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ORIGINAL ARTICLE

Unconscious trauma patients: outcome differences between southern Finland and Germany—lesson learned from trauma-registry comparisons

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Abstract
Purpose International trauma registry comparisons are scarce and lack standardised methodology. Recently, we performed a 6-year comparison between southern Finland and Germany. Because an outcome difference emerged in the subgroup of unconscious trauma patients, we aimed to identify factors associated with such difference and to further explore the role of trauma registries for evaluating trauma-care quality.
Methods Unconscious patients [Glasgow Coma Scale (GCS) 3–8] with severe blunt trauma [Injury Severity Score (ISS) ≥16] from Helsinki University Hospital's trauma registry (TR-THEL) and the German Trauma Registry (TR-DGU) were compared from 2006 to 2011. The primary outcome measure was 30-day in-hospital mortality. Expected mortality was calculated by Revised Injury Severity Classification (RISC) score. Patients were separated into clinically relevant subgroups, for which the standardised mortality ratios (SMR) were calculated and compared between the two trauma registries in order to identify patient groups explaining outcome differences.
Results Of the 5243 patients from the TR-DGU and 398 from the TR-THEL included, nine subgroups were identified and analyzed separately. Poorer outcome appeared in the Finnish patients with penetrating head injury, and in Finnish patients under 60 years with isolated head injury [TR-DGU SMR = 1.06 (95 % CI = 0.94–1.18) vs. TR-THEL SMR = 2.35 (95 % CI = 1.20-3.50), $p = 0.001$ and TR-DGU SMR = 1.01 (95 % CI = 0.87–1.16) vs. TR-THEL SMR = 1.40 (95 % CI = 0.99-1.81), $p = 0.030$]. A closer analysis of these subgroups in the TR-THEL revealed early treatment limitations due to their very poor prognosis, which was not accounted for by the RISC.
Conclusion Trauma registry comparison has several pitfalls needing acknowledgement: the explanation for outcome differences between trauma systems can be a coincidence, a weakness in the scoring system, true variation in the standard of care, or hospitals' reluctance to include patients with hopeless prognosis in registry. We believe, however, that such comparisons are a feasible method for quality control.

Keywords Trauma registry · Registry comparison · Quality of trauma care · Severe injuries

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Introduction

In evaluating and improving quality of care important tools are trauma registries [1–3]. International comparisons between trauma systems are still scarce and lack a universal methodology. Quality comparison between hospitals and trauma systems, however, often requires comparison of the standardised mortality ratio (SMR), the ratio between observed and expected mortality. A higher observed than predicted mortality (SMR > 1) indicates a performance

poorer than average, and a higher predicted than observed mortality (SMR < 1) indicates one better than average. Comparing performance between institutions and countries necessitates careful patient-selection with adequate case-mix adjustment and functional prediction models [4]. Several such models exist for case-mix adjustment in trauma. The Trauma Score and Injury Severity Score (TRISS) from 1987 is the most common [5–7]. The Revised Injury Severity Classification (RISC) score, introduced in 2009 and based on data from the German Trauma Registry, has, when compared to TRISS, demonstrated an improved predictive performance, however [8, 9].

Our earlier trauma registry study suggested that trauma patients with a pre-hospital Glasgow Coma Scale (GCS) value less than 9 have a better outcome in Germany than in southern Finland [10]. That study revealed differences across the trauma systems, especially in pre-hospital treatment: in Germany, an emergency physician is almost always present on scene, and helicopter use is widespread, while in southern Finland only half the severely injured patients meet a doctor on scene and rarely have helicopter evacuation. Intubation of the unconscious trauma patient on scene was also less common in Finland (81 %) than in Germany (95 %).

Our present study on treatment and outcome investigates differences between southern Finland and Germany in clinically relevant subgroups of unconscious trauma patients. Their possibly differing outcomes, as we hypothesized, may in part depend on differences in pre-hospital care. Another goal of our study was to explore the roles, the challenges, and the limitations of trauma registries in benchmarking processes and in quality control.

Materials and methods

Trauma registries

In Finland, no strict national guidelines exist for pre- or intra-hospital care of trauma patients, nor any nation-wide trauma registry. In southern Finland, Helsinki University Hospital's trauma centre (HU trauma centre), with a catchment area of almost 2 million (one-third of the Finnish population), centralizes treatment of severe blunt injuries of adult patients (>16 years). Thus far, the HU trauma centre is the only hospital with a trauma registry in Finland: the Trauma Registry of Helsinki University Hospital (TR-THEL). It was established in 2005 as a benchmarking project to improve regional trauma-patient outcome. Three trauma nurses have reviewed all trauma admissions to the HU trauma centre from the beginning of 2006 onwards and entered all New Injury Severity Score (NISS) ≥16 patients into the registry.

The German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie, DGU) established the TraumaRegister DGU® (TR-DGU) in 1993. The majority of participating hospitals are German (90 %), but increasingly, hospitals from other countries contribute as well: at the moment, Austria, Belgium, Finland, Luxembourg, Slovenia, Switzerland, The Netherlands, United Arab Emirates, and China. Currently, the hospitals entering approx., 30,000 cases into the database annually number 600. The TR-DGU aims to enrol all patients reaching the hospital alive who are admitted via the emergency room followed by subsequent intensive care unit (ICU) care; this includes patients who die before ICU admission.

Both registries collect data in four consecutive time-stages from the trauma event to hospital discharge: pre-hospital phase, emergency room and initial surgery, ICU, and discharge. Documentation includes detailed information on patient characteristics, injury patterns, comorbidities, pre- and in-hospital management, course of ICU treatment, relevant laboratory findings including data on transfusion, and outcome.

Patient inclusion

Of patients with a first-measured pre-hospital GCS (primary GCS, pGCS) 3–8 entered into the TR-THEL and the TR-DGU between January 2006 and December 2011, we excluded those younger than age 16, as well as those with penetrating trauma without head injury, transferred patients, and patients with missing baseline risk data (by the RISC). From the TR-DGU, only those German level-1 trauma centres were considered, who treated annually more than 50 major trauma patients (ISS ≥ 16).

Data collection and analysis

All parameters from the TR-THEL and the TR-DGU were subject to a comparability check, and variables with an identical definition were imported into a joint database for analysis. All comparisons are based on real measurements; no imputations for patients with missing data were performed. Certain parameters, such as some laboratory tests, received range limits (lowest and highest possible value).

Patients were divided into several clinically relevant subgroups for which we calculated individual SMRs for the TR-THEL and the TR-DGU patients. Expected mortality calculations used prognoses derived from the RISC [8]. The difference between observed and expected mortality (observed minus expected mortality rate) as well as the standardised mortality ratio (SMR: observed divided by expected mortality rate) with 95 % confidence intervals we calculated for each subgroup based on the respective

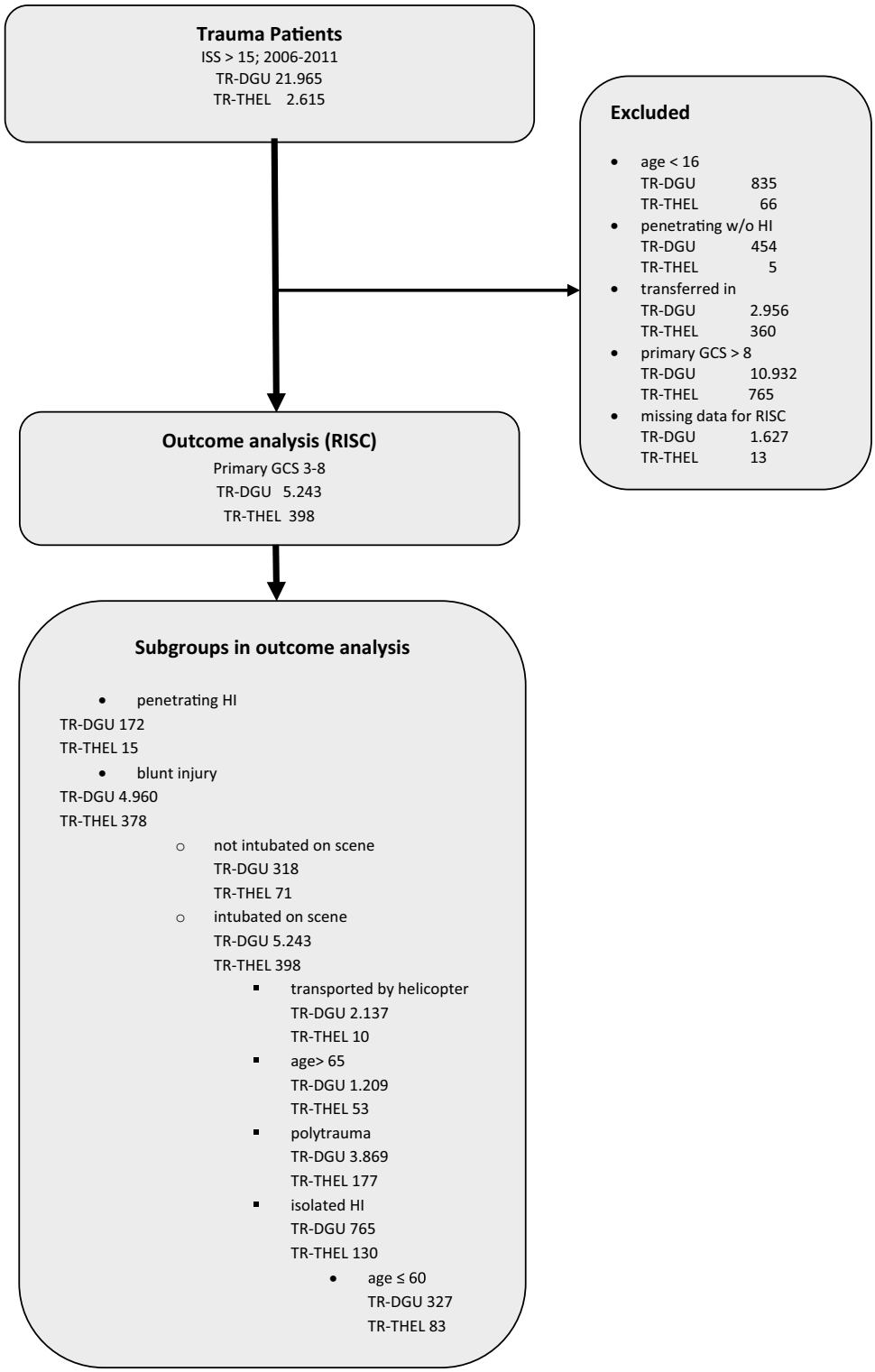

Fig. 1 Flow diagram of included and excluded patients and their subgroups in outcome analysis. *ISS* injury severity score, *TR-DGU* the German Trauma Registry, *TR-THEL* Helsinki University Hospital's trauma registry, *GCS* Glasgow Coma Scale, *RISC* Revised Injury Severity Classification score, *HI* head injury

confidence interval for the observed mortality rate. Differences in the SMR were compared by *t* test.

Primary outcome measure was mortality, defined in the TR-THEL as death in hospital within 30 days after admission and in the TR-DGU as hospital mortality. For reason of comparability, this analysis considered patients in the TR-DGU who died beyond day 30 to be survivors.

The statistical analyses used SPSS statistical software (IBM Corp., Version 20.0. Armonk, NY, USA).

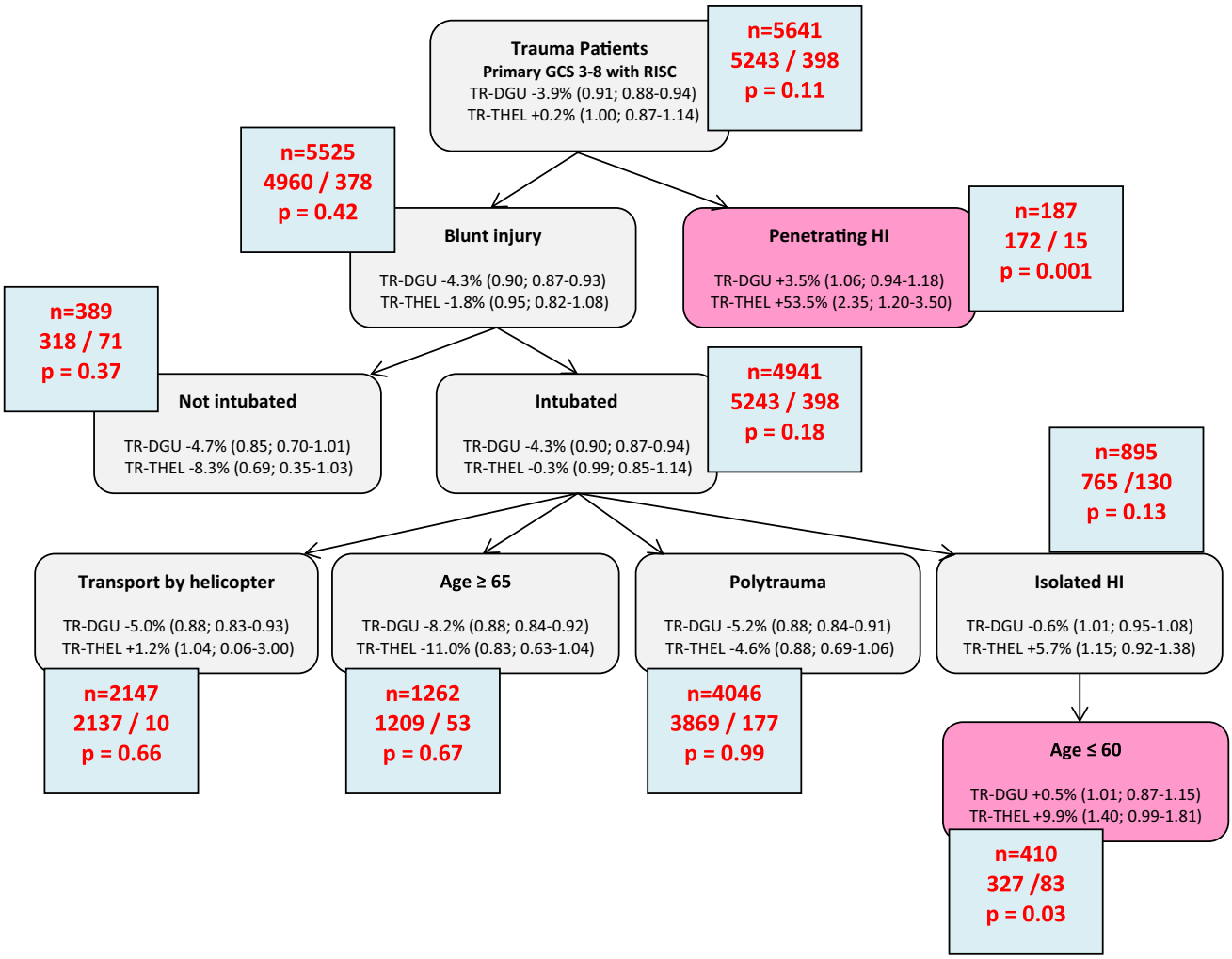

Fig. 2 Difference between observed and expected mortality by subgroup. Standardized Mortality Ratio (SMR) with 95 % CI is shown in *brackets*. *Red* indicates statistically significant difference in outcome. Abbreviations as for Fig. 1

Results

A total of 85 hospitals from the TR-DGU met the inclusion criteria, providing a total of 5243 patients. Those from the TR-THEL numbered 398 (Fig. 1).

Overall mortality in unconscious patients with ISS ≥ 16 was 34.9 % in the TR-THEL and 40.5 % in the TR-DGU. Differences between observed and expected mortality are shown in Fig. 2 for respective subgroups.

Subgroup analysis revealed a statistically significant difference in SMR between trauma registries in patients with penetrating head injury (subgroup A) in favour of TR-DGU ($p = 0.001$). The absolute difference between observed and expected mortality was +53.5 % in the TR-THEL (SMR 2.35, 95 % CI 1.20–3.50) and +3.5 % in the TR-DGU (SMR 1.06, 95 % CI 0.94–1.18).

Subgroup analysis of patients with blunt injury mechanism showed no overall difference in SMR between the TR-THEL and TR-DGU. Nor did division of patients with blunt injury mechanism into intubated-on-scene versus not-intubated-on-scene show any significant difference. Further subgroup analysis of intubated patients with a blunt injury mechanism showed no differences between the trauma registries regarding patients transported by helicopter, patients ≥65 years, those with polytrauma, or those with isolated head injury (defined as head AIS ≥ 3, no other AIS > 2). Patients with isolated head injury were subject to further analysis, where a statistically significant difference in adjusted mortality between the TR-THEL and the TR-DGU appeared for patients ≤60 years (subgroup B). In the TR-THEL, 37 % ($n = 31/83$) of these had an unknown injury mechanism, while in the TR-DGU the mechanism of injury was unknown only in 10 % (Fig. 2).

Two authors (T.B., L.H.) reviewed the medical records for subgroups A and B from TR-THEL to find further

Table 1 Deceased patients in TR-THEL in the subgroup of penetrating head injury

Patient	Injury mechanism	Background	Operation	Day of death from admission	Place of death
1	GSW	Self-inflicted	No	0	ER
2	GSW	Self-inflicted	No	0	ER
3	GSW	Self-Inflicted	No	6	ICU
4	GSW	Self-inflicted	Yes	0	ER
5	GSW	Shot	Yes (ICP)	3	ICU
6	GSW	Self-inflicted	No	0	ICU
7	GSW	Self-inflicted	No	1	ICU
8	GSW	Self-inflicted	No	0	ICU
9	GSW	Self-inflicted	No	0	ER
10	GSW	Self-inflicted	No	1	ICU
11	GSW	Self-inflicted	No	6	Ward
12	GSW	Self-inflicted	No	2	Ward
13	GSW	Shot	No	1	ICU
14	GSW	Self-inflicted	No	0	ICU

GSW gun shoot wound, *ER* emergency room, *ICU* intensive care unit, *ICP* intracranial pressure monitor

Table 2 Deceased patients in TR-THEL with unknown injury mechanism (found unconscious) in the subgroup fulfilling the criteria of blunt injury + intubated on scene + isolated head injury + age $\leq$ 60 years

Patient	Diagnosis	Operation	Alcohol %	Day of death from admission
1	aSDH + contusion	No	2.9	2
2	aSDH	Yes (decompressive craniectomy)	2.7	8
3	Multiple contusions	No	2.6	8
4	aSDH	No	2.6	4
5	aSDH + ICH	No	3.6	1
6	aSDH + EDH	Yes (craniotomy)	3.9	9
7	aSDH	Yes (craniotomy)	4.4	14
8	aSDH + contusion	No	<0.2	0

aSDH acute subdural hematoma, *ICH* intracerebral hematoma, *EDH* epidural hematoma

information on patient characteristics, injury mechanism, injuries, and treatment.

In subgroup A, only 15 penetrating head injury patients with pGCS $\leq$ 8 appeared in TR-THEL during the study period. Of these, 14 died, all due to a gun shot to the head at close range (Table 1).

In subgroup B, of 31 patients with unknown injury mechanism, 8 died within 30 days of admission in the TR-THEL. All were found unconscious, the time of the injury was unclear, and of the 8, 7 (88 %) tested positive for alcohol (range 2.6–4.4 %) (Table 2).

Discussion

Our retrospective study comparing treatment processes and outcome based on two trauma registries in two European countries showed severity-adjusted outcomes to be very similar in the overall group as well as in most subgroups. Differences in outcome appeared in only two subgroups.

Trauma outcome results based on registry data reflect the performance of the whole treatment chain, including pre-hospital as well as in-hospital treatment. A notable difference in pre-hospital care between the Finnish and German trauma systems is Finland's significantly lower rate of on-scene physicians and intubation of unconscious patients. The present study, however, showed no significant difference in adjusted outcomes between unconscious patients who were intubated versus unconscious patients who were not intubated on the scene in either southern Finland or in Germany. Accordingly, the decision not to intubate the patients with pGCS 3–8 did not seem to add to mortality. The lack of pre-hospital physicians, however, is a significant risk factor for inappropriate pre-hospital transfer of patients with traumatic brain injury (TBI), thus delaying appropriate care, and this has been associated with increased risk of death [11, 12]. Although patients not

primarily transported were excluded, inadequate pre-hospital transfers should be a factor considered in future studies.

Patients with a penetrating head injury and younger patients (age ≤60 years) with isolated head injury had a worse outcome in southern Finland than in Germany. Review of deceased patients' files in the TR-THEL revealed that some treatment limitations were due to their early hopeless prognosis, for which the RISC does not account. But such patients should also exist in the TR-DGU, even though practices on calling off treatment may differ among hospitals or trauma systems. Although evaluating mortality is an essential part of outcome comparisons and is less subject to measurement error than is nonfatal outcome, it may not always be the worst possible outcome, particularly for patients with severe brain injury. Information on quality of life, for example 1 year after the injury, hardly exists in trauma registries. It would be a valuable addition to performance evaluations especially in patients with severe brain trauma [13]. In addition to outcome, process and structure are two other crucial components of quality in health care evaluation as defined by Donebian in 1966 [14]. These were not analyzed here.

A detailed analysis of the deceased TR-THEL patients with isolated head injuries, especially penetrating one, raises the question of RISC's ability to calculate prognosis reliably in patients with severe isolated head trauma. Our recent article showed the performance of RISC as a prognostic tool to be poorer for patients with isolated head injury [15]. This highlights methodological limitations of the SMR comparison between trauma registries. An updated version of the RISC appeared recently with better performance for outcome prediction in patients with head injuries [16]. Furthermore, the use of specifically developed prediction models (such as the IMPACT or the CRASH) for patients with TBI should be considered in future TBI benchmarking studies. [17–19].

The present study has several limitations. First, the approach of repeated subgroup analysis leads to a high risk for random errors (type-one error), and, due to a low number of patients in subgroups, for incidental findings (type-two error). Second, the TR-THEL and the TR-DGU have different data-collection procedures and inclusion criteria. In the TR-THEL, three dedicated and trained trauma register nurses collect and code the data from a single trauma centre into a hospital registry. The TR-DGU contains data from many different hospitals coded by multiple persons. Although multiple plausibility checks are implemented, this could possibly lead to increased errors in data input. Third, those patients with missing data for baseline risk analysis were excluded from outcome analysis; no imputations were done. In the TR-THEL, only 0.5 % patients had missing data, indicating the high quality of these data. In the TR-DGU, data were missing for 7.5 % of the patients. This is a potential bias, if the missing data are not missing at random. Fourth, the central inclusion criterion of the patients in this study was a primary GCS of 3–8 on scene. Although GCS is widely used by pre-hospital personnel in both Finland and Germany, the GCS number coded is a subjective estimate. In one study, GCS demonstrated poor inter-observer reliability [20]. Fifth, the outcome measure was defined as 30-day hospital mortality. No deaths outside the hospital or, in the TR-THEL, beyond 30 days of admission are recorded. In patients with TBI, 30-day hospital mortality is a poor outcome measure, as it significantly underestimates mortality rates. Thus, using hospital mortality as the endpoint may cause bias if discharge practices differ. [21] Sixth, obvious differences also exist in pre-hospital systems between Finland and Germany and in hospital profiles between the HU trauma centre and the German level-one trauma centres. Differences across trauma and hospital systems can be considered as a limitation of the study, but on the other hand, provide the possibility to discover the effect of differences in treatment on outcome. To minimize any bias due to these limitations mentioned above, the data were carefully transformed into properly comparable variables, resulting in a subset of data from both registries that then served for analysis.

Differences in outcome noted in our study could stem from random statistical findings (due to both type I and II errors), weakness of the applied prediction model, differences in care and treatment processes, or even from hospitals' reluctance to include in registries patients with hopeless prognosis (such as close-range gun-shots to the head); most probably the explanation is a combination of all four. Our study raised several questions as to the applicability of trauma-registry comparison between trauma systems in the benchmarking process, especially to TBI patients. We consider, however, that such evaluations and comparisons should be made regularly in modern hospitals; continuous quality improvement is an integral component of trauma centre care. Despite its limitations, trauma registry comparisons serve as a means of quality control and assist in evaluating any changes needed in treatment protocols or in distribution of resources inside a hospital.

Conclusion

Trauma registry comparison has several pitfalls needing acknowledgement: the explanation for outcome differences between trauma systems can be a coincidence, a weakness in the scoring system, true variation in the standard of care, or even hospitals' reluctance to include patients with hopeless prognosis in registry. We believe, however, that such comparisons are a feasible method for quality control: identification and detailed analysis of subgroups with

an unexpected result may help to improve our knowledge about trauma care.

Compliance with ethical standards

Conflict of interest Tuomas Brinck, Rahul Raj, Markus Skrifvars, Riku Kivisaari, Jari Siironen, Rolf Lefering and Lauri Handolin declare that they have no conflict of interest.

Ethical standards Given the retrospective nature of the study, a waiver for ethical assessment was granted and the study protocol was approved by the administrative board of the TR-THEL, and was registered and approved according to the publication guideline of the TR-DGU (No. 2012-053).

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