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QUALITY INDICATORS FOR PATIENTS WITH TRAUMATIC BRAIN INJURY IN INTENSIVE CARE UNITS

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Abstract:

Introduction: *Traumatic brain injury (TBI) is one of the major cause of trauma-related death and hospital admissions. Therefore, patients with (severe) TBI need specialized neuro intensive care treatment at an intensive care unit (ICU).* ***Objective:*** *The purpose of the study was to identify the quality indicators for traumatic brain injury patients in ICUs.* ***Methods:*** *We applied a previously researched quality indicator set based on a Delphi study to the CENTER-TBI study. That study consisted 17 structure, 16 process, and 9 outcome indicators for adult patients with TBI at the ICU. It was appraised that this initial set would be in need of further validation.* ***Results:*** *A total of 24 (11 structure, 7 process, and 6 outcome indicators) of the 42 indicators of the Delphi set were recruited from the CENTER-TBI database.* ***Conclusion:*** *Future researches should centre the implementation and quality improvement efforts and continuous re assessment of the quality indicators.*

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INTRODUCTION:

Traumatic brain injury (TBI) causes a number of health and economic burden around the world (1). Patients with moderate and severe TBI are at high risk for poor outcomes and mostly require intensive care unit (ICU) admission. In these patients, evidence-based treatment options are insufficient and large variations in outcome and daily ICU practice exist (2).

In the USA it is noted that approximately 1.5 to 1.7 million people experience TBI per year (3). Worldwide, the burden is even higher, with 10 million cases estimated each year (4). Approximately one fourth of these cases are classified as severe.

In 1995, the Brain Trauma Foundation (BTF) first published guidelines for the management of severe TBI, and has twice revised the guidelines, most recently in the third edition published in 2007 (5). The recommendations and management strategies enumerated in these documents show the base of intensive care unit (ICU) management. Nonetheless, they remain largely based on lower-level recommendations owing to a lack of high-quality evidence (6).

Research to develop more evidence-based and thereby uniform treatment strategies for patients with TBI has high recommendation. Still, breakthrough intervention strategies are less (7) and guideline recommendations remain insufficient. Therefore, new strategies, such as precision medicine and routine quality measurement, are being investigated to opperate research and clinical practice ahead (8). Daily quality measurement using suitable indicators can follow quality improvement, for example, through recognizing best practices and internal quality improvement processes. The potential of quality indicators to better care has already been demonstrated in other clinical setups, in other ICU populations like sepsis or stroke patients, and in children with TBI (9).

To improve patient outcome international registries can contribute, by identifying areas in need of quality improvement, informing health policies, and increasing transparency and accountability, as shown in other medical fields, like cancer, acute coronary syndrome, and cystic fibrosis (10). Benchmarking TBI management between ICUs can only be reliable when standardized quality indicators are taken in account and case-mix correction is used (11). Quality indicators can be grouped into structure, process, and outcome indicators. As no quality indicator set is available for patients with TBI, we recently performed a Delphi study to reach consensus on a quality indicator set (12).

However, there are also examples of quality indicators that do not positively alter the quality of care. There may be certain reasons, such as lack of validity and reliability, poor data quality, or lack of support by clinicians (13). Deploying poor indicators has opportunity costs due to administrative hazard while distorting healthcare standards. An evaluation of a putative quality indicator is inherently multidimensional, and when applied to identify best practice or benchmark hospitals, validity and reliability and uniform definitions are all equally essential (14).

The purpose of this study is to validate the consensus-based quality indicator set. We hereto analysed patients included in a large dataset of patients with TBI from the Collaborative European Neuro Trauma Effectiveness Research in Traumatic Brain Injury (CENTER-TBI) study. Data gathered for CENTER-TBI included a detailed information of ICU facilities and patient outcomes in 54 centres, thus providing an opportunity to evaluate the effectiveness of the newly developed indicator set (15).

METHODS:

In this validation study, we applied a previously acknowledged quality indicator set based on a Delphi study to the CENTER-TBI study. That study consisted 17 structure, 16 process, and 9 outcome indicators for adult patients with TBI at the ICU. It was apprised that this initial set would be in need of further validation (16).

Data

A multicentre, observational cohort study conducted in Europe, which included patients between 2014 and 2018, in CENTER-TBI study (Clinicaltrials.gov NCT02210221) (17). The study contained 4509 patients. Patients who had clinical diagnosis of TBI, presentation within 24 h of injury, an indication for CT scanning were included in the CENTER-TBI study, and the exclusion criterion was a previously existing (severe) neurological disorder that could confound outcome assessments. We took ICU patients for this study as the consensus-based indicators were basically made for the ICU. So, the inclusion criteria for our study were (1) adults older than 22 years and (2) admitted to the ICU. Procedures of ICU care (vitals, treatments, and therapy intensity levels) were taken on a regular basis. Outcomes were examined at the ICU and at 3, 6, 12 months. Furthermore, questionnaires were filled by participating centres on structures and processes of care (Provider Profiling questionnaires (18)).

Indicator scores
At centre level the structure indicator scores were calculated on the basis of Provider Profiling questionnaires and impression as the number of centres that described that the structure was either present or absent.

Process indicators were mentioned as the number of patients adherent to the indicator (numerator) divided by the number of patients to which the indicator could have applied per centre (denominator).

Outcome indicators were measured as the event ratio of the indicator per centre (numerator) divided by the total number of patients which could have scored on the indicator (denominator). The median score were calculated for the Glasgow Outcome Scale Extended (GOSE) and Short Form-36 version 2 (SF-36).

Discriminability
To measure discriminability (between-centre variation), we ascertained the between-centre differences in adherence to quality indicators to calculate their probability for benchmarking and quality betterment (19).

Between-centre difference for structure indicators was calculated by the number of centres having that structure. We put an arbitrary threshold adherence to structure and process indicators, for moderate discriminability at 70–80% and for minimum0 discriminability at 80–90%. The discrimination between centres is decreased by such high levels of adherence.

The between-centre difference of process and outcome indicator scores were quantified with the median odds ratio (MOR) (20). The MOR shows the odds of being adherent to a basic indicator for two patients with the same patient characteristics from two randomly selected centres. The larger the between-centre variation, the higher the MOR (a MOR equal to 1 indicates no variation).
For process and outcome indicators, we considered a low (unadjusted) interquartile range on scores (IQR < 10) or non-significant (adjusted) between-centre differences or a MOR of 1.1 or less as poor discriminability. Case-mix- and uncertainty-adjusted process and outcome indicator scores per centre were mentioned in caterpillar plots.

Validation of the quality indicators
The effectiveness of the quality indicators were on the basis of three criteria: statistical uncertainty, discriminability, and feasibility (21). The thresholds on these criteria were not reported by any other previous studies, so we set a prior thresholds based on consensus.

Feasibility
Data quality and ease of quality indicator calculation addressed feasibility (22).
The feasibility was quantified by the completeness of the variables needed to identify the indicators. We set an arbitrary threshold of > 80% completeness of data (of denominator) to measure feasibility.

Statistical uncertainty
The reproducibility of a quality indicator is referred as reliability and is frightened by unclear indicator descriptions and statistical uncertainty (23). We resolute whether we could compute indicators in a linear way or made minor variations to definitions. Statistical uncertainty was set up by random variation due to low numbers of events..

The median number of events across centres determined the statistical uncertainty for outcome indicators. We set the threshold for high statistical uncertainty at < 20 events.

Statistical analysis:
Frequencies and percentages described the baseline centre and patients' features. A random-effect logistic regression analysis was used to measure between-centre variation of process and outcome indicator scores. A random effect model (random effect for centre) was used to account for the fact that indicator scores in centres with a small number of patients can have highest values due to random variation. Also, only centres with > 20 admitted ICU patients were included. We used the extended International Mission for Prognosis and analysis of Clinical Trials in TBI (IMPACT) prognostic model to correct for case-mix: core, CT and lab (24), and injury severity score (ISS). We used $\tau 2$ (variance of random effects) to calculate MOR.

Case-mix- and uncertainty-adjusted process and outcome indicator scores per centre are represented in 'caterpillar' plots. p values for the importance of the between-centre variation were calculated with a likelihood ratio test comparing a model with and without a random effect for centre. A mixture distribution is needed to calculate the p value as the null hypothesis is on the boundary of the parameter space (25).

For the calculation of random effect models, missing data were imputed with multiple (N = 7) imputation with the MICE package from R. Statistical analyses were performed in R statistical software.

RESULTS:
A total of 24 (11 structure, 7 process, and 6 outcome indicators) of the 42 indicators of the

Delphi set could be recruited from the CENTER-TBI database.

Feasibility

Generally the feasibility of structure indicators was high (overall more than 88% available data). Feasibility was poor for one process indicator: 'mechanical DVT prophylaxis within 24 hours' (47% available data). Feasibility was high for outcome indicators, except for the SF-36 MCS and PCS scores (31% available data) recruited after 7 months (due to loss to follow-up). One process and one outcome indicator showed low feasibility.

Baseline data

Around 37% of patients admitted to ICU were older than 65 years and were mostly male. According to the baseline GCS score, 44% had severe, 19% moderate, and 48% mild TBI. The majority of patients suffered from polytrauma. Road traffic accidents or incidental falls were most related reasons of injury.

Discriminability

Between centres variation scores was lower for structure indicators for 'existence of a protocol', 'availability of a neurosurgeon 24/7 within 30 minutes after call', and '24/7 availability of a CT scan and radiologist review', due to high overall adherence values among centres. For process indicators, high variation was found for all indicators ($p < 0.001$). Overall, five structure (three with moderate performance), two process, and four outcome indicators showed low discriminability.

DISCUSSION:

We represented that it was easy to obtain most quality indicators from a recently proposed, consensus-based, quality indicator set for traumatic brain injury (TBI) at the ICU on the basis of sufficient data completeness. The suboptimal adherence scores in combination with between-centre variation propose a potential for quality improvement, basically for process and outcome indicators. However, statistical uncertainty was generally high for outcome indicators, making them less appropriate for quality improvement purposes and benchmarking particularly. Based on the evaluation of feasibility, discriminability, and statistical uncertainty, in this validation study, we instituted 11 structure indicators, 7 process indicators, but none of the outcome indicator out of 24 indicators to be suitable for quality measurement and improvement. Overall, the quality of ICU care can be upgraded for patients with TBI, and our analysis gives a useful case of how quality indicators for ICU care in TBI can be measured in a large database.

The very first time the quality indicator set to be developed and validated in adult patients with TBI admitted to the ICU. We have condensed quality indicators with the potential to be implemented for benchmarking and quality betterment. Firstly, in a given dataset, we endorsed lowering the initial set by sparing indicators with a low percentage available data (poor feasibility). The low feasibility on some process indicators might be descripted by the convolution and high resource needs of recruiting data on process indicators. However, feasibility could be better with automatic data withdrawal in the future. Secondly, quality indicators with high between-centre variation and moderate adherence rates (discriminability) can be used to improvise the quality of care and for benchmarking. Thirdly event rates of outcome indicators were certainly low (even over a study duration of 4 years), mentioning that outcome indicators have a poor potential for quality improvement in this study population due to high statistical uncertainty.

Over time, registration and use of the quality indicators could provide further insights into their role in quality improvement and benchmarking and allow their re-evaluation and refinement.

Previous studies have also reported that large between-centre variations in procedures of TBI care across Europe (26). This between-centre variation could be described by difference in adherence to guidelines. Although 87% of centres reported that they complied with the Brain Trauma Foundation (BTF) guidelines, actual evaluation of real-time practice may be different (27). Another previous study mentioned the activity of quality indicators in children with TBI. Although their indicators varied from those in the current study, they found a lower variation in adherence rates (between 59% and 76%) (28). For general ICU many registries exist—or trauma care (28). The outcome indicators we tested are also used in current ICU registries but did not perform well in our study. For example, in our study, the outcome score for decubitus ulcers approached 2%, while in Dutch hospitals, decubitus was found in around 6% of patients (29).

There are many strengths of the study. First, we measured the potential of consensus-based quality indicators in a large clinical dataset, while most previous researches only report a Delphi study to mention quality indicators and only a few pilot tested studies described quality indicators before implementation (30). Second, the CENTER-TBI database was used to derive the indicator scores, which contains a substantial quantity of patients with TBI across many ICUs.

Consequently, this analysis gives the first opportunity to study indicator performance and between-centre variation in TBI management on a larger scale. The only one exclusion criteria was named in CENTER-TBI database, so it shows a cohort generalizable to the TBI population.

There were some limitations of our study also. The organizational data were only partly gathered in CENTER-TBI. The questionnaires might be indefinite on which the structure indicators were based. Patients of all severities (including early deaths) were included for analyses. We described feasibility as the completeness of the data, while other aspects of feasibility, such as accessibility, timeliness, and missing data at a centre level, could not be addressed. Statistical uncertainty was shown in the numerous event rates, while also other aspects as intra- and inter rater reliability of medical coders are important but could not be addressed. However, assessment of such correlations with the outcome, in the larger data sets, could be included in the ongoing evaluation of quality indicators.

Moreover, the implementation of the quality indicators in a European registry will make it possible to assess TBI patient data over time and among countries in future. Our study also demonstrates some pitfalls, since some of these indicators are difficult and complicated to assess retrospectively. Such data collection could, however, be optimized by routine registration of timing of events and processes, automatic data recruitment, and clear definitions. Overall, the methods illustrated in this study can be used to optimize future data collection to calculate quality indicators and to identify areas in need of further research.

CONCLUSIONS:

A consensus-base quality indicator set in a large prospective TBI study (CENTER-TBI) was validated by this study. In severely ill patients with TBI, the quality of care appears compliant to the betterment in different areas as mentioned by sub-optimal adherence rates and between-centre difference for numerous quality indicators. Furthermore, our analysis generally shows good feasibility and discriminability but high statistical uncertainty for many outcome indicators. Future researches should centre the implementation and quality improvement efforts and continuous re assessment of the quality indicators.

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