Trauma	155 (71,4%)	33 (21,3%)	122 (78,7%)	0,34
Hospital Comarcal	62 (28,6%)	9 (14,5%)	53 (85,5%)	
Tiempos de Respuesta				
Llamada – llegada a escena, media (SD)	00/26 ± 00/28	00/21 ± 00/15	00/23 ± 00/22	0,68
Mediana (IQR)	00/17 (00/10-00/30)	00/17 (00/13-00/31)	00/18 (00/10-00/34)	0,84
Tiempo en escena	00/23 ± 00/17	00/22 ± 00/15	00/23 ± 00/18	0,33
Llamada – llegada al hospital	00/21 (00/12-00/30)	00/17 (00/14-00/31)	00/17 (00/13-00/31)	
	01/14 + 00/42	01/08 ± 00/28	01/15+ 00/44	
	01/05 (00/43-01/36)	01/03 (00/50-01/19)	01/05 (00/44-01/39)	

fue en la escala de Glasgow 12 + 5 puntos, RTS 11+ 1,3 puntos y el NISS de 29 +10.

La variable dependiente fue la supervivencia a los 30 días, y en relación con esta variable, los cruces de las posibles variables predictoras asociadas con la misma, quedan reflejados en la tabla 2.

Los tiempos de respuesta desglosados por pacientes que sobreviven o fallecen se reflejan en la Fig.2.

El análisis de regresión logística incluyendo las variables predictoras que resultaron significativas en el análisis bivalente y los tiempos de respuesta quedan reflejados en la tabla 3.

La precisión del modelo 1 queda representado por la curva *Receiver Operating Characteristic* (ROC) y el área comprendida bajo la misma que es del 93% queda reflejado en la Fig. 3.

Tabla 3. Regresión logística de los factores independientes asociados a la mortalidad de los politraumatizados, Variable dependiente (fallecimiento=1/ supervivencia=0), OR con sus correspondientes intervalos de confianza al 95%,

Modelo 1. Variables cuantitativas	OR	IC 95%	p
Edad	1,11	1,03-1,19	0,006
RTS prehospitalario	0,36	0,17-0,78	0,010
NISS	1,20	1,06-1,35	0,003
Intervalo 1/ llamada-llegada al escenario	1,00	0,99-1,01	0,926
Intervalo 2/ llegada-salida del escenario	1,00	0,98-1,02	0,892
Intervalo 3/ llamada-llegada a Urgencias	1,00	0,99-1,01	0,624

Modelo 2. Variables cualitativas dicotómicas	OR	IC 95%	p
Edad	4,47	2,43-7,55	0,003
RTS prehospitalario	16,00	10,51-21,03	0,000
NISS	12,56	9,31-17,45	0,001
Intervalo 1/ llamada-llegada al escenario	1,00	0,91-1,02	0,835
Intervalo 2/ llegada-salida del escenario	1,00	0,93-1,03	0,820
Intervalo 3/ llamada-llegada a Urgencias	1,00	0,85-1,07	0,532

Los ajustes se han realizado en el **Modelo 1** por las variables cuantitativas/ edad, RTS prehospitalario y NISS que son aquellas que se han seleccionado entre las que presentaban significación estadística en el análisis bivariante y coherencia desde el punto de vista clínico y de gestión del paciente, Se incluyen los tiempos de respuesta como variables de estudio, En el **Modelo 2** se han incluido las mismas variables convertidas en dicotómicas/ edad (mayor o menor a 50 años)/ RTS (mayor o menor a 7)/ NISS (mayor o menor a 29)/ intervalo 1 (mayor o menor de 17 min.)/ intervalo 2 (mayor o menor de 21 min.)/ intervalo 3 (mayor o menor de 65 min), Se han utilizado como punto de corte las medias en el caso de la edad, RTS y NISS y las medianas debido a la dispersión de los valores en los tiempos de respuesta.

DISCUSIÓN

Tal y como reconoce Prat en su publicación¹⁰, a pesar de ser el tiempo una pieza clave en un sistema de atención al trauma, el registro sistemático y el análisis de estos resultados son desconocidos en nuestro entorno, de ahí la importancia de difundir los resultados de los diferentes estudios que se llevan a cabo en nuestro país.

Las características de los PPT incluidos en nuestra base son muy parecidas a los encontrados en la base alemana *Deutsche Gesellschaft für Unfallchirurgie* (DGU) y otras de nuestro país coincidiendo plenamente en una edad media cercana a los 50 años, con un predominio de varones (70%), con un tipo de lesiones casi totalmente contusas (solamente un 5% de lesiones penetrantes) y de tipo accidental. Casi la

mitad de la casuística la aportan los accidentes de tráfico, seguidos por las caídas de baja energía (25% de los casos)¹⁰⁻¹².

En cuanto a las diferencias en nuestra base el *Injury Severity Score* (ISS) medio es de casi 22 mientras que en la base alemana es de 17. Es llamativa también una menor tasa de intubación prehospitalaria en nuestro caso (16% frente al 23% de la DGU) y una mayor mortalidad (19% en Navarra frente al 10% de la DGU y Cataluña)^{10,12}. No sabemos exactamente a qué obedecen dichas diferencias si bien una posibilidad es la inclusión en nuestra base de un grupo de pacientes ancianos con gran mortalidad y lesiones encefálicas severas a los que dada su situación de calidad de vida previa no se llega a intubar ni se realizan acciones agresivas. Se trata de pacientes ancianos frágiles, en tratamiento anticoagulante que su-

fren caídas accidentales y que en muchas ocasiones acaban en fallecimiento ya que se limita el esfuerzo terapéutico^{7,9}.

En nuestra base nos hemos ceñido estrictamente a los criterios de inclusión definidos por el estilo Utstein y pensamos que las diferencias con otros grupos pueden provenir de este grupo de pacientes que posiblemente no se incluyen en otras bases⁸.

Los tiempos de respuesta obtenidos en nuestro estudio son muy similares a los obtenidos en otros estudios en países desarrollados y con características similares a los de nuestra región¹²⁻¹⁶. Un estudio francés que compara la gestión realizada en PPT por SAMU (atención medicalizada) con la filosofía de estabilización y traslado, frente a la realizada por bomberos de cargar y correr, muestra una mejor tasa de supervivencia de dichos pacientes a pesar de presentar índices de gravedad peores. En nuestra región, la gestión de los PPT se adapta a dicha filosofía de atención medicalizada y traslado y las conclusiones de su estudio serían aplicables a nuestro caso¹⁷. Los tiempos de respuesta son mayores en el caso de los pacientes trasladados por SAMU pero no influyen en la supervivencia¹⁸.

En la línea anteriormente expuesta, un estudio de Irán demuestra que la mortalidad se asoció con la gravedad de las lesiones y largos tiempos de transporte prehospitalario. En pacientes gravemente heridos que recibieron intervenciones de soporte vital avanzado se observaron tendencias de supervivencia positivas a pesar de aumentar los tiempos de transporte¹⁹.

En los estudios evaluados a nivel nacional, no se hace referencia a tiempos de respuesta, con lo que no existe un parámetro nacional con el que comparar nuestro estudio¹⁰.

En cuanto a la influencia de los tiempos de respuesta en la supervivencia, diferentes estudios sugirieron que el aumento de los tiempos de respuesta prehospitalarios se asociaron con un aumento de la mortalidad de los PPT^{11,15}, no obstante estas afirmaciones han sido contestadas en otras ocasiones por otros autores que ponen en

tela de juicio este hallazgo y lo atribuyen a sesgos relacionados con muestras pequeñas de pacientes quirúrgicos altamente seleccionados, pacientes generados en áreas rurales con largos tiempos de respuesta o muestras mixtas que incluían pacientes con paro cardíaco no traumático²⁰⁻²².

El término "hora de oro" es utilizado para identificar la necesidad de atención urgente de los PPT. Este concepto implica que la morbi-mortalidad se ve incrementada si el cuidado no se instaura en la primera hora después de la lesión y justifica la atención precoz de estos pacientes con los medios adecuados. Sin embargo, diferentes estudios reconocen que no hay datos objetivos que avalen dicho concepto⁶.

Algunos estudios centrados en pacientes muy específicos que se pueden beneficiar de intervenciones prehospitalarias "salvadoras" como las víctimas de trauma penetrante torácico, demuestran que los pacientes más graves llegaron a los centros de traumatología antes. La mortalidad estuvo fuertemente asociada a la gravedad de la lesión, y por ese motivo a pesar de los tiempos pre-hospitalarios más cortos se asociaron con una mayor supervivencia¹⁶. Como ya se ha dicho, en nuestra base las heridas penetrantes torácicas son muy escasas y difícilmente van a tener relevancia estadística por este motivo y por tanto tampoco los tiempos de respuesta prehospitalarios asociados a su tratamiento.

Una interesante revisión sistemática de 46 artículos demuestra que la mayoría de la investigación en trauma es favorable al traslado rápido sin actuaciones que puedan demorar su acceso al hospital en caso de trauma penetrante, y en casos de corta distancia a un hospital. En los pacientes con lesiones graves en la cabeza, el soporte vital avanzado proporcionado por los paramédicos y la intubación pueden ser perjudiciales. Si la atención prehospitalaria es proporcionada por un sistema medicalizado con experiencia, dichas intervenciones pueden ser beneficiosas para los pacientes con lesiones múltiples y lesiones cerebrales severas. Sin embargo reconoce que los resultados son contradictorios²³.

En un estudio con 3.656 pacientes, de los cuales fallecieron el 22%, en el análisis multivariante tampoco se encontró asociación significativa entre el tiempo y la mortalidad por cualquiera de los intervalos (respuesta, en el lugar del siniestro, transporte y tiempo total¹⁴.

En relación con la denominada “hora de oro”, diferentes autores reconocen que aunque hay pacientes gravemente lesionados, que pueden requerir actuaciones tiempo-dependientes para sobrevivir (desobstrucción de la vía aérea, ventilación, control de hemorragia externa en un sitio compresible, etc.), para la mayoría de los pacientes puede no haber efecto medible. También es plausible que la “hora de oro” dependa principalmente de la rapidez de las intervenciones en los hospitales (tiempo de realización de TAC o tiempo de primera intervención quirúrgica de control de daños, y por ello los tiempos de respuesta “per se”, no entran en los análisis de regresión logística como variable relacionada con la supervivencia, como sucede en nuestro estudio.

Una línea interesante de investigación es la de algunos autores que critican el estudio de Newgard y col y piden que se den más datos de los 1.385 pacientes que murieron en la escena y fueron excluidos del estudio. Para estos pacientes se desconocía el intervalo de la intervención prehospitalaria y no se podía concluir que el tiempo no tuvo ningún efecto sobre su muerte^{24,25}. En nuestro estudio tampoco contamos con tiempos de respuesta de estos pacientes, pero en la comparación que establecimos entre ambos grupos hemos demostrado que son varones en un porcentaje mayor, más jóvenes, con aumento de los sucesos autolíticos penetrantes posiblemente por armas de fuego y con una gravedad de las lesiones muy superior al otro grupo. Parece razonable pensar que los tiempos de respuesta no son los responsables del fallecimiento de nuestros pacientes en la denominada “hora de oro”, sino la gravedad de las lesiones.

Little afirma que más que en la “hora de oro”, los proveedores de salud deben centrarse en la “oportunidad de oro” para

proporcionar la mejor atención al paciente crítico controlando las situaciones que amenacen la vida del paciente y trasladándolo al centro apropiado en condiciones óptimas²⁶.

En nuestro estudio, las diferencias en los tiempos de respuesta entre los pacientes que sobreviven y fallecen son muy pequeñas, incluso dándose la paradoja de que el tiempo total es menor en los que fallecen. Tal y como queda demostrado por la estadística multivariante esto se debe a la gravedad del paciente que hace que los sistemas prehospitalarios sean lógicamente más rápidos en estos pacientes¹⁶.

El estudio de la DGU sobre 15.103 pacientes presentó un tiempo en escena de 33 minutos (ligeramente superior a los nuestros) e identificó las intervenciones y las condiciones características con un impacto significativo en los tiempos en la escena del accidente. La intubación se asoció con tiempos más prolongados, mientras que la situación de coma se asoció con la reducción del mismo. Los tiempos totales son muy similares a los recogidos en nuestra serie y se encuentran en torno a los 60 minutos¹².

En traumatismos craneales con AIS >3 se demostró aumento de la supervivencia en los pacientes que llegaron antes al hospital, pero el beneficio puede extenderse más allá de la “hora de oro”. No hubo evidencia de mejores resultados en los pacientes que llegaron dentro de los primeros 60 minutos tras el accidente⁴.

El estudio tiene algunas limitaciones como ser una muestra de pacientes relativamente pequeña si se compara con las grandes bases internacionales. Asimismo hay una pérdida de 215 casos en los que no hay tiempos de respuesta y otros 8 erróneos, lo que puede dificultar el análisis de los resultados. Tampoco se incluyen en el análisis los pacientes fallecidos *in situ* y tal y como han comentado algunos autores, sería muy interesante conocer los tiempos de respuesta de los pacientes que no llegan vivos al hospital^{24,27}. Dicho interrogante abre una nueva línea muy interesante en este tema.

Del estudio, concluimos que la mortalidad de los pacientes politraumatizados

atendidos por el Sistema de Emergencias Médicas en nuestra región está influida por su fragilidad determinada por la edad y por la intensidad de la agresión sufrida medida por el *Triage-Revised Trauma Score* (T-RTS) y por el *New Injury Severity Score* (NISS). Los tiempos de respuesta prehospitalarios son suficientemente buenos como para no influir significativamente en el fallecimiento de dichos pacientes.

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IV

ORIGINAL

Validación del Modelo de Predicción de Mortalidad de Navarra y su comparación con el Revised Injury Severity Classification Score II en los pacientes con traumatismo grave atendidos por el Sistema de Emergencias de Navarra

Bismil Ali Ali¹, Rolf Lefering², Mariano Fortún Moral³, Tomás Belzunegui Otano^{1,4}

Objetivo. Validar el Modelo de Predicción de Mortalidad de Navarra (MPMN), y compararlo con el Revised Injury Severity Classification Score II (RISC II) para predecir la mortalidad en los pacientes con traumatismo grave (PTG).

Método. Estudio analítico de cohorte retrospectivo de PTG (New Injury Severity Score –NISS– >15 puntos) atendidos por el Sistema de Emergencias de Navarra entre 2013-2015. La variable resultado fue la mortalidad por cualquier causa a los 30 días. Se calcularon los modelos de riesgo MPMN y RISC II. El rendimiento de los modelos se evaluó con la curva característica operativa del receptor (COR) y el área bajo la curva (ABC), la precisión con la mortalidad observada y predicha, y la calibración con la prueba de Hosmer-Lemeshow.

Resultados. Se incluyeron 516 pacientes con una edad media de 56 (DE 23) años, de los cuales 363 (70%) fueron varones. Noventa (17,4%) pacientes fallecieron a los 30 días. La mortalidad a 30 días predicha para el modelo MPMN y RISC II fue de un 16,4% y 15,4%, respectivamente. El ABC de la COR para el modelo MPMN fue de 0,925 (IC95% 0,902-0,952) y para el modelo RISC II fue de 0,941 (IC95% 0,921-0,962) (p de DeLong = 0,269). La calibración del modelo MPMN fue de 13,6 (p = 0,09) y del modelo RISC II fue de 8,9 (p = 0,35).

Conclusiones. Los modelos MPMN y RISC II muestran buena capacidad de discriminación para predecir la mortalidad global a los 30 días entre los PTG.

Palabras clave: Trauma. Modelos predictivos. Calidad asistencial al trauma. Mortalidad.

Mortality in severe trauma patients attended by emergency services in Navarre, Spain: validation of a new prediction model and comparison with the Revised Injury Severity Classification Score II

Objective. To validate the Mortality Prediction Model of Navarre (MPMN) to predict death after severe trauma and compare it to the Revised Injury Severity Classification Score II (RISCII).

Methods. Retrospective analysis of a cohort of severe trauma patients (New Injury Severity Score >15) who were attended by emergency services in the Spanish autonomous community of Navarre between 2013 and 2015. The outcome variable was 30-day all-cause mortality. Risk was calculated with the MPMN and the RISCII. The performance of each model was assessed with the area under the receiver operating characteristic (ROC) curve and precision with respect to observed mortality. Calibration was assessed with the Hosmer-Lemeshow test.

Results. We included 516 patients. The mean (SD) age was 56 (23) years, and 363 (70%) were males. Ninety patients (17.4%) died within 30 days. The 30-day mortality rates predicted by the MPMN and RISCII were 16.4% and 15.4%, respectively. The areas under the ROC curves were 0.925 (95% CI, 0.902–0.952) for the MPMN and 0.941 (95% CI, 0.921–0.962) for the RISCII ($P=0.269$, DeLong test). Calibration statistics were 13.6 ($P=0.09$) for the MPMN and 8.9 ($P=0.35$) for the RISCII.

Conclusions. Both the MPMN and the RISCII show good ability to discriminate risk and predict 30-day all-cause mortality in severe trauma patients.

Keywords: Trauma. Risk models. Quality of trauma care. Mortality.

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V

ORIGINAL RESEARCH

Open Access



Epidemiological comparison between the Navarra Major Trauma Registry and the German Trauma Registry (TR-DGU®)

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Abstract

Background: International benchmarking can help identify trauma system performance issues and determine the extent to which other countries also experience these. When problems are identified, countries can look to high performers for insight into possible responses. The objective of this study was to compare the treatment and outcome of severely injured patients in Germany and Navarra, Spain.

Methods: Data collected, from 2010 to 2013, in the Navarra Major Trauma Registry (NMTR) and the TraumaRegister DGU® (TR-DGU) were compared. Both registries followed the Utstein Trauma Template (European Core Dataset) for documentation of trauma patients. Adult patients (≥ 16 years) with New Injury Severity Score (NISS) being >15 points were included in this study. Patients who had been admitted to the hospital later than 24 h after the trauma, had been pronounced dead before hospital arrival, or had been injured by hanging, drowning or burns, were excluded. Demographic data, injury data, prehospital data, hospital treatment data, time intervals, and outcome were compared. The expected mortality was calculated using the Revised Injury Severity Classification score II (RISC II).

Results: A total of 646 and 43,110 patients were included in the outcome analysis from NMTR and TR-DGU, respectively. The difference between observed and expected mortality was -0.4% (standardized mortality ratio [SMR] 0.97; 95% CI 0.93–1.04) in Germany and 1.6% (SMR 1.08; 95% CI: 1.02–1.14) in Navarra. Differences in the characteristics of trauma patients and trauma systems between the regions were noted.

Conclusion: The higher observed mortality in Navarra is consistent with the epidemiological characteristics of its population. However, to improve the quality of trauma care in the Navarra trauma system, certain improvements are necessary. There were less young adults with severe injuries in Navarra than in Germany. It is possible to compare data of severely injured patients from different countries if standardized registries are used.

Keywords: Severe trauma, Trauma registry, Registry comparison, Quality of trauma care

Background

Major trauma is a leading cause of death and disability [1]. Despite the importance of injuries, there are no strict national guidelines for trauma care in Spain, nor is there a nation-wide trauma registry. It has been shown that trauma registries are valid tools to assess and improve trauma care [2]. The great value of trauma registries lies in their potential to perform benchmarking at regional, national or international level [2].

The Navarra Major Trauma Registry (NMTR) was created in 2010 in Navarra, a region of northern Spain bordering France [3]. For benchmarking purposes, this registry follows the recommendations of the uniform Utstein style for documentation of severe trauma in Europe [4].

The outcome of emergency care of severely injured patients in Navarra has been compared previously. Gomez de Segura et al. compared the Navarra Emergency System and Atlantic Pyrenees (France) using data from 2001 to 2002. The results showed that despite more aggressive approach and employment of great resources, the French comprehensive emergency system didn't show greater survival rates among injured patients compared to Navarra [5].

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In Europe, the UK Trauma Audit and Research Network (TARN), the German Trauma Registry (TR-DGU®), the Dutch trauma registry, the Norwegian Trauma Registry and the Swedish Trauma Registry are well established nationwide trauma registries. The TR-DGU, a national initiative for documentation of care of severely injured patients in Germany, was founded in 1993 [6]. Nijboer et al. compared the demographics, injury mechanisms, treatment, and mortality of severely injured trauma patients (ISS >15) treated in 2005 in a level-one trauma center in Queensland (Australia) and in 59 German level-one trauma centers. The results exhibited that, despite the differences in trauma systems especially, in pre-hospital care, between both countries, the observed mortality was lower than expected in both Australia and Germany [7].

A similar study was performed by Brink et al. comparing treatment and survival of severely injured patients (NISS > 15) treated between 2006 and 2011 in Germany and Southern Finland. The authors concluded that the overall outcome results of both regions were similar and registry comparison is a feasible method of quality control in a trauma center [8].

Brilej et al. also evaluated the quality of treatment of 155 severely injured patients treated in 2006–2007 at the General Hospital Celje (Slovenia) using Trauma and Injury Severity Score (TRISS) and Revised Injury Severity Classification (RISC) methodology. The study concluded that, despite some differences between Germany and General Hospital Celje, RISC analysis performed better than TRISS in terms of discrimination, calibration and precision [9].

International benchmarking can help identify trauma system performance issues and determine the extent to which other countries also experience these. When problems are identified, countries can look to high performers for insight into possible responses. In addition, by using an international perspective, comparisons can inform benchmarks and targets for national and/or provincial governments. For successful benchmarking, meaningful performance benchmarks that can guide health policy and patient care decisions must be drawn from comprehensive, systematically collected, and valid data [10]. In Spain, data are limited at national level, and most of the well-established trauma registries are at regional or provincial level, such as the NMTR [11].

The main aim of the present study was to compare the Injury profile, treatment and outcome of severely injured patients in Navarra (Spain) and Germany using trauma registries in the respective countries.

Methods

Study populations

For this study, data from the NMTR and the TR-DGU® between January 1, 2010 and December 31, 2013 were

used. For both registries, patients eligible for inclusion in this study were adults >15 years who had been injured by external agents with any type of intent and New Injury Severity Score (NISS) over 15 points. Patients who had been admitted to the hospital later than 24 h after the trauma, who had been declared dead before hospital arrival, who did not exhibit signs of life upon their arrival to the hospital, who did not respond to resuscitation techniques, who had been injured by hanging or drowning, or burnt patients without other traumatic injuries, were excluded.

Trauma system in Navarra and Germany

Navarra is an autonomous province in Northern Spain with an area of 10,421 km² and a population of 637,000 inhabitants. The emergency care system of Navarra is publicly funded, providing coverage to the entire population. The system is divided in three areas: Pamplona, Tudela and Estella. There are three hospitals that treat severe trauma patients in the region, through which all relevant information is included in the NMTR [3]. Navarra's first recognized Major Trauma Service (comparable to a Level 1 trauma center), the Complejo Hospitalario de Navarra (CHN) in Pamplona, is the only tertiary referral hospital in the region. The two local hospitals (Reina Sofia in Tudela and Garcia Orcyoyen in Estella) can provide initial trauma care while waiting for the right moment to transport the patient to the CHN.

Prehospital management was performed by a coordination center. The center mobilizes the resources for out-patient care (physicians or paramedics) taking into account the seriousness of the victim's condition, referring them to the appropriate hospital emergency services. Paramedic resources (basic life support ambulances) include certified ambulance assistant technicians. Physician-staffed services (ambulances and helicopters with advanced life support) responsible for medical assistance include physicians, registered nurses and certified assistant technicians. In Pamplona, there are two physician-staffed ambulances strategically positioned that provide medical assistance to the whole area. The areas of Tudela and Estella each have one physician-staffed ambulance, at their hospitals.

Pre-hospital and hospital physicians are usually family doctors with post-graduate emergency medicine training. Around 200 trauma patients with NISS >15 are annually registered in Navarra.

Germany has a multi-payer healthcare system with two main types of health insurance: obligatory health insurance for work-related accidents and general health insurance [12]. In Germany, physician-operated emergency medical services manage most pre-hospital traumas. There are 52 physician-staffed helicopters, approximately 1000 physician-staffed ambulances and numerous paramedic-

staffed ambulances. A physician at scene sees almost all serious trauma cases. Doctors working pre-hospital and hospital are physicians with a post-graduate emergency medicine training and certification; usually they are anesthesiologists [13].

In both Navarra and in Germany, trauma care is performed following the Advanced Trauma Life Support guidelines. One major difference is the resuscitation in the emergency department. In Navarra, emergency physicians perform resuscitations, whilst in Germany, it is done by a surgeon-directed trauma team. These are general surgeons with extensive experience in trauma care including fracture management [7]. Therefore, the number of involved specialties, and subsequently doctors, is often lower than in Navarra.

The registries: NMTR and TR-DGU®

The NMTR was created in 2010 with the aim of internal and external benchmarking [3]. This is a comprehensive population registry strictly tailored to the variables and categories defined by the European Utstein Core Dataset for documentation of trauma patients [4]. Based on the Abbreviated Injury Scale (AIS), the injuries suffered by each patient are entered using a computer application. This application contains an adapted list of 152 injuries based on the revised AIS 1985 version [14], sorted by the six body regions of the Injury Severity Score (ISS), with their appropriate AIS severity level.

Database inclusion criteria were patients injured by external agents of any kind with a NISS >15. Exclusion criteria were: patients admitted to the hospital more than 24 h after injury; patients declared dead before arrival at hospital or with no signs of life on hospital arrival and no response to hospital resuscitation; asphyxia; drowning; or burnt patients with no other trauma injuries [4].

A Web application, that allows the cooperation by various users in the registry of patient data, was developed. Approximately 150 people, all doctors from the Navarra's hospital and prehospital emergency care departments and intensive care units (ICU) of the public health system, used the application. A data manager was responsible for the general supervision and administration of the system, as well as for verifying the compliance of the inclusion criteria and of the introduction of patient data. Data was checked for completeness and plausibility; inconsistencies and missing data were handled through the hospital. Automatically generated reports on completeness of data were available at any time.

A patient can receive treatment at different hospitals: the system enables the collaboration between several hospitals and the possible management of transfers. A trauma patient may have several hospital records (one in each hospital), in which case the system generates a review by using a predefined algorithm, post-analysis of

the various records. Consequently, the information on the patient's admission status and the outcome of a trauma case are always available.

The NMTR also includes information about trauma patients who died on the scene or while being transported to the hospital [15]. Furthermore information about the severity of the injury at the scene of a motor vehicle crash, calculated by Structural Deformity Index (SDI), is also documented in the NMTR [16]. The use of the SDI can assist prehospital and hospital health care providers if particular serious injuries are suspected and anatomical and physiological criteria are not definitive.

The TraumaRegister DGU® of the German Trauma Society (*Deutsche Gesellschaft für Unfallchirurgie, DGU*) was founded in 1993. The aim of this multi-centre database is the pseudonymised and standardised documentation of severely injured patients. Injuries were coded according to the AIS, version 2008. The TR-DGU uses a reduced version with only 450 codes for documentation where similar codes with the same severity level were merged [6].

The documentation includes detailed information on demographics, injury pattern, comorbidities, pre- and in-hospital management, the course in the ICU, relevant laboratory findings including transfusions, and the outcome of every patient. The inclusion criterion is the admission to the hospital through the emergency department and subsequent ICU/ICM care or reach the hospital with vital signs and death before being admitted to the ICU.

The infrastructure for documentation, data management, and data analysis was provided by the AUC - Academy for Trauma Surgery (*AUC - Akademie der Unfallchirurgie GmbH*), a company affiliated to the German Trauma Society. The scientific leadership was provided by the Committee on Emergency Medicine, Intensive Care and Trauma Management (Sektion NIS) of the German Trauma Society. Participating hospitals submitted their pseudonymised data to a central database via a web-based application. Scientific data analysis was approved following a peer review procedure established by Sektion NIS.

The participating hospitals are primarily located in Germany (90%), but a rising number of hospitals of other countries contribute data as well (at the moment from Austria, Belgium, China, Finland, Luxembourg, Slovenia, Switzerland, The Netherlands, and the United Arab Emirates). Currently, the information of approximately 30,000 cases yearly, from over 600 hospitals, have been entered in the database. However, for the analysis in this study, only patients treated in German hospitals were considered.

The participation in the TR-DGU® is voluntary. For hospitals associated with TraumaNetzwerk DGU® however, the entry of at least a basic data set is obligatory for quality assurance.

Comparisons

In this study, the following parameters were compared between the NMTR and the TR-DGU[®]: age, sex, pre-injury ASA, injury scoring, injury pattern, mechanism of injury, injury distribution, pre-hospital timings, transportation method, pre-hospital intubation, treatment at hospital, discharge destination and mortality. NMTR documents 30-day mortality defined as death within 30 days after injury or before discharge from the main hospital while TR-DGU[®] documents hospital mortality. For reasons of comparability patients who died beyond day 30 were considered survivors in this analysis. Regarding injury coding, in TR-DGU[®] injuries were graded according to reduced (450 codes) version of AIS08. This reduction was possible due to numerous detailed injury descriptions (codes) with the same severity level. Such codes were merged into a single code, conserving the appropriate severity descriptor. On the other hand, according to the revised AIS85 version, a list of 152 injuries was used in the NMTR. Note that in this list, most of injuries have the same injury severity level, for instance: grade 3 for femur fractures, etc. So, NMTR reported the injury severity level instead the full AIS code. A few injuries thus had a different severity level as in the actual version of AIS used in TR-DGU[®].

Expected mortality was defined as the average value of individual prognosis derived from the Revised Injury Severity Classification II (RISC II), a prognostic score developed from the TR-DGU[®] data. For the TR-DGU[®] we excluded the early transfer out patients (< 48 h) from the descriptive analysis because there was a risk of double counting; these patients may have been documented as “transfer in” patients from the receiving hospital; furthermore, outcome was missing in these cases so they were also excluded for RISC II calculations (Fig. 1). In addition, patients who were transferred in from another hospital were also excluded because RISC II scores and initial status on admission were not available for these study subjects [6].

NMTR and TR-DGU[®] parameters were checked for comparability, and transformations had to be made for some of the variables before the analysis. Comparisons are based on real measurements; no imputations for patients with missing data were performed. The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS version 23, IBM Inc., Armonk NY, USA).

Ethics approval

Navarra’s Local Medical Ethics Committee approved this study under Pyto 2016/48. The study is also in line with the publication guidelines of the TraumaRegister DGU[®] and registered as TR-DGU[®] project ID 2014–038.

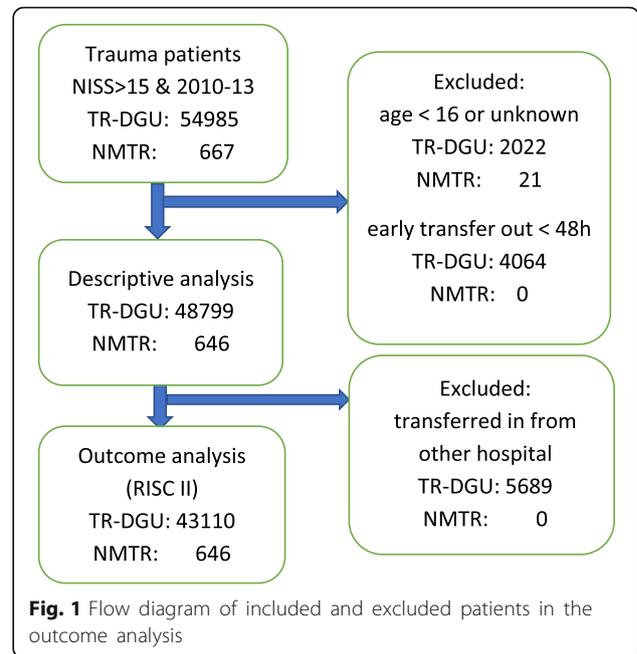


Fig. 1 Flow diagram of included and excluded patients in the outcome analysis

Results

Patient characteristics

For descriptive analysis, the present study included data of 646 patients from NMTR attended in three hospitals of Navarra and data of 48,799 patients attended in 611 hospitals with documentation in TR-DGU[®]. Figure 1 shows the flow chart of included and excluded patients.

Patient transfer patterns were similar in both trauma systems, with major trauma patients generally transferred from smaller hospitals to major trauma centers for definitive management. In Navarra, 22.4% (170 out of 646) of the patients were transferred between facilities; while in Germany this percentage was 11.7% (5689 out of 43,110).

Table 1 Characteristics of severely injured patients between Germany and Navarra (Spain)

Total no. of patients	NMTR	TR-DGU
	646	48,799
Primary cases (directly admitted from scene and treated in the receiving hospital)	476 (73.6%)	43,110 (88.3%)
Age, mean (SD)	57.9 ± 21.9	51.6 ± 20.7
	M: 58	M: 51
Male Gender	441 (68.3%)	34,919 (71.9%)
ASA (3 or 4)	55 (8.5%)	6627 (15.8%)
ISS, mean (SD) median (M)	20.4 ± 9.7	24.1 ± 11.9
	M: 17	M: 22
NISS, mean (SD) median (M)	26.5 ± 9.6	30.7 ± 13.7
	M: 25	M: 27

Table 1 shows the characteristics of the patients included in the analysis. The average age at the time of injury was 57.9 ± 21.9 years in Navarra and 51.6 ± 20.7 years in Germany. The percentage of trauma patients by age group between both regions is shown in Fig. 2.

Injuries: mechanism, type, and distribution

Information related to injuries is shown in Table 2. The number of traffic accidents was higher in the TR-DGU[®] compared to the NMTR (55.6% vs 36.3%), while more low-height falls were attended in hospitals of Navarra compared to German hospitals (34.5% vs 20.0%).

Figure 3 shows the distribution by age group of traffic accidents in the two registries and Fig. 4 displays the distribution by age group of low-height falls regarding to in both registries. A higher rate of chest, extremities, and abdominal trauma was determined from the Germany registry in comparison to Navarra registry (53.1% vs 42.5%, 31.4% vs 12.0 and 13.6% vs 8.2%, respectively). The prevalence of head injuries was higher in NMTR than TR-DGU[®] (61.5% vs 47.0%). However, isolated head injuries (e.g. AIS-code ≥ 3 in the head region, all other AIS-codes < 2) were slightly more common in German hospitals compared to Navarra’s hospitals (15.0% vs 13.9%, respectively).

Prehospital setting

Prehospital details between both regions are shown in Table 3. In Germany, more patients were treated by

physician-staffed ambulances than in Navarra (67.4% vs. 58.1%, respectively). Helicopters were more often used to transport trauma patients in Germany (25.8%) than Navarra (4.3%). German patients receive more volume than Navarra patients (88.6% with a median of 1000 ml vs 62.3% with a median of 500 ml). Regarding response times, Navarra’s prehospital team spend more time on scene than German teams ($0:34 \pm 0:21$ vs $0:30 \pm 0:17$).

More unconscious patients were observed in Germany (24.2%) than in Navarra (14.6%). Intubation rates were higher in Germany than in Navarra (36.6% vs 11.8%, respectively). Furthermore, patients with GCS < 9 on scene were more intubated by German prehospital teams than Navarra teams as shown in Table 4.

Diagnostic procedures and treatment at hospitals

Data on CT scans and surgical interventions, the prevalence in ICU, days ventilated (all intubated days and possible continuous positive airway pressure [CPAP] treatment counted together), the length of hospital stay, and the discharge destination are presented in Table 5.

More CT scans were performed in Navarra’s hospitals than in German ones (96.2% vs 88.4%, respectively). However, more whole-body CT scans were made in Germany in comparison to Navarra (77.1% vs. 44.4%, respectively). It took more time to perform the first post-admission CT scan and the first surgical intervention in Navarra versus Germany ($0:43$ and $1:52$ vs. $0:23$ and $1:23$, respectively).

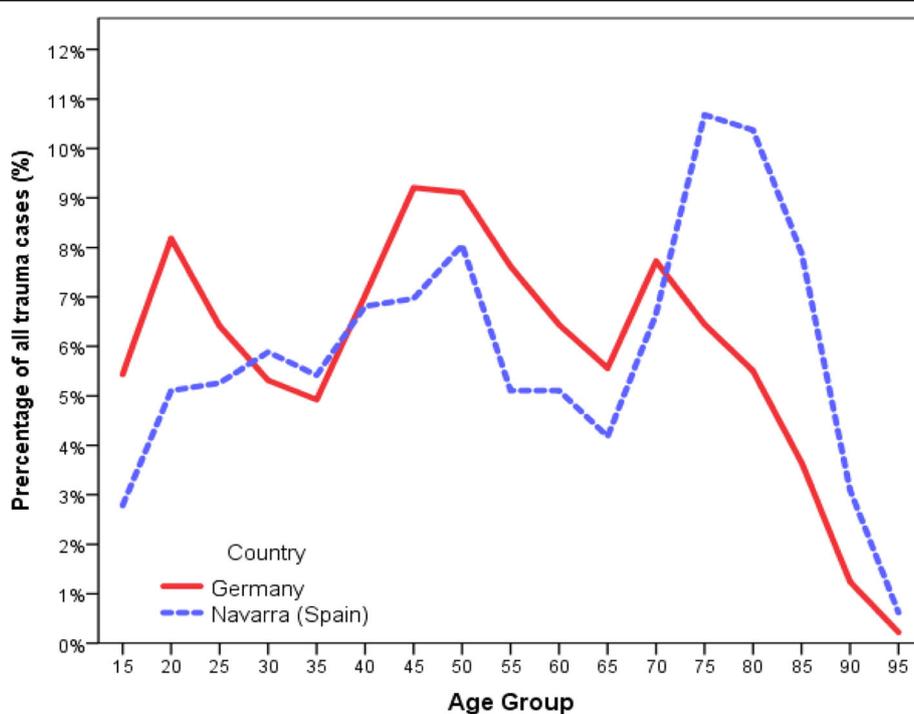


Fig. 2 Percentage of patients by age group presenting with traumatic injuries in Navarra (Spain) and Germany

Table 2 Type, intention and mechanism of injury

Injury: Type, mechanism and distribution	NMTR	TR-DGU
Type of injury		
Blunt	620 (96.0%)	44,233 (95.9%)
Mechanism of injury		
Motor vehicle injury	112 (17.3%)	10,969 (23.2%)
Motorcycle injury	49 (7.6%)	6583 (13.9%)
Bicycle injury	34 (6.0%)	3699 (7.8%)
Pedestrian	36 (5.4%)	3216 (6.8%)
Gunshot wounds	3 (0.9%)	304 (0.6%)
Stabbing	11 (2.4%)	577 (1.2%)
Hit by blunt object	31 (5.5%)	1322 (2.8%)
Low fall (<3 m)	250 (34.5%)	9472 (20.0%)
High fall (>3 m)	91 (13.2%)	8275 (17.5%)
Others	29 (4.7%)	2700 (5.3%)
Road traffic accidents	231 (36.3%)	24,988 (55.6%)
Injury distribution		
Bran injury (AIS head ≥3)	397 (61.5%)	22,927 (47.0%)
Isolated head injury (AIS head ≥3, all other injuries AIS ≤ 1)	90 (13.9%)	7337 (15.0%)
Relevant thorax trauma (AIS ≥ 3)	274 (42.5%)	25,916 (53.1%)
Relevant abdominal trauma (AIS ≥ 3)	53 (8.2%)	6648 (13.6%)
Relevant injuries of the extremities (AIS ≥ 3)	77 (12.0%)	15,327 (31.4%)

Patients were more likely to be admitted to the ICU in German hospitals than in Navarra's hospitals (91.4% vs. 36.0%, respectively). High percentage of ventilated patients (52.5% vs. 23.2%), more ventilation days (8.8 ± 11.5 vs. 5.8 ± 8.5) and longer periods of hospitalization were determined in Germany in comparison to Navarra (21.0 ± 20.9 vs. 12.1 ± 14.0 days).

Outcomes

30-day mortality was 21.6% in NMTR and 14.9% in TR-DGU*. Figure 5 shows the mortality rate of trauma patients by age group in both regions. The difference between the observed and expected mortality of all patients was -0.4% (standardized mortality ratio [SMR] 0.97; 95% CI 0.93–1.04) in Germany and 1.6% (SMR 1.08; 95% CI: 1.02–1.14) in Navarra.

In Navarra, 64.4% (401 out of 646) of patients were discharged home directly from the hospital, compared with 52.2% (21,497 out of 48,799) in Germany. The number of patients discharged to rehabilitation services was higher in Germany than in Navarra (32.3% vs. 2.9%).

Discussion

The overall results of this study show that the adjusted mortality rates of severely injured patients treated in Navarra and Germany are comparable. RISC II prognosis considered in this study display slightly lower predicted mortality than the actual mortality available from the NMTR. This might be because a score derived prognosis refers to the expected outcome in the development population [17]. For RISC II, this is a trauma population mostly treated in Germany for the 2010/11 period [6].

Other reasons that support the observed differences could therefore also might be due to the difference in

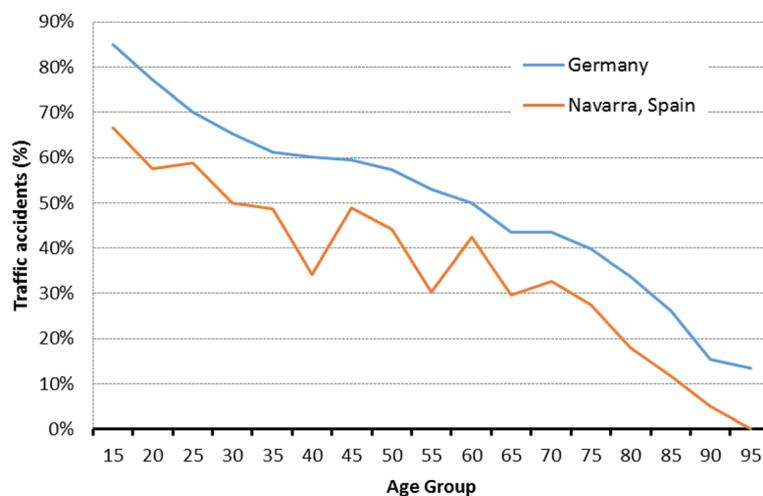


Fig. 3 Percentage of traffic accidents by age group in both study regions

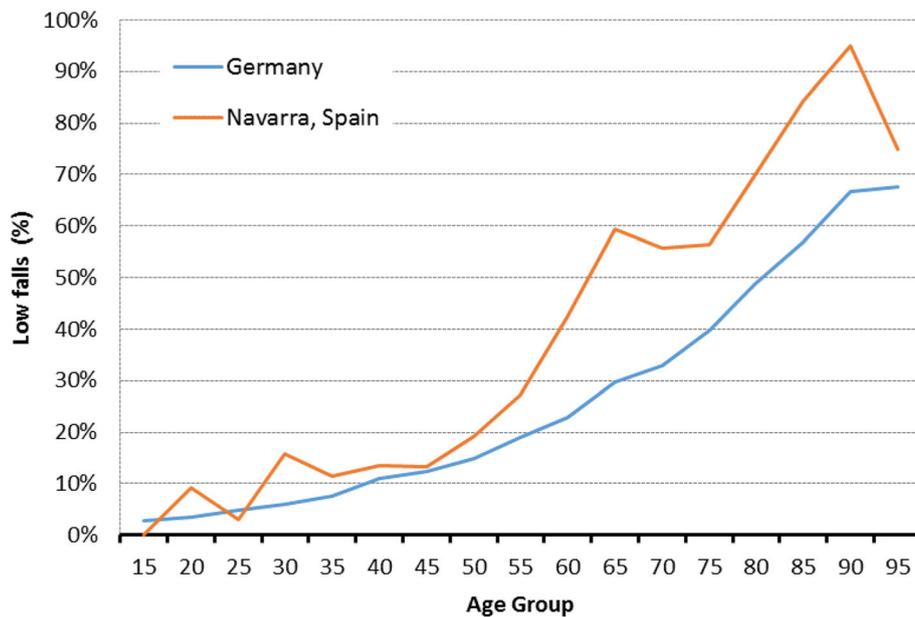


Fig. 4 Percentage of low falls by age group in Navarra (Spain) and Germany

Table 3 Prehospital data

Pre-hospital data ^a	NMTR	TR-DGU
Systolic Blood Pressure (SBP)	131.1 ± 25.0 M: 130	126.1 ± 36.1 M: 130
Glasgow Coma Scale (GCS)	12.8 ± 3.6 M: 15	11.7 ± 4.4 M: 14
Unconscious (GCS ≤ 8)	94 (14.6%)	9836 (24.2%)
Intubation	76 (11.8%)	15,538 (36.6%)
Cardio-pulmonary Resuscitation (CPR)	3 (0.5%)	1750 (4.1%)
Volume administration	401 (62.3%)	36,485 (88.6%)
Amount of Volume, if given (ml)	444 ± 409 M: 500	1001 ± 656 M: 1000
Transport		
Physician-staffed ambulance	375 (58.1%)	28,197 (67.4%)
Ambulance without physician	201 (31.1%)	2324 (5.6%)
Helicopter	28 (4.3%)	10,807 (25.8%)
Private vehicle	42 (6.5%)	514 (1.2%)
Time from accident/alarm to arrival at scene	0:19 ± 0:12 M: 15	0:20 ± 0:18 M: 15
On scene time	0:34 ± 0:21 M: 30	0:30 ± 0:17 M: 26
Time from accident/alarm to hospital	1:06 ± 0:33 M: 1:01	1:08 ± 0:36 M: 1:00

^aonly primary admitted cases from TR-DGU

the trauma care systems and/or different populations in both registries.

There are some striking differences between Germany and Navarra regarding the profile of the injured patients. Figure 2 shows three peaks for individuals aged 20 and younger, 45–50, and 70 for the German patients and two peak points for those between 45 and 50 and 75–80 for the Navarra patients. It can be presumed that occurrence of trauma between the ages of 21 to 50 is dominated by a higher number of motor vehicle accidents or work-related accidents. It can also be inferred that the increase in trauma after the age of 65 is due to the weakening of the body and reduced attention.

In addition, Lefering et al. revealed that increasing age is a risk factor for post-trauma mortality [6]. Giannadous and co-workers reported that the mortality rate for patients ≥65 years in England and Wales, in 2008, was significantly higher than in younger trauma patients [18]. In the present study, Navarra patients were older than German ones which may explain the higher mortality found in this study (Fig. 5).

Most mechanisms of injury in both data registries were classified as blunt trauma, particularly in vehicle-related accidents and falls. However, more vehicle-related accidents and a high percentage of young injured patients were seen in the German data (Fig. 3). Drunk driving, drowsy driving, and careless driving are several examples of the causes of motor vehicle accidents, and all of them are prominent in young men in general [19]. The high percentage of young injured people in Germany compared to the observed in Navarra

Table 4 Prehospital intubation rate according to GCS 9–15 and GCS 3–8 between Germany and Navarra (Spain)

	NMTR		TR-DGU	
	GCS 9–15	GCS 3–8	GCS 9–15	GCS 3–8
Intubation n (%)	13 (2.4%)	63 (67.0%)	5987 (19.5%)	8764 (89.2%)
No intubation n (%)	539 (97.6%)	31 (33.0%)	24,653 (80.5%)	1056 (10.5%)

Table 5 Hospital data and outcomes of severely injured patients of both regions

Hospital data and outcomes	NMTR	TR-DGU
Arterial Base Excess	-4.5 ± 5.0 M: -4.0	-2.3 ± 4.9 M: -1.6
Coagulation: INR	1.2 ± 0.6 M: 1.0	1.2 ± 0.6 M: 1.1
Systolic BP	130 ± 26 M: 129	126 ± 32 M: 130
Blood transfusion (%)	80 (12.4%)	6445 (13.3%)
Computed Tomography (CT) performed (%)	621 (96.2%)	43,158 (88.4%)
Whole body CT performed (%)	284 (44.4%)	37,260 (77.1%)
Time to first CT scan	0:43 ± 0:23 M: 0:40	0:23 ± 0:18 M: 0:19
Time until first emergency intervention	1:52 ± 1:05 M: 1:39	1:23 ± 0:39 M: 1:20
ICU treatment (%)	232 (36.0%)	44,621 (91.4%)
Ventilated (%)	150 (23.2%)	25,601 (52.5%)
Ventilation days (if ventilated)	5.8 ± 8.5 M: 1	8.8 ± 11.5 M: 4
Length of hospital stay (days)	12.1 ± 14.0 M: 7	21.0 ± 20.9 M: 16
Type of first intervention		
Damage control thoracotomy	15 (2.3%)	974 (2.0%)
Damage control laparotomy	22 (3.4%)	2304 (4.7%)
Limb revascularization	10 (1.5%)	266 (0.5%)
Interventional radiology	13 (2.0%)	116 (0.2%)
Craniotomy	39 (6.0%)	2797 (5.7%)
Observed mortality (30 days)	140 (21.6%)	6423 (14.9%)
Expected mortality (RISC II)	129 (20.0%)	6595 (15.3%)
Discharge destination (survivor only)		
Home	401 (80.8%)	21,497 (52.2%)
Rehabilitation	22 (4.4%)	13,318 (32.3%)
Another hospital	73 (14.8%)	4908 (11.9%)
Other facilities		1496 (3.6%)
Glasgow Outcome Scale at discharge		
Good recovery	416 (64.4%)	22,932 (47.0%)
Moderate disability	41 (6.3%)	11,377 (23.3%)
Severe disability	38 (5.9%)	4238 (8.7%)
Persistent vegetative state	1 (0.2%)	910 (1.9%)
Died in hospital	150 (23.2%)	7580 (15.5%)
Survivor not classified		1762 (3.6%)

percentage may be due to the traffic culture and the relatively liberal speed limits on the German highways. In Navarra, the speed limit in highways is 100 km/h and 120 km/h in motorways.

Both registries revealed a high rate of falls from a low height, particularly in subjects >60 years of age (Fig. 4). Older people make up a large and increasing percentage of the population. As people grow older, there is a higher risk of falls and consequent injuries. Several studies have reported high rates of fall-related mortality among the elderly [20, 21].

The proportion of elderly people continues its upward trend. Consequently, there is an increase of falls from a low height as well as of injuries such as severe head trauma. In this study, a higher number of older patients and percentage of head traumas in the NMTR have been documented in comparison to TR-DGU®.

After having identified some differences between the two trauma populations, the next step is to determine if there are regional (Germany vs Navarra) distinctions in the treatment of trauma patients and the organization of trauma care.

In Navarra, paramedic resources for patient transport are used more frequently than in Germany. This is due to the Navarra's prehospital organization. A significant percentage of patients were transferred from the villages (periphery) in Navarra. In some cases, doctors sent patients in an ambulance accompanied by a paramedic, after attending them at the scene of the accident. In other cases, doctors attended the patient at the scene of the accident then the patient was handed over to another ambulance team. Furthermore, changes in trauma patient profiles has led to modifications of the resource activation protocols by Navarra's coordination center. For example, transfer of conscious elder patients with isolated head injury after low fall to hospitals is delivered by paramedic ambulances. In the past, these patients were also attended by physician-staffed resources but only for the transfer. Given the limited number of physician-staffed ambulances in Navarra, and cost effectiveness requirements, protocols have been updated to adjust better to trauma needs and the seriousness of the case.

Helicopters as a mean for the transport of patients are widely used in Germany [22], mainly because of the traffic congestion at highways, while they are rarely used in Navarra. One reason that may contribute to the

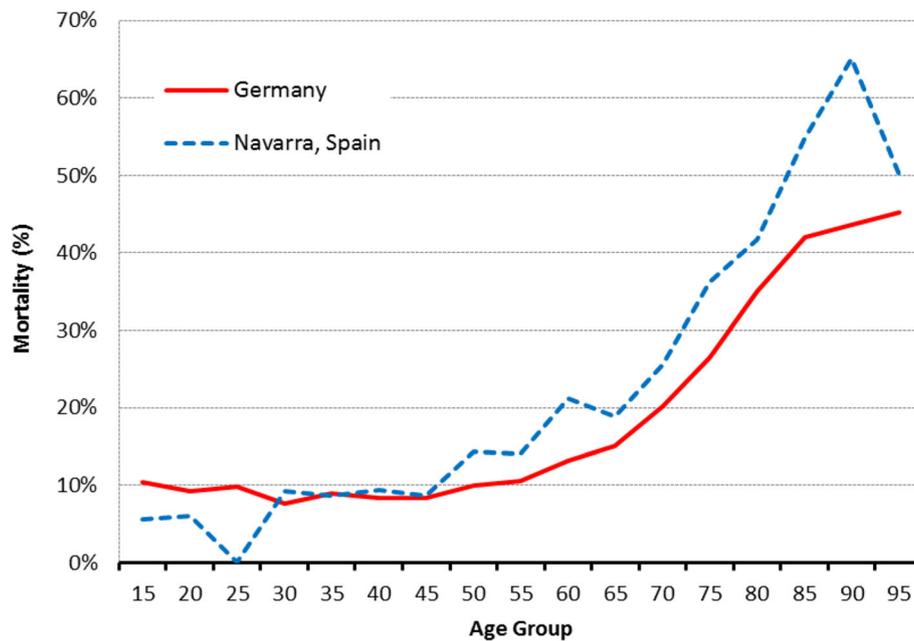


Fig. 5 Mortality of patients by age group presenting with traumatic injuries in Navarra (Spain) and Germany

reduced use of helicopter resources in Navarra is the limited experience in health resource mobilization of the coordinator. Bad weather conditions in Navarra also prevent their use for the transport of trauma patients. Further investigation on the coordination and management of helicopters in Navarra should be undertaken.

Prehospital intubation rates documented in TR-DGU[®] were more over two-fold higher than the recorded in NMTR, with even higher values in the past [23]. There are several possible explanations for this. First, patients transported by helicopter tend to be intubated more frequently before being transported because intubation during the flight is a difficult task. In this study, the use of helicopters for the transport of trauma patients by German prehospital teams was significantly higher than in Navarra. Second, relevant chest injuries detected in prehospital setting may lead doctors to intubate patients. In this study, higher rates of chest injuries were documented in TR-DGU[®] than in NMTR. Third, in Germany, prehospital intubation was quite common in recent years, and even GCS 15 patients were intubated in approximately 50% of polytrauma cases in the 1990s [23]. Fourth, the low percentage of intubation seen in Navarra may be because doctors preferred airway management methods different from endotracheal intubation. On the one hand, several studies have reported increased failure rates and severe complications in trauma patients who were intubated prehospitally [24]. Furthermore, airway management with other instruments like classic laryngeal mask airway, Combitube and

Laryngeal Tube have proven to be useful in prehospital airway management [25].

Furthermore GCS ≤ 8 is a general indication for intubation in Germany as well as in Navarra. In this study, NMTR has shown lower intubation rates even in patients with GCS ≤ 8 (Table 4). As previously explained, the use of supraglottic airway devices may be one of the reasons for not intubating these patients in the prehospital settings. Another reason could be the presence at the scene of the accident of an emergency physician. As has been reported that about 5.6% of trauma patients from Navarra are transferred to the hospital in private vehicles. Other factors involved as the training of prehospital emergency medical services or the time taken to transfer the patients may also have contributed to these results [26]. However, additional critical evaluation is required in this subgroup of patients, since the prehospital guidelines of Navarra recommend endotracheal intubation of all patients with GCS < 9 and it is considered as one of the quality indicators of Navarra prehospital trauma organization. The increase in the number of non-intubations for patients with initial GCS ≤ 8 can be considered as a failure of the system in the prehospital organization, so that this measure should be given special attention when reorganizing prehospital care [8].

Even with similar prehospital response times between both regions, more trauma patients received volume and more volume was administered in Germany than in Navarra. Debate continues regarding the strategy of fluid management in trauma, however aggressive crystalloid resuscitation needs to be avoided [27]. These findings

should be taken into account for further improvement in the German prehospital setting.

Hospital treating severe trauma patients in Germany are divided into three categories – supraregional (I), regional (II) and local (III), according to their resources. When participating in the TraumaNetzwerk DGU®, each trauma center has to fulfil clearly defined standards for structure, process and outcome quality, as well as criteria for expertise and capacity [28]. In Navarra, as already mentioned in the Methods section, only three hospitals treat severe trauma patients in the entire area. CHN is the only tertiary referral hospital comparable to a level I trauma center since it can provide total care for every aspect of injury – from prevention through rehabilitation. However, it does not meet the minimum requirement for annual volume of severely injured patients established by the American College of Surgeon [29]. Furthermore, no specific requirements have been established for hospitals to treat severe trauma patients in Navarra. The other two hospitals in Navarra provide primary life-saving trauma care to trauma patients as local German trauma centers (level III), especially when primary transportation to regional trauma center is not possible [28].

More CT scans were performed in Navarra in comparison to German hospitals; however, the percentage of whole body CT scans was lower in Navarra. This is explained because in our hospitals doctors are still using selective CT scan rather than whole body CT scan. There is a lack of solid scientific evidence in favor of whole body CT scan [30, 31]. Several retrospective and prospective studies agreed on a time benefit in favor of whole body CT scanning but no consensus was obtained regarding a possible survival benefit [30, 32–34]. Furthermore, despite the favorable characteristics of CT scanning, it is still associated with a high radiation dose and might affect health care costs [35]. Despite the lack of proper scientific evidence, an increasing number of trauma centers are using whole body CT scan during trauma survey, either as a supplement to or as a replacement for conventional imaging [30, 32]. It has been shown that whole body CT in high-energy trauma does not affect patient care if the patient is mentally alert, not intoxicated and does not show signs of other than minor injuries when evaluated by a trauma-team. The risk of missing important traumatic findings in these patients is very low. Observation of the patient with reexamination instead of imaging may be considered in this group of often young patients where radiation dose is an issue [36].

It took more time to perform the first CT scan in Navarra than in Germany. Accordingly, the time to first surgical intervention also increased. Probably, doctors attending trauma patients in Navarra take more time to

evaluate these patients. Furthermore, the CT scanner in Navarra hospitals is located far from the resuscitation room and it takes some time to get there and perform the imaging. It was shown that the location of the CT scanner in or near the trauma room, as opposed its location at the Radiology Department, could also have a beneficial effect on the outcome [37]. Changes should be done in hospital protocols and infrastructures to reduce these times in Navarra.

Increased ICU utilization in Germany is reflected by the high proportion of patients admitted to the ICU, as seen in this study. It can be presumed that more severe cases tend to be admitted in the ICU. In this study, the severity of German trauma patients measured by ISS and NISS, was higher than that of Navarra trauma patients. Furthermore, different indications for critical care admission may also explain the difference of ICU admission found in this study. For example, in Germany non-intubated patients with bilateral lung contusions and chest tubes are usually monitored in the ICU [38]. In Navarra, the same patient is usually monitored on the emergency observation room (discharge within 24-72 h after injury) or on a regular ward.

In Germany, a higher number of trauma patients were on mechanical ventilation as well as for longer periods. Parenchymal lung injuries, such as pulmonary contusion, may require oxygenation and ventilation support through mechanical ventilation strategies [39]. For example, in this study higher rates of chest injuries were recorded in TR-DGU® in comparison to the NMTR. Furthermore, mechanical ventilation is one of the main reasons to admit patients to the ICU [40] even in Germany [41]. In Navarra, it is often provided in the emergency observation room or general chest ward rather than in the ICU.

Study patients in Germany stayed longer in the hospital in comparison with the stay in Navarra. Some studies have examined the length of hospitalization in trauma patients, indicating that prehospital interventions such as endotracheal intubation and other procedures performed by prehospital teams at the site of the trauma can be associated with other complications such as pneumonia. This may prolong hospital stays [42]. In this study, more prehospital intubations were performed by German prehospital teams than by Navarra teams.

German patients were transferred more frequently to rehabilitation facilities. Rehabilitation services are limited in Navarra and it is often done at home or in a local hospital, while German patients are transferred to a rehabilitation center [7].

The Navarra registry and TR-DGU®, both have different data collection procedures and inclusion criteria, a limitation of this study. In Navarra, as mentioned in the Methods section, patients were included into the

database thanks to the collaboration of various users from different levels. A supervisor was responsible for data completeness, made sure the inclusion and exclusion criteria were met, and of the compliance of the Utstein style variables of each registered patient. TR-DGU® contains data from many different hospitals coded by multiple people. Although multiple plausibility controls are implemented, there is no data verification source for preventing entry errors. To minimize bias due to the previously mentioned limitation, definitions were carefully checked, and data were transformed into comparable variables where necessary. Some variables like ventilation days (if ventilated) was defined again for this analysis, as the Utstein template is not clear [4]. The different AIS versions used by both registries is a major limitation of this study and it may have affected the results of this comparison. Specifically, the outcome prediction may be affected in this comparison and requires a careful interpretation. Although for the majority of injuries the severity levels were not changed during the AIS revisions. It has been shown that different AIS versions (e.g. AIS98 vs. AIS08) are not always comparable [43]. However, a systematic assessment of AIS85 versus AIS08 was lacking. It has previously been shown that a comparison of survival for trauma registries that use different AIS editions is possible [44]. For trauma registries, a more contemporary AIS version should be adopted in order to enhance comparability with other registries. NMTR will update its AIS severity levels according to the recommendations by the Utstein trauma template [4].

Differences across the trauma systems and hospitals offer an opportunity to compare the different ways of treating trauma patients, which would not be possible within an existing system. In this study, the analysis of large versus small trauma centers between both regions could not be carried out. On one hand, choosing only larger trauma centers would result in a biased selection of cases. On the other hand, the number of hospitals in Navarra were too small to justify a subgroup analysis regarding size of hospital.

This comparison between the NMTR and the TR-DGU® shows there are areas in need of further improvement in both systems. Actions like massive publicity campaigns, tightening the penal code and speed limits (particularly on highways), may reduce the vehicle accidents in Germany and consequently reduce the percentage of injuries among the youngest population. Changes at hospital and prehospital level are needed in both systems to improve trauma quality care in both countries. Strategies to reduce the rate and severity of low-height falls may translate into positive results for trauma patient survival rates.

Conclusions

Both trauma registries, the NMTR and the TR-DGU®, provide data for epidemiological comparison and international

benchmarking. The higher observed mortality determined in Navarra follows the epidemiological characteristics of its population. However, improvements are necessary at prehospital and hospital level to increase trauma quality care in Navarra. There were less young adults with severe injuries in Navarra than in Germany. It is possible to compare severely injured patients from different countries if standardized registries were used.

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Availability of data and materials

The data that support the findings of this study are available from [Academy for Trauma Surgery (AUC - Akademie der Unfallchirurgie GmbH), a company affiliated to the German Trauma Society & Polytrauma group of Navarra] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [Academy for Trauma Surgery (AUC - Akademie der Unfallchirurgie GmbH), a company affiliated to the German Trauma Society & Polytrauma group of Navarra].

Authors' contributions

BA and RL designed the study. BA and RL performed the analyses. BA, MF, TB and RL collected the data. BA and RL performed the statistical analysis and interpreted the results. BA drafted the manuscript. All authors critically reviewed the manuscript. All authors read and approved the final version of this manuscript.

Ethics approval and consent to participate

This study received approval from the Local Medical Ethics Committee of Navarra, Spain under Pyto 2016/48. The present study is also in line with the publication guidelines of the TraumaRegister DGU® and registered as TR-DGU® project ID 2014-038.

Consent for publication

not applicable.

Competing interests

The authors declare that they have no competing interests.

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