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Assessment of patient-reported outcomes after polytrauma: protocol for a systematic review

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ABSTRACT

Introduction Survivors of polytrauma experience long-term and short-term burden that influences their lives. The patients' view of relevant short-term and long-term outcomes should be captured in instruments that measure quality of life and other patient-reported outcomes (PROs) after a polytrauma. The aim of this systematic review is to (1) collect instruments that assess PROs (quality of life, social participation and activities of daily living) during follow-up after polytrauma, (2) describe the instruments' application (eg, duration of period of follow-up) and (3) investigate other relevant PROs that are also assessed in the included studies (pain, depression, anxiety and cognitive function).

Methods and analysis The systematic review protocol is developed in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols statement. MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Cochrane Central Register of Controlled Trials and the trials registers ClinicalTrials.gov and WHO International Clinical Trials Registry Platform will be searched. Keywords, for example, 'polytrauma', 'multiple trauma', 'quality of life', 'activities of daily living' or 'pain' will be used. Publications published between January 2005 and the most recent date (currently: August 2016) will be included. In order to present the latest possible results, an update of the search is conducted before publication. The data extraction and a content analysis will be carried out systematically. A critical appraisal will be performed.

Ethics and dissemination Formal ethical approval is not required as primary data will not be collected. The results will be published in a peer-reviewed publication.

PROSPERO registration number CRD42017060825.

Strengths and limitations of this study

- ► To the best of our knowledge, there are no published systematic reviews providing an overview of assessed patient-reported outcomes after polytrauma, different instruments used to measure these as well as the application of these instruments.
- ► This systematic review will report the identified instruments used to assess quality of life, social participation and activities of daily living, and describe their application.
- ► We will show additional measures for further relevant patient-reported outcomes following polytrauma, for example, pain, depression, anxiety and cognitive function.
- ► A limitation of the review might be that publications will be included which were published since 2005. It cannot be ruled out in that case that relevant literature published before 2005 is missing.

INTRODUCTION

Severe injuries represent a leading cause of death and permanent disability.[1] Especially in the central European region, such severely injured patients are termed as 'polytrauma patients' or as being 'polytraumatised'. 'Polytrauma' is defined as having at least two severe injuries in different body regions that are potentially life threatening. In the Anglo-American literature, these patients are mostly referred to as 'multiple-injury', 'multiple-trauma' or 'severely injured'. All these descriptions have in common that a certain degree of injury is required. The severity of trauma is usually indicated by the Injury Severity Score (ISS).[2] In general, an ISS ≥16 falls within the definition of polytrauma, multiple-trauma or severely injured patients.[1 3] In the following, we use the term polytrauma. Comparing the incidence of trauma is challenging, considering the different definitions or conditions of trauma, and due to inconsistencies in the available data.[4] In 2015, according to the TraumaRegister DGU®, a German registry that cover patients with severe injuries, the number of severely multiply injured patients was 17 630 (ISS ≥16).[5] In 2012, the number of severely multiply injured patients (ISS ≥16) reached approximately 18 400 per year. This corresponds to a cumulative incidence of 0.02% per year for Germany.[6] Persons affected are mostly men (72%) with a mean age of 46.5 years.[7]

Due to strategies for early advanced life support, high quality in healthcare services, progress in treatment options and more traffic safety, survival rates after polytrauma are increasing. However, survivors are faced with long-term and short-term burden after polytrauma: 1 year after polytrauma, patients continue to suffer from persisting problems with mobility (34%), self-care (15%) and activities of daily living (ADL) (51%). Furthermore, they experience pain and/or discomfort (58%) as well as anxiety and/or depression (37%).[8] Relevant disabilities, such as respiration limitations, paraplegia or tetraplegia, are major causes for 40% of those affected not returning to their former workplace[6 9] and impact on socioeconomic and quality-of-life aspects.[9–11] For the necessary acute and rehabilitative care, the social economic impact is estimated to be €106 000 per patient. In Germany, additional costs of €935 000 accrue if patients do not return to their former workplace.[9]

Consequently, the aim to reduce short-term and long-term burden after polytrauma is critically important.[9 11] Thus, clinical parameters are necessary to support treatment processes and services in acute care facilities and to display short-term outcomes. Additionally, evaluations capturing a patient's view of short-term and long-term outcomes in terms of, for example, psychological and physical factors, functional status and social interaction, are becoming increasingly important for doctors and nurses as well as for patients and their family members.[11 12] The measurement of these patient-reported outcomes (PROs), which can also be reported, for example, by relatives in case of mental disability, is important for completing the assessment of relevant clinical outcomes after injury. To assess the impact of a polytrauma on quality of life (QoL) and other relevant PROs, it is necessary to question the patients.[12 13] The preferred gold standard is a measurement at multiple times during the follow-up period to track trends and focus on long-term conditions and outcomes associated with polytrauma.[13] Therefore, it is necessary to know which instruments for assessing PROs are applied and how. So far, no systematic review has been identified providing an overview of assessed PROs after polytrauma, different instruments used to measure these as well as the application of these instruments. Thus, this systematic review will provide an overview of instruments used to measure PROs, including QoL and other currently reported outcome measures for patients with polytrauma, and describe their application in detail.

Currently the TraumaRegister DGU® collects data on emergency care, treatment in shock rooms, intensive care unit and discharge.[3 12] Regarding the comprehensive evaluation of the short-term and long-term burden, the register plans to expand their measurement battery by assessing PROs, for example, QoL.

AIM OF THE STUDY

The aim of this systematic review is to:

1. collect instruments that assess PROs (QoL, social participation and ADL) during the follow-up after polytrauma;
2. describe the application of these instruments in detail (eg, duration of period of follow-up, frequency of application and time of measurements during follow-up);
3. investigate other relevant PROs that are additionally assessed in the included studies (eg, pain, depression, anxiety and cognitive function) without reporting the application of instruments in detail.

METHOD

The systematic review protocol is developed in line with the quality requirements of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement,[14] and the PRISMA statement will be considered during the review procedure.[15] The protocol was registered on 8 April 2017 at PROSPERO (registration number CRD42017060825). Prior to publication an update of the search will be performed to be able to present the latest results.

Databases

The literature search will be conducted in the following databases: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Cochrane Central Register of Controlled Trials and the trials registers ClinicalTrials.gov and WHO International Clinical Trials Registry Platform. To ensure literature saturation, reference lists of eligible studies will be examined for further relevant publications.

Search strategy

The search strategy will be developed in cooperation with a specialist for systematic reviews using database-specific-controlled vocabulary and additional free-text terms. Online supplementary appendix A provides the MEDLINE search strategy that will be adapted to the other databases accordingly.

Inclusion and exclusion criteria

Studies will be included if they match the following inclusion criteria: (1) the study assesses PROs, such as QoL/health-related QoL, social participation, ADL, pain, depression, anxiety or cognitive function in people aged 18–75 years during a temporally clearly defined follow-up period after polytrauma (injuries involving at least two different areas of the body or organ systems, ISS >15, Abbreviated Injury Scale (AIS) ≥3); (2) all kinds of original empirical research that were published between 1 January 2005 and currently 3 August 2016; (3) English or German language publications will be considered and (4) the full text of the study is available (ie, for contacting the authors). The interest in QoL in research and its implication in practice has been growing since 2005.[16] As one of our main aims is to collect instruments measuring QoL, we decided to include publications as of 2005. Our

procedure is supported by the burgeoning perspective in clinical research on PROs and its relevance for the future in addition to clinical data.[17] A further reason was to capture the most recent developments in research on PROs. Therefore, we looked specifically for publications from the last 11 years.

Studies will be excluded from this review if they mention one of the following criteria: (1) an ISS ≤15 or an AIS <3 or no reporting of ISS or AIS; (2) low-energy injuries, single or mono injuries or geriatric injuries, burn injuries, war injuries (group of veterans or military staff are excluded), cancer and other chronic diseases as secondary diagnosis; (3) publications in which the primary aim does not focus on PROs and (4) grey literature, books, letters/short reports, abstracts, editorials, comments or discussion papers as well as case studies, systematic reviews and meta-analysis. However, systematic reviews and meta-analysis will be screened to identify further appropriate studies.

Study selection process

On the basis of predefined inclusion and exclusion criteria, suitable publications will be selected by title and abstract, and independently screened by two reviewers. A third reviewer will solve differences concerning the inclusion or exclusion of studies. In order to foster the process of suitability decisions, inclusion and exclusion of the first 50 publications by title and abstract screening will be discussed between the two reviewers. Subsequently, two reviewers assessing eligibility for final inclusion in this review will screen the full texts of the remaining publications again independently. A third reviewer will solve conflicts in the final inclusion or exclusion of studies. Inter-rater reliability will be determined after the title abstract as well as after the full-text screening.

Data extraction and synthesis

The data extraction will be performed according to the requirements of Cochrane reviews.[18] For data extraction, two experienced researchers will use a piloted data extraction sheet independently. Extracted data from the included studies will provide an overview of: first author and publication year, study design, country, study population (number of subjects, proportion of men, mean age with SD and range, kind of injury, ISS, AIS and other characteristics), treatment, aim of the study, findings, and, furthermore, for the reported PROs according to aim 1, applied instruments to assess these PROs, description of the instrument, data collection (method of assessment, time of measurements, length of follow-up period, quality criteria of instruments (eg, validity and reliability) and modifications of the instruments. Furthermore, the result of the critical appraisal of the study quality will be added.

Critical appraisal

In the final selection of eligible studies, two reviewers will independently perform a quality appraisal to assess the methodological quality and the risk of bias in each study type using standardised checklists of the UK National Institute for Health and Care Excellence[19] or Scottish Intercollegiate Guidelines Network[20] or the Mixed Method Appraisal Tool.[21] Reviewers will resolve disagreements through discussion.

DISCUSSION

We will perform the proposed systematic review to generate an overview of the instruments used to assess PROs in the field of polytrauma. The results of this systematic review will serve as a basis to expand the TraumaRegister DGU® with a focus on QoL measures. Likewise, the additional knowledge on further PROs, for example, pain, depression, anxiety and cognitive function, might emphasise the patients' perspectives on relevant outcomes after polytrauma and lead to its consideration in the provision of health services. Subsequently, healthcare providers and policy-makers may draw their attention on this topic and will implement the assessment of PROs in decision-making regarding the treatment process.

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Contributors AI is the guarantor. IG, MR, SA, SK and AI drafted the manuscript. IG, MR, AH-F, M-IM, SA and SK developed the search strategy. AI, IG, MR, SA, SK, KM, AH-F, MI-M, SF, JS and JW contributed to the development of the selection criteria, the risk of bias assessment strategy and data extraction criteria. AI, IG, MR, SA, SK, KM, AH-F, MI-M, SF, JS and JW read, provided feedback and approved the final manuscript.

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