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Brinck, T.

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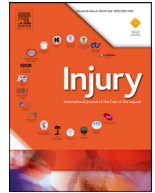
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Trauma-registry survival outcome follow up: 30 days is mandatory and appears sufficient

T. Brinck*, M. Heinänen, L. Handolin, T. Söderlund

Department of Orthopaedics and Traumatology, Trauma Unit, Helsinki University Hospital and University of Helsinki, Topeliuksenkatu 5, PB 266, FI-00029 HUS, Helsinki, Finland

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ABSTRACT

Introduction: Thirty-day in-hospital mortality is a common outcome measure in trauma-registry research and benchmarking. However, this does not include deaths after hospital discharge before 30 days or late deaths beyond 30 days since the injury. To evaluate the reliability of this outcome measure, we assessed the timing and causes of death during the first year after major blunt trauma in patients treated at a single tertiary trauma center.

Methods: We used the Helsinki Trauma Registry to identify severely injured (NISS ≥ 16) blunt trauma patients during 2006 to 2015. The Population Register center of Finland provided the mortality data for patients and Statistics Finland provided the cause of death information from death certificates. Disease, work-related disease, medical treatment, and unknown cause of death were considered as non-trauma related deaths. We divided the 1-year study period into the following three categories: in-hospital death before 30 days (Group 1), death after discharge but within 30 days (Group 2), and death 31 to 365 days since admission (Group 3).

Results: We included 3557 patients with a median NISS of 29. Altogether, 21.8% (776/3557) patients died during the first year since the injury. Of these non-survivors, 12.7% (450) were in Group 1, 4.0% (141) in Group 2, and 5.2% (185) in Group 3. Non-traumatic deaths not directly related to the injury increased substantially as the time from the injury increased and were 2.0% (9/450) in Group 1, 13.5% (19/141) in Group 2, and 35.7% (66/185) in Group 3.

Conclusion: Thirty-day mortality is a proper outcome that measures survival after severe blunt trauma. However, applying only in-hospital mortality instead of actual 30-day mortality may exclude non-survivors who die at another facility before day 30. This could result in over-optimistic benchmarking results. On the other hand, extending the follow-up period beyond 30 days increases the rate of non-traumatic deaths. By combining data from different registries, it is possible to address this challenge in current trauma-registry research caused by lack of follow up.

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Introduction

The quality evaluation of care for severely injured patients utilizes data from trauma registries. A common outcome definition in trauma-registry studies is the 30-day in-hospital mortality [1]. The adequacy of this outcome measure in benchmarking has been challenged, as deaths after hospital discharge before 30 days or late deaths beyond 30 days since the injury are not included. Trauma registries, with some exceptions, do not follow up patients after discharge. Thus, information on mortality after initial hospitaliza-

tion is usually missing. On the other hand, the definition of 30-day in-hospital mortality could include deaths possibly not related to the trauma itself but occurring for some other reason in hospital after severe injury [2]. The cause of death information is not routinely collected in trauma registries. Therefore, possible non-traumatic deaths are included in outcome comparisons.

The landmark study by Trunkey from 1983 describing the trimodal distribution of traumatic deaths demonstrated that immediate deaths were due to severe traumatic brain injury (TBI) and spinal cord injuries or as a result of trauma to the heart or great vessels. This was followed by a second peak within the first hours after the injury due to exsanguination and severe TBI. Late deaths over 1-week post-injury, the third peak, occurred because of sepsis and multi-organ failure [3]. Later research supported a gradual

* Correspondence author.

E-mail address: tuomas.brinck@hus.fi (T. Brinck).

decline in mortality rather than a trimodal distribution of fatality. Nevertheless, the overwhelming majority of deaths occur during the first hours after the injury [4-8].

To develop an improved prediction model for trauma, Bouamra et al. linked the data of almost 130 000 trauma patients with median Injury Severity Score (ISS) of 9 from the Trauma Audit and Research Network (TARN) with the Office of National Statistics database in the UK. This allowed an accurate identification of patient outcome at 30 days instead of mere in-hospital mortality. The authors noted 572 deaths after discharge but within 30 days of admission. These non-survivors were older, not severely injured, GCS was normal, and most had a recorded comorbidity. [9]

Research on late mortality after severe trauma is scarce. The effect of deaths beyond 30 days since injury on overall mortality is dependent on the patient population. Davidson et al. found that age strongly predicted risk of death during the follow-up period and time to death following injury [10]. Low-energy injuries in a frail population, such as hip fractures among the elderly, lead to a near doubling of mortality at 1 year after hospital discharge [9]. Concentration on major trauma only stresses the importance of the early peak in mortality after severe trauma, while the effect of the injury itself on deaths after initial hospitalization seems to diminish [6,11-16].

The need for quality control and benchmarking in modern healthcare is increasing and the role of trauma registries in this process regarding major trauma is essential. However, trauma registries only cover the initial phase (often no longer than 30 days) since the injury. It is necessary to ensure that the data collected during the first month after the injury are adequate especially when used for outcome comparisons. Thus, we should expand our view also beyond the immediate post-injury period. By combining the data from the trauma registry with different existing governmental administrative registries, we can follow up severely injured patients and obtain a more comprehensive picture of the effects of severe trauma. Accordingly, by obtaining autopsy-based cause-of-death information, it would be possible to investigate which proportion of late deaths are related to the severe trauma itself.

The aim of our study is to assess the timing and causes of deaths during the first year after severe blunt trauma in patients treated at a single tertiary trauma center.

Methods

The Helsinki University Hospital's trauma registry (Helsinki Trauma Registry, HTR) was used for patient identification from 1 January 2006 to 31 December 2015. In this study, we included patients with a New Injury Severity Score (NISS) ≥ 16 and a blunt mechanism of injury. In the case of several admissions to the HTR for one patient during the study period, only the first admission was included. The HTR is a local trauma registry in the trauma unit of the Helsinki University Hospital, which centralizes the treatment of severe blunt injuries among adult patients (≥ 16 years). The catchment area includes 1.8 million inhabitants (25% of the total Finnish population) and extends 200 km in southern Finland.

The Population Register center of Finland provided patient mortality data. This governmental data repository contains data collected by law that covers 100% of Finnish citizens and foreign citizens residing permanently in Finland. The data were collected on 1 August 2017 and a minimum of 1-year follow up was obtained for all patients. We divided the 1-year study period into the following three categories: in-hospital death before 30 days (Group 1), death after discharge but within 30 days (Group 2), and death 31 to 365 days since the admission (Group 3).

Statistics Finland provided the cause of death information (disease, work-related disease, accident, medical treatment, suicide, homicide, war, and unknown). Statistics Finland is the only Finnish

public authority specifically established for the gathering and storing of statistical data. The cause of death information from Statistics Finland in this study is based on death certificates. Finnish law requires that an autopsy be performed on all individuals who died due to an accident, under obscure circumstances, and who died or are suspected to have died due to violence (both self-inflicted and otherwise).

The death certificates have the following three sections in the cause of death: 1a, the disease or condition immediately causing the death; 1b, intermediate cause; and 1c, the underlying cause of death. Classification of deaths to traumatic and non-traumatic deaths is based on the underlying cause of death (1c). Disease, work-related disease, medical treatment, and unknown were considered as non-trauma related deaths. Trauma patients who died due to infection are defined such that the underlying cause of death (1c) is trauma and the immediate cause of death (1a) is infection.

Pre-existing comorbidities in the study's patient cohort were assessed by the American Society of Anesthesiologists (ASA) grading, which is routinely collected by the HTR [17].

The results are expressed as mean \pm SD, as median with 25% and 75% quartiles, or as percentages as appropriate. Kaplan-Meier survival analysis was used to analyze 1-year survival.

For this register study, no ethics committee approval was required according to Finnish law. The Helsinki University Hospital scientific review board and the review boards of the Population Register center and Statistics Finland approved the study.

Results

From the 10-year study period, we included 3557 patients from the HTR. Median NISS was 29 (IQR 24,38). Mean age was 50.5 years and 72.6% were male. The most common injury mechanism was traffic accident (32.1%), followed by low fall (26.1%) and high fall (23.8%) (Table 1).

Mortality in Group 1 was 12.7% ($n = 450$), 4.0% ($n = 141$) in Group 2, and 5.2% ($n = 185$) in Group 3. Trauma as the underlying cause of death but infection as the immediate cause of death was identified as follows: 6.1% in Group 1, 39.3% in Group 2, 41.2% in Group 3. The non-traumatic deaths increased as time increased from admission: 2.0% (9/450) in Group 1, 13.5% (28/591) in Group 2, and 35.7% (66/185) in Group 3 (Table 2).

Fig. 1 shows the cumulative survival in the following three Kaplan-Meier curves: 1. all patients, 2. non-traumatic deaths ex-

Table 1

Demographics of the patient population ($n = 3557$). Data obtained from Helsinki University Hospital's trauma registry and the Population Register center of Finland.

Age, mean (SD) (years)	50.5 (20.5)
Male gender, n (%)	2581 (72.6)
Mechanism of injury	
High fall (%)	23.8
Low fall (%)	26.1
Traffic accident (%)	32.1
Other (%)	18.0
NISS, median (IQR)	29 (24,38)
ICU admission (%)	78.9
ICU LOS, mean (SD) (days)	5.6 (7.4)
Hospital LOS, mean (SD) (days)	11.8 (12.5)
In-hospital mortality (%)	12.9
30-day mortality (%)	16.6
1-year mortality (%)	21.8

SD: standard deviation; IQR: interquartile range; NISS: New Injury Severity Score; ICU: intensive care unit; LOS: length of stay.

Table 2

Mortality, non-traumatic deaths and traumatic deaths with infection as an immediate cause of death in Groups 1–3.

	Mortality, n = 3557	Non-traumatic deaths	Traumatic deaths with infection as immediate cause
Arrival-to-discharge within 30 days (Group 1)	n = 450 12.7%	n = 9 2.0%	n = 27 (441) 6.1%
Discharge-to-30 day (Group 2)	n = 141 4.0%	n = 19 13.5%	n = 48 (122) 39.3%
31-to-365 day (Group 3)	n = 185 5.2%	n = 66 35.7%	n = 49 (119) 41.2%

Table 3

Characteristics of all patients and Groups 1–3.

	All patients, n = 3557	Non-survivors, in-hospital within 30 days, n = 450	Non-survivors, discharge to 30 days, n = 141	Non-survivors, 31–365 days, n = 185
NISS, median (IQR)	29 (24, 38)	41 (29, 50)	27 (25, 37)	29 (25, 38)
Age, years	50.5 ± 20.5	58.0 ± 20.2	68.6 ± 15.4	63.0 ± 16.0
Age ≥ 60 years,%	36.7%	53.8%	73.8%	56.8%
Head AIS > 3,%	52.9%	82.2%	79.4%	78.4%
ASA 3–4,%	10.1%	16.9%	31.9%	21.1%
GCS 3–8,%	22.5%	57.6%	35.5%	23.8%
SBP <90,%	5.8%	14.7%	5.0%	3.8%
Median time from injury to death, days	6 (1, 28)	1 (0, 5)	14 (7, 21)	134 (57, 222)

NISS: New Injury Severity Score; IQR: interquartile range; AIS: Abbreviated Injury Scale; ASA: American Society of Anesthesiologists; GCS: Glasgow Coma Scale; SBP: systolic blood pressure.

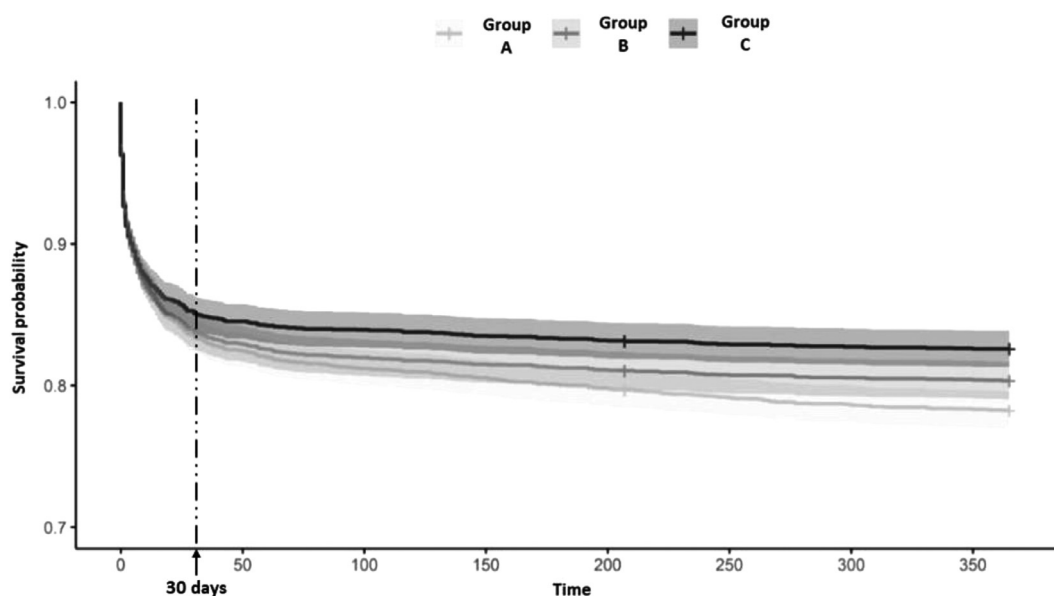


Fig. 1. Cumulative survival during 1-year post injury with 95% confidence intervals. Group A: all patients; Group B: non-traumatic deaths excluded; Group C: patients with trauma as an underlying cause of death, but infection as an immediate cause of death excluded.

cluded, 3. patients with trauma as an underlying cause of death, but infection as an immediate cause of death excluded. The non-traumatic deaths begin to appear at 25 days and infections at 10 days post-admission.

The discharge destination of non-survivors in Group 2 is shown in Table 3. In this group, most (66.9%) of the patients were discharged to a ward of a step-down hospital and only one patient (0.7%) was discharged home after initial hospitalization.

The characteristics of all patients and non-survivors in three groups is presented in Table 4. In Group 1 the median time from admission to death was 1 day and the patients were younger (mean 58 years), more often unconscious (57.6% with GCS 3–8),

and more severely injured (median NISS 41) when compared with Groups 2 and 3.

Discussion

In this study, we assessed the timing and causes of death of patients with major trauma treated at a single tertiary trauma center. We noted that 12.7% of these severely injured patients died in hospital before 30 days, 4.0% after discharge but within 30 days, and 5.2% after 30 days until 1 year since the injury. In these three categories, autopsies revealed an increase of non-traumatic deaths not directly related to the injury itself (2.0%, 13.5%, 35.7%, respectively).

Table 4
Discharge destination of patients in Group 2 and all patients.

Discharge destination	Non-survivors, death after discharge to 30 days, <i>n</i> = 141	Discharge destination, all patients, <i>n</i> = 3557
Another ICU / HDU (higher treatment level)	<i>n</i> = 41 28.9%	<i>n</i> = 475 13.4%
Another intermediate or low care somatic hospital ward	<i>n</i> = 95 66.9%	<i>n</i> = 1835 51.6%
Home	<i>n</i> = 1 0.7%	<i>n</i> = 656 18.4%
Rehabilitation or other facility	<i>n</i> = 4 2.8%	<i>n</i> = 139 3.9%

ICU: intensive care unit; HDU: high-dependency unit.

Thus, we consider that 30-day mortality, but not only in-hospital mortality, is an adequate outcome measure describing survival following severe injury.

A limitation of trauma registries is that they do not routinely follow up patients after hospital discharge. A traditional outcome measure used in benchmarking is 30-day in-hospital mortality as defined in the Utstein criteria, which provides recommendations for the reporting of data following major trauma [1]. This means that patients transferred early to another hospital from the primary registry-keeping unit who die before day 30 are recorded as survivors. This so-called “right censoring” is plausible in outcome comparisons if length of stay (LOS) and discharge policies differ between hospitals. Right censored data refers to the area on the right hand side of the Kaplan-Meier survival curve excluded from analysis at a given time point, in this study hospital discharge [18,19].

We have previously performed outcome comparisons regarding severely injured patients between our unit and e.g. German level-I trauma hospitals. While the adjusted outcome results are comparable, we observed that LOS in our unit is significantly shorter than in German hospitals (mean LOS 12 vs 25 days). According to the previously published data from the German Trauma Registry, approximately 10% of in-hospital deaths occur between days 12 and 25 post-injury [6]. This suggests an estimated 1% addition to the observed mortality in our data [20,21]. Our present data show that this is an underestimation; the mortality of patients treated at our unit increased by 4.0% after discharge but within 30 days. This right censoring is more apparent in our previous comparison regarding elderly patients with severe brain injury between HTR (30-day in-hospital mortality, median LOS 9 days) and Navarra, Spain (actual 30-day mortality) [22]. Similarly, bias favoring our unit due to right censoring is evident in comparison regarding severely injured patients between HTR and trauma registry at the North Estonia Medical center in Tallinn (median LOS 12 days vs 26 days, respectively) [23].

The policy to discharge patients early in our unit is due to a limited number of ward beds. The goal is to step down injured patients to another hospital as soon as medically possible, which is when intensive care unit (ICU) care is no longer necessary and no further surgical procedures are planned. It can be argued that the most severely injured patients with the highest risk of death are followed up in a university hospital longer, and patients with less severe injuries on the way to a good recovery are discharged earlier to another unit. This would mean that early discharge would not have a significant effect when comparing mortality between units with differing discharge practices. However, this does not seem to be the case based on the results of our study. In particular, elderly patients (73.8% > 60 years) with comorbidities (31.9% with ASA 3–4) are discharged early to a step-down unit if the prognosis is poor and they are not likely to benefit from operations and ICU treatment. This is why non-survivors who die at another facility before day 30 post-injury are excluded.

Early deaths dominate post-traumatic mortality, as observed in many previous studies and our current study. The gradual decline in mortality after trauma, instead of the classic trimodal distribution as described by Trunkey, is also supported by our data [3–8]. However, there is ongoing, albeit minor, excess mortality lasting up to at least 1 year post-injury. Previous research shows that in patients with brain injury, mortality increases up to at least 6 months after the injury [24,25]. In our data, this excess mortality beyond 30 days is partly explained by non-traumatic deaths not directly related to the index injury. Furthermore, in our evaluation of causes of death based on autopsies, infection as an immediate cause of death (but trauma as an underlying cause of death) increased from 6.1% in 30-day hospital mortality to 42.1% in deaths beyond 30 days since the injury. These infections are typically pneumonia in bedridden patients with severe brain or high spinal cord injury with serious deterioration in consciousness, coughing ability, or both. Thus, the cause of death can be evaluated as the result of the index injury but as such does not describe the quality of initial hospital treatment after severe trauma.

In previous studies on trauma patients, it has been stated that mortality after trauma needs to be measured beyond hospital discharge or 30-day mortality to assess the complete impact of injury [10,12]. We must note that these studies also include less severely injured patients. Thus, our patient population with only severe blunt injuries and a median NISS of 29 is not comparable with these studies on long-term survival of trauma patients. The emphasis on outcome evaluations should not only be on surviving the injury but also on the quality of life in longer-term follow-up. This is highlighted in patients with TBI, in which the patient is alive but in a vegetative state post-injury. Future effort should be invested into developing means for follow-up and creating proper functional outcome measures after severe injury. This would change the current benchmarking to assess the long-term effects of severe trauma [26].

For the present study, we acknowledge the limitations of registry studies, such as its retrospective design. In addition, our study only included patients with blunt trauma and our findings do not necessarily apply to penetrating injuries. The strengths of our study include its focus on severely injured patients treated at only a single tertiary trauma center, the availability of all autopsy records, and the previously validated, high-quality data characteristic of the HTR [27,28].

Conclusion

Thirty-day mortality is a proper outcome measure for survival after severe blunt trauma. However, applying in-hospital mortality instead of actual 30-day mortality excludes non-survivors who die at another facility before day 30. This could result in over-optimistic benchmarking results. On the other hand, extending the follow-up period beyond 30 days increases the proportion of non-

traumatic deaths. By combining data from different registries, it is possible to overcome the challenge of current trauma-registry research caused by lack of follow up.

Declaration of Competing Interest

The authors (Tuomas Brinck, Mikko Heinänen, Lauri Handolin, Tim Söderlund) declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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