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Original Investigation

Effectiveness of Traumatic Brain Injury Management Guideline Introduction in Hungary

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ABSTRACT

AIM: To describe the impact of the Traumatic Brain Injury management guideline introduction in Hungary.

MATERIAL and METHODS: Hospital discharge records (HDR) including age, gender, codes of interventions applied, ICD codes of diagnosed disorders of patients admitted between 01/01/2004 and 31/12/2010 with the diagnosis of intracranial injury (S06 by ICD10) from every inpatient institution in Hungary were collected from the database of National Health Insurance Fund (NHIF). The Case Fatality Ratios (CFR) for one week, one month and six months were calculated for the periods before and after the guideline introduction. The change of CFRs was applied as indicators for change of clinical quality elicited by the guideline.

RESULTS: The centers together at one week, one month and six months had pre-guideline introduction CFRs of 23.4%, 37.7% and 47.5% and post-guideline introduction CFRs of 22.1%, 39.1%, and 50.0% respectively. The secondary institutions together at one week, one month and six months had pre-guideline introduction CFRs of 21.5%, 34.8% and 46.3% and post-guideline introduction CFRs of 21.9%, 37.0%, and 48.9% respectively. None of the CFRs showed significant change.

CONCLUSION: The effectiveness of TBI management guideline adaptation in Hungary is poor. Without supportive financing and external auditing system, guideline introduction alone cannot achieve standard clinical practice and a reduction in CFR.

KEYWORDS: Case fatality ratio, Guideline, Guideline introduction, Hungary, Traumatic brain injury

INTRODUCTION

Traumatic brain injury (TBI) is a major cause of death and disability in the world harboring significant public health and socio-economic importance. TBI is estimated to be the primary cause of mortality and disability among young individuals and is associated with a cost of over $76 billion ($384,864,000/100,000/year) in the USA (12), and at least €33 billion (€ 77,550,000/100,000/year) in Europe (7). According to the Center for Disease Control and Prevention (CDC) in 2016, about 823.7/100,000/year emergency department visits were associated with TBI - either alone or in combination with other injuries. Epidemiological data on TBI from the European Union are scarce, but do indicate an incidence of hospitalized TBI of approximately 235/100,000/year, although substantial variation exists between European countries (11).

In order to reduce the disability, mortality and socio-economic burden of TBI, guidelines (1) for managing TBI need to be adhered to. The implementation of guidelines produces improved efficiency and outcomes for healthcare professionals and patients beginning with pre-hospital phase and extending throughout long-term application of care. If all trauma centers in the USA adopted the guidelines, the CDC projects a $ 3.8 billion savings in associated cost (2). Although TBI management guidelines are widely published, their

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implication is seldom assessed and the guideline adherence is hardly documented (1,10).

If TBI management guidelines are properly adhered to, the pre-hospital management of TBI should lead to correct identification of TBI, optimal treatment in the ambulance/emergency room and direct transfer to a TBI trauma center. The in-hospital management of TBI will produce reduced duration of intensive care unit/hospital stay, reduced healthcare cost, decreased death and disability (6) by 30%-50% and improved neurological outcome (5) upon discharge by 30%-50%. The post-hospital management of TBI would lead to faster rehabilitation and timely re-integration of a patient into the society (15). Adherence to guideline possesses further great potential for managing TBI in terms of helping to standardize clinical management of TBI (hence, ensure quality control) and aid data collection for further audit/benchmarking and research purposes.

The disease burden of serious intracranial trauma is continuously high in Hungary, especially among middle aged men representing the leading cause of death in the young, active population. The reported incidence of TBI patients in Hungary is 140/100,000/year. The proportions of mild, moderate, and severe cases are 67%, 23%, and 11%, respectively. The case fatality ratio (CFR) was extremely high in Hungary: the estimated CFR for hospitalized TBI cases was 45% in 2002 (4). To exploit the evidence based guidelines opportunities, the Hungarian Ministry of Health introduced the guideline of TBI care in 2006, which was established on recommendation of Brain Trauma Foundation (1). It focused on the pre-hospital and clinical management of patients, but it was not supported by reformulated financing protocols and establishment of quality monitoring.

The study aimed to describe the impact of the guideline introduction on the degree of care centralization and the CFR for the Hungarian severe TBI patients, in order to describe the usefulness of guideline introduction without parallel introduction of an audit system.

■ MATERIAL and METHODS

National Health Insurance Fund (NHIF), the only institution responsible for financing the inpatient neuro-traumatology care in Hungary, provided the data as hospital discharge records (HDR). NHIF HDR contains patients' data such as age, gender, zip code of residential address, date of admission, codes of interventions applied, International Classification of Diseases (ICD) codes of diagnosed main disorders, date of discharge, date of death (if it happened). Direct assessment of TBI severity was not possible in this studied dataset because the NHIF HDR does not contain the Glasgow Coma Score (GCS). Instead, the severe TBI cases (sTBI) were defined by ICD code and clinical intervention codes. Patients with S06 diagnosis of intracranial injury and with a code of external ventricular drainage application were considered as sTBI subjects. The HDR of sTBI patients admitted between 01/01/2004 and 31/12/2010 recorded in every inpatient institution of Hungary were included in the database analyzed by our investigation. The records were pseudonymized, and the pseudo-identifiers were used to link the episodes of care to patients. Severe TBI patients who died at the scene of trauma or before arrival to the hospitals were not included in the study population.

Age and sex specific incidence of sTBI was calculated for Hungary using demographic data of the Hungarian population provided by the Hungarian Central Statistical Office.

The institutions that took part in the sTBI care were described by the number of patients first admitted by them. By evaluating the pathways of sTBI patients, the TBI centers and secondary institutions were differentiated. Hungary has a declared hierarchy of institutions devoted to TBI care. Unfortunately, this levelling system is neither enforced by health authorities nor adhered to in the practice. In fact, the patient pathways are determined by the traditional relationship between neurosurgeons and the emergency care providers in a certain catchment area, beside the geographical position of injury. Hence, centers had to be determined by a statistical approach in our analyses, instead of by the misleading official categorization. Centers and secondary institutions were distinguished by the number of patients admitted in the study period. A Lorenz curve like graph was constructed to show the level of centralization which plotted the cumulative percentage of the total number of patients in the function of the top percentage of institutions that treated the highest number of patients. The biggest institutions altogether treated 50% of the patients and were considered as centers while the rest of institutions as secondary.

The CFR was calculated for the period of one week, one month and six months after the first hospital admission of sTBI patients. Age group and gender specific CFRs for the whole country were also calculated for each studied year. The center and secondary institution specific CFRs were calculated, as well, and compared by chi-square test to check the change in time.

The indicator for centralization of care (number of patients admitted in centers over number of patients admitted in secondary institutions), the center and secondary institution specific CFRs were computed for the whole study interval (2004-2010), period before (2004-2006) and after (2007-2010) guideline introduction. The period specific results were compared by chi-square test.

To control for the potential confounding effect of patients demographic characteristics, the determinants of CFRs were investigated by multivariate logistic regression models where the sex and age of sTBI patients, the level of first admitting institution (classified as centers or secondary institutions), and time of the admittance (distinguishing before and after guideline introduction periods) were the explanatory variables.

The results of statistical tests were considered as significant if the p-value was less than 0.05. All the statistical computations were carried out by PASW Statistics 18.

The database was processed anonymously. The processing of the data was a secondary analysis and according to the contemporary Hungarian legal requirement, ethical permission was not necessary to carry out analyses. The research protocol was reviewed, permitted and in concordance with the Internal Data Safety and Patient Rights Board of the Hungarian Health Insurance Fund.

■ RESULTS

The total number of discharge episodes during the study duration was 77,442 episodes of 7,230 patients. Male dominance was observed (Table I). The average age of males and females was not different. Among females, the age group of 75-84 years was at highest risk. Among males, the highest risk period was wider (Figure 1). There were 3,391 fatal outcomes detected in 6 months of the hospital admittance. CFR at one week post-injury was 21.9% (21.2% among males and 23.6% among females), which was elevated up to 36.8% (36.1% and 38.8%) at one month, and up to 48.0% (47.0% and 50.4%) at six months.

At one week, in males, the highest CFRs were in the ninth and fourth decades (with CFRs of 46.2% and 26.2%). While in females, the highest CFRs were observed in third and ninth decades (with CFRs of 41.9% and 35.7%). At one month, in males, the highest CFRs were detected in age groups 95 and 90 (with CFRs of 76.9% and 61.5%) and in females, in age groups 95 and 90 (with CFRs of 61.5% and 60.7%). At six months, in males, the highest CFRs have been described in age groups 95 and 90 (with CFR of 84.6% and 69.8%) in females in age groups 95 and 90 (with CFRs of 92.3% and 75.0%) (Figure 2).

Throughout the study period, the CFR in one week, in one month and in 6 months remained the same for almost all age groups before and after 2006 when the guideline was introduced (Figures 3-5).

A total of 57 institutions took part in the study with 8 (referred as centers) providing 50 % of the care (Figure 6). There was

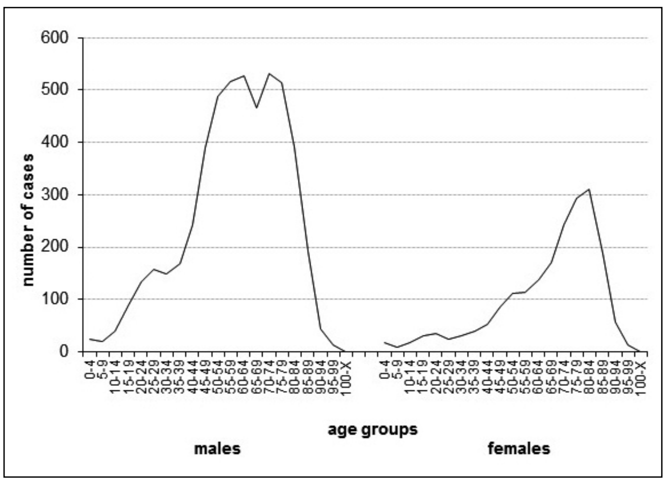

Figure 1: Number of age- and sex-specific cases of traumatic brain injuries in Hungary (2004-2010) according to the hospital discharge records of the National Health Insurance Fund.

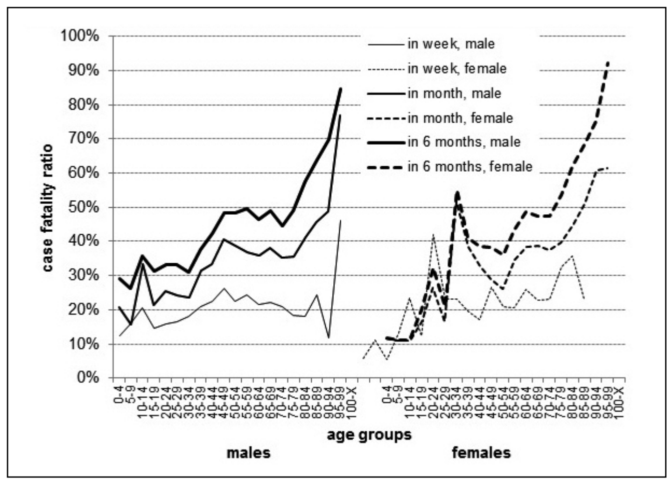

Figure 2: Age- and sex-specific case fatality ratio of traumatic brain injury in Hungary (2004-2010) for 1 week, 1 month, and 6 months according to the hospital discharge records of the National Health Insurance Fund.

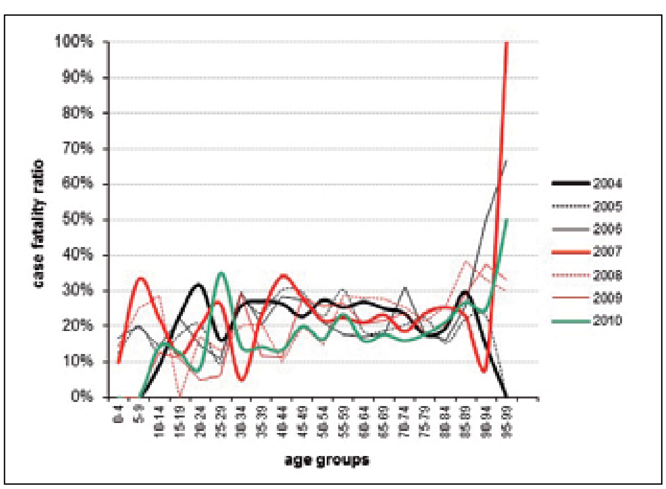

Figure 3: Time trend of age-specific case fatality ratio (CFR) of traumatic brain injury in Hungary (2004-2010) for 1 **week**.

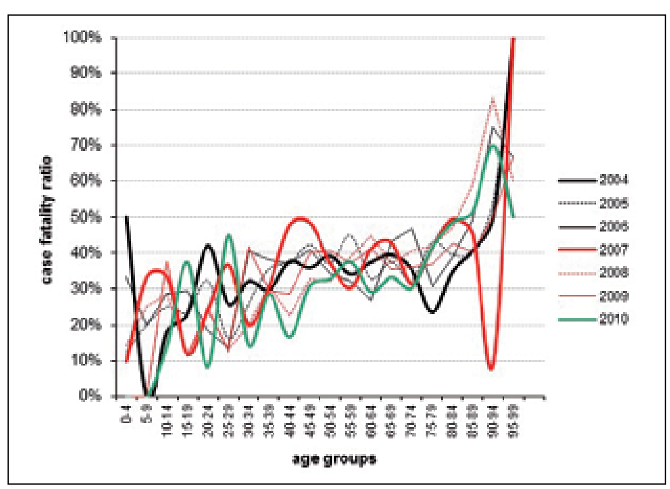

Figure 4: Time trend of age-specific case fatality ratio (CFR) of traumatic brain injury in Hungary (2004-2010) for 1 **month**.

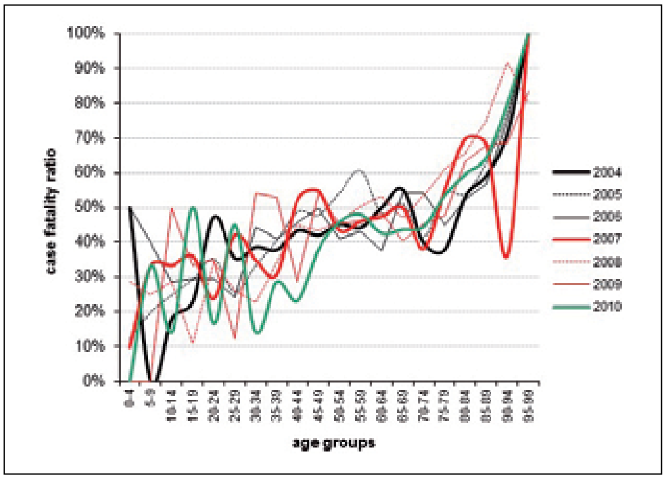

Figure 5: Time trend of age-specific case fatality ratio (CFR) of traumatic brain injury in Hungary (2004-2010) for 6 **months**.

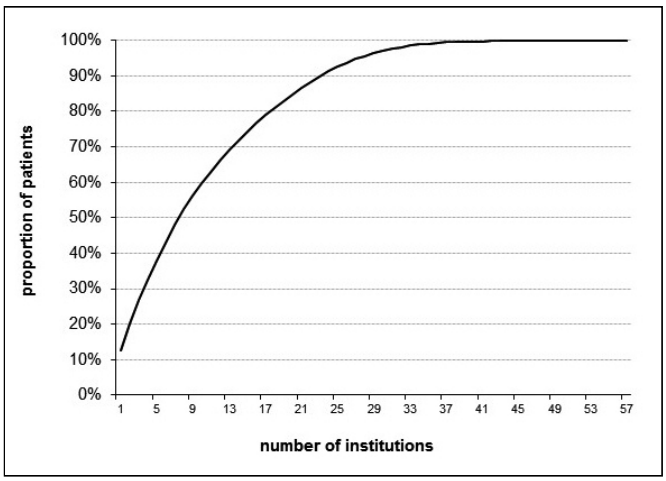

Figure 6: Cumulative proportion of severe traumatic brain injured patients in the function of the cumulative number of institutions providing the care in Hungary (2004-2010) according to the hospital discharge records of the National Health Insurance Fund.

an increase in care centralization according to the ratio of the center to secondary institutions treated number of patients. (0.85 vs 1.07; p<0.001) (Table I).

The centers together at one week, one month and six months had CFRs of 22.6%, 38.6% and 48.9% respectively. The secondary institutions together at one week, one month and six months had CFRs of 21.7%, 35.9% and 47.6%. Differences were not significant for the one week and for the 6 months period (p=0.358, and p=0.267). The centers' CFR was significantly higher for 1 month (p=0.018). The centers and the secondary institutions specific CFR showed no change when the before and after guideline introduction periods were compared (Table I).

According to the multivariate statistical evaluation, sex was not a CFR influencing prognostic factor for any survival interval, but the higher age proved to be risk factor for each CFR studied. Neither the level of first admitting institution nor the time period of care had any significant influence on CFRs (Table II).

■ DISCUSSION

Main Findings

In this study, data (HDRs) from the NHIF was analyzed. Our results demonstrated a steady, high case fatality in the Hungarian TBI population undergoing external ventricular drain (EVD) installation, and "no effect" of the introduction of scientific evidence-based practice guidelines in 2006 was revealed. Though, the guideline introduction coincided with moderate increase of centralization. The unreduced CFR in Hungary suggested that the existence of guidelines *"per se"* will not result in outcome improvement and additional measures (audit of care, enforcement of guideline compliance) should also be introduced (8).

Like in Hungary, TBI guidelines were introduced in other European countries and in the USA many years ago, but in most of these countries, there is a long term tradition of external quality management in clinical care. Further, if there is negligence in medical practice, it can result in lawsuit and also there is competition between the medical institutions. These factors establish the guideline adherence which varies in countries remarkably (between 18-100%), but contributes to significant reduction in mortality (3).

In the last few decades, several Eastern and Middle European countries introduced scientific evidence-based practice guidelines to comply with European legislations and regulations mandatory to participate in international multicenter studies and collaborations. Nevertheless, policy makers did not necessarily cope with these guidelines in terms of introducing novel approaches in health care financing and quality assurance.

Similarly to the majority of these countries, such "mechanisms" do not exist in the Hungarian health care either and a desperate need for contemporary audit systems has long been voiced by clinical and scientific societies. Due to the lack of external pressure, the hospital managements neglect the internal resource allocation needed to improve the resource demanding guideline adherence. Former small scale studies as well as a cross sectional snapshot-like questionnaire based analysis of the care for TBI in Hungary revealed similar results and led to the same conclusions about the reasons of high in-hospital mortality and limited adherence to the international guidelines. This nationwide survey, however, was unable to provide a trend analysis neither supplied data on long term outcome (4).

Strengths and Limitations

The database provided by NHIF was nation-wide with complete national coverage ensuring the fairly high power in the statistical evaluations. However, there are some obvious limitations of such a health insurance data based study: (1) NHIF monitors the financing of care but not the quality of care; (2) the financial interest of the hospital may lead to bias of

Table I: Influence of Guideline Introduction in 2006 on Care Centralization and Case Fatality Ratios

	Whole period (2004-2010)	Before guideline (2004-2006)	After guideline (2007-2010)	p-value*
Male/Female	2.58 (5211/2019)	2.77 (2387/861)	2.44 (2824/1158)	0.015
Age (years), Mean ± SD	60.89±19.23	59.01±19.30	62.41±19.04	<0.001
Centers/Secondary institutions, (N/N)	0.97 (3551/3679)	0.85 (1492/1756)	1.07 (2059/1923)	<0.001
CFR in 1 week in centers, N (%)	803 (22.6%)	349 (23.4%)	454 (22.1%)	0.454
CFR in 1 week in secondary institutions, N (%)	798 (21.7%)	377 (21.5%)	421 (21.9%)	0.803
CFR in 1 month in centers, N (%)	1369 (38.6%)	563 (37.7%)	806 (39.1%)	0.570
CFR in 1 month in secondary institutions, N (%)	1322 (35.9%)	611 (34.8%)	711 (37.0%)	0.345
CFR in 6 months in centers, N (%)	1736 (48.9%)	709 (47.5%)	1027 (50.0%)	0.416
CFR in 6 months in secondary institutions, N (%)	1753 (47.6%)	813 (46.3%)	940 (48.9%)	0.351

***for comparison of 2004-2006 and 2007-2010 periods. *CFR:* Case fatality rate.*

Table II: Influence of Guideline Introduction on Case Fatality Ratio of Severe Traumatic Brain Injured Patients in Hungary according to Multivariate Logistic Regression Analysis Controlled for Age and Sex of the Patients and for the Level of Institution Providing the Care

		OR	p-value
CFR in 1 week	sex (female/male)	1.110	0.099
	age (year)	1.004	0.018
	level of institution (center/secondary)	1.061	0.300
	guideline introduction (after/before)	0.962	0.502
CFR in 1 month	sex (female/male)	1.006	0.907
	age (year)	1.012	<0.001
	level of institution (center/secondary)	1.095	0.064
	guideline introduction (after/before)	1.042	0.405
CFR in 6 months	sex (female/male)	0.994	0.906
	age (year)	1.017	<0.001
	level of institution (center/secondary)	1.061	0.213
	guideline introduction (after/before)	1.045	0.359

***CFR:** Case fatality rate.*

reported data; (3) data collection could not make distinction between severe and mild TBI cases by the usual GCS classification; (4) and there were no data on the process of clinical treatment apart from the EVD application. However, the case definition and the quality of data collection was not changed in the study period. Therefore, the time trend analysis yielded reliable results on change of care centralization and CFR in time.

The average incidence of TBI in Europe is 235/100,000/year with a range of 150-300/100,000/year (18). The incidence of TBI in Hungary estimated as 140/100,000/year is only a bit less than this European reference (4). Our study estimated 72.3/100,000/year the incidence of sTBI. Considering the former Hungarian observation on the severity of TBI cases in Hungary, the estimated number of TBI patients according to our present investigation is 957/100,000/year if it is supposed that all studied sTBI patients meet the severe TBI criteria. It seems impossibly high. If it is assumed that sTBI definition corresponds to severe and moderate TBI cases, then the TBI incidence estimated by our study dataset is 212/100,000/year which is in the European reference range. It is probable that our working case definition included severe and moderate TBI cases as well. On the other hand, our study underestimated both incidence rate and number of fatal outcomes. Presumably due to the excluded cases with lethal pre-hospital outcome, and cases which reached the hospitals but due to the very severe clinical status, the invasive surgical interventions were not perfomed before lethal outcome. Although, the study was not aimed to determine the exact incidence and case fatality for TBI or for severe TBI in Hungary, taking into consideration the above mentioned validity issues, the observed high CFRs for sTBI demonstrated that the Hungarian care for TBI patients was far less effective than it should be on the basis of the country's general development (9,13,14).

In Hungary, the highest CFRs in women at six months were found in the young adults (35 years old) and the elderly (>90 years old) while the highest CFRs in men at six months were found in the middle aged (50 years old) and elderly (>90 years old) groups. The combined CFRs for both sexes at six months were highest at the age group of 95 (with CFR of 88.5 %). A similar trend of high CFR in the elderly was reported in other European countries and the USA (13,16,17). The similarity between published articles and our observed age dependence of CFR shows that our design is reliable in dealing with the time trend of CFR.

■ CONCLUSION

On the basis of our study which utilized hospital discharge records by which the severe traumatic brain injury incidence was slightly underestimated but rigorous case definition was applied, the lethal outcome was not reduced after the introduction of evidence based guideline in the TBI patients who did not die at the scene of the trauma or during transport to hospital, and whose clinical statuses at admission were not too serious to prevent the neurosurgical invasive intervention, but whose brain trauma were serious enough to indicate EVD application. The guideline introduction without supportive financing and external auditing cannot achieve the desired quality improvement in countries with a legal environment and economic development similar to Hungary.

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