



Development of a German fracture register to assess current fracture care and improve treatment quality: a feasibility study

Marc Beirer
Chlodwig Kirchhoff
Peter Biberthaler

- Continuous evaluation of current treatment methods is crucial in orthopaedic trauma surgery.
- Existing fracture registries substantially contribute to improving fracture care and quality of life in trauma patients.
- Currently there is no universal German fracture register recording the patient-centred outcome of non-surgical as well as surgical fracture treatment in all anatomical regions.
- Conclusions regarding nationwide fracture treatment and quality of care are only significant to a limited extent.

Keywords: German fracture register; patient-centred; treatment quality; fracture; evidence

Cite this article: *EFORT Open Rev* 2017;2:474–477.
DOI: 10.1302/2058-5241.2.160086

Background

In the context of increasingly limited resources in health-care systems, safety and efficiency have to be proven for all medical treatment procedures. Whilst orthopaedic surgeons do agree on a gold standard regarding the treatment of some types of fractures, there is usually no universal consensus concerning the type of implant, and therefore regional fracture treatment is determined by the surgeon's preference.^{1,2} Double-blinded, randomised controlled trials (RCTs) are considered the gold standard for evaluating healthcare interventions.³ In the hierarchy of evidence, RCTs present the most reliable form of scientific trial influencing healthcare policy and clinical practice. This applies especially in the testing of newly-developed drugs compared with placebos.

In trauma surgery, however, the double-blinded, randomised comparison of non-surgical and surgical treatment

methods is clinically not feasible. Nevertheless, representative data are required for optimal treatment quality in different patient populations. Present follow-up trials contain highly homogeneous patient groups created by strict inclusion and exclusion criteria. However, these study results cannot be applied without limitations to the multimorbid patients who are treated in day-to-day clinical practice. In contrast, in medical registries, treatment results can be evaluated in an unselected patient group representing the real care situation.⁴ Therefore registry data should be viewed as complementary to RCTs to provide a powerful basis for the development of evidence-based treatment guidelines.^{5,6} Medical registries have gained more and more attention in the evaluation of the current healthcare situation, quality of treatment and future care requirements.⁴

The aim of this article is to give an overview of currently available fracture registries and to describe the proof-of-concept of the development of a German fracture register (GFR).

Current fracture registries

Swedish Fracture Register (SFR)

In 2011 the SFR was introduced at Sahlgrenska University Hospital in order to acquire an improved understanding of the epidemiology and treatment outcomes of fractures.⁷ A team of system developers, project managers and orthopaedic surgeons collaborated during the development process. Starting with fractures of the tibia and humerus in 2011, the long bones, shoulder, pelvis, foot, hand and spine were included step by step in the register. All Swedish people of at least 16 years of age with a fracture diagnosed by radiographs, computed tomography (CT) or magnetic resonance imaging (MRI) are included. Outcome assessment is performed by two patient-based outcome measurement tools: the Euroqol 5 dimensions

three-level and the Short Musculoskeletal Function Assessment, which are sent to the patient shortly after primary treatment and one year later to evaluate their recovery. Except for the questionnaires, the SFR is fully web-based. In December 2014, 26 hospitals participated in the SFR and more than 103 000 fractures were registered up to September 2015. The participating departments can obtain up-to-date statistics for their department and the register as a whole regarding a particular type of fracture, gender, age group or treatment during a specific time period. The SFR is approved by the Swedish Data Inspection Board, and according to Swedish law individual written consent is not needed for individual registration.

One of the major findings of the SFR concerns the association between the patho-anatomical fracture pattern and patient characteristics in fractures of the proximal humerus.⁸ In 2011 two-thirds of humeral fractures occurred as a result of simple or unspecific falls among people over 50 years of age. The authors conclude that osteoporosis and an increased propensity to fall constitute relevant risk factors for humeral fractures. Therefore, epidemiological data from fracture registries can contribute to improved future fracture prevention and treatment.

An excellent example of co-operation between existing registries is the collaboration between the Swedish Hip Arthroplasty Register and the Swedish National Hip Fracture Register. The 4467 patients with proximal femur fractures were retrospectively evaluated with a mailed patient-reported outcome questionnaire.⁹ The authors found a substantial response rate of 79% (n = 3513) and the results suggested that total hip arthroplasty as a treatment for femoral neck fractures is associated with less pain and greater satisfaction at short-term follow-up compared with both internal fixation and hemi-arthroplasty.

Norwegian Hip Fracture Register (NHFR)

The NHFR was initiated in October 2004 with the support of the Norwegian Orthopaedic Association. In January 2005 the register started a nationwide registration of hip fractures with the objective of collecting epidemiological data to assess the results of different treatment strategies and to identify inferior surgical approaches.¹⁰ At each of the participating 55 hospitals one surgeon is responsible for the data transfer to the register. The relevant information regarding patients, fracture pattern and treatment modality is entered into a form following surgical treatment. However, non-surgically-treated hip fractures are not included in the register. Recording of data is performed with the use of a patient-based questionnaire after 4, 12 and 36 months. The EuroQol is used and is a standardised non-disease-specific instrument that focuses on mobility, self-care, usual activities, pain/discomfort and anxiety/depression.¹¹ All participating departments receive an annual report including a survival analysis of

osteosynthesis and arthroplasties for hip fractures performed at the department.

Trochanteric and subtrochanteric fractures can be treated with either an intramedullary nail or an extramedullary sliding hip screw. Due to a lack of evident guidelines both implant types are in use, and the decision usually depends on the individual surgeon. However, Matre et al¹² reported a significantly lower re-operation rate, less pain and more satisfaction in patients treated using intramedullary nailing in comparison with extramedullary sliding hip screw after the analysis of 2716 patients. According to these findings fracture registries provide scientific evidence which lead to a rethinking and re-evaluation of day-to-day surgical practice.

Danish Fracture Database (DFDB)

The DFDB was established in 2011 to create a national register that covers all types of fractures.¹³ The objectives were to assess the outcome of surgical fracture treatment, to identify risk factors and to monitor the implants used. In March 2014, 13 Danish hospitals covering approximately 65% of the entire Danish population were participating in the DFDB. Recent developments and adjustments are discussed at an annual meeting. The relevant data are entered in an online database by the operating surgeon after the surgical procedure. Patient-related (gender, age and American Society of Anesthesiologists score), trauma-related (operated side, date and time of fluoroscopy, trauma mechanism, neuro-vascular status, pathological fracture) and surgery-related data (type of procedure, type of fracture, method of osteosynthesis/arthroplasty) are recorded. In the first year the surgical treatment of approximately 100 000 fractures were registered in the DFDB. The most common primary adult fractures were located at the proximal femur, the distal radius and the malleoli. The proximal femur, malleoli and tibial shaft were the most frequent anatomical regions requiring re-operation. Discomfort from orthopaedic implants, infection and failure of osteosynthesis were the most common indications for re-operation. Andersen et al¹⁴ found a significantly lower extent of supervision of surgical procedures performed by junior residents, senior residents and attendings outside regular working hours. However, the authors did not perform a correlation between unsupervised surgical procedures and the potential influence on the complication rate. Fracture registries may help to monitor fracture treatment quality with regards to the surgeon's experience and the extent of supervision.

Registries of the German Society for Orthopaedics and Trauma

In Germany several orthopaedic registries exist under the auspices of the Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (German Society for Orthopaedics and Trauma) to determine and to improve fracture care.¹⁵ The

pelvic register was established in 2004 and currently includes approximately 13 000 patients in Germany (31 hospitals), Belgium (four hospitals) and Sweden (one hospital). Data concerning fracture treatment,¹⁶ different implant types¹⁷ and the influence of assisted navigation¹⁸ as well as the clinical outcome¹⁹ are recorded. In 2012, the spine register of the Deutsche Wirbelsäulengesellschaft (German Society for Spine Surgery) arose from the European spine register 'Spine Tango' and contains non-surgical and surgical treatment methods for several spine diseases. In 2015 over 12 000 patients from 30 hospitals were included.¹⁵ The Trauma Register of the Deutsche Gesellschaft für Unfallchirurgie (German Trauma Society) was established in 1993 for registration of the medical care of severely injured patients with the objective of recording the trauma care situation and trends in treatment, as well as to develop evidence-based treatment guidelines. Over the last 20 years the register has compiled a large amount of data regarding injury pattern,²⁰ trauma mechanisms²¹ and medical care structures.²² A hand trauma register was established in July 2014 to record the severity and frequency of hand injuries with the aim of improving the safety and quality of clinical outcomes. In addition, in keeping with the ageing population a geriatric trauma register was initiated with a focus on fractures of the proximal femur including periprosthetic fractures, with the aim of decreasing mortality and improving mobility as well as rehabilitation and re-integration into the pre-trauma domestic setting. Regarding degenerative joint diseases the German endoprosthesis register (Endoprothesenregister Deutschland) started with inclusion of hip and knee arthroplasties. Implants are recorded by scanning the related barcode and between July 2013 and May 2015 310 hospitals participated and transmitted data on approximately 105 000 patients.¹⁵

There is currently no German fracture register that records the outcome of non-surgical as well as surgical treatment of fractures in all anatomical regions. Conclusions regarding nationwide fracture treatment and quality of care are therefore only significant to a limited extent.

Development of a German all-fracture-type register

In general the physician-based examination does not necessarily correlate with patient satisfaction.²³ Therefore, joint-specific patient-centred outcome questionnaires have been developed. Self-assessment scores allow for an easy and cost-effective evaluation of treatment outcome and patient satisfaction. Even immobile patients can be reached by the avoidance of long travel distances. The authors of this paper have developed and validated self-assessment questionnaires for the shoulder,²⁴ elbow,²⁵ wrist²⁶ and knee.²⁷ The single questions focus on physical symptoms,

activities of daily life, sports and recreational activities, physical function and joint-related quality of life. Typical joint-specific functional abilities are depicted as photographs to assess the range of movement as an essential parameter in outcome evaluation. In addition, the Munich Shoulder Questionnaire (MSQ) and the Munich Knee Questionnaire (MKQ) enable the calculation of valid and established patient-based outcome scores (MSQ: Shoulder Pain and Disability Index, Disabilities of the Arm, Shoulder and Hand, Constant Score; MKQ: Knee Injury and Osteoarthritis Outcome Score, International Knee Documentation Committee Score, Lysholm Knee Score, Western Ontario Meniscal Evaluation Tool Score, Tegner Score). All questionnaires show high validity, reliability and responsiveness in a heterogeneous patient group²⁴⁻²⁷ and allow for a broad application in clinical research without limitation to specific joint disorders or patient groups. Therefore, we decided to use these questionnaires for data acquisition in a German fracture register.

As a first step we identified and contacted all patients with specific tracer diagnosis (e.g. fractures of the proximal humerus, the clavicle and the scapula in the shoulder region) over the previous ten years who had been treated surgically as well as non-surgically in our level one trauma centre. All patients (n = 5771) were asked to participate in the registration process by mail and after obtaining written informed consent the responsible physician recorded the patient- (e.g. age, gender, comorbidities, profession, medication), trauma- (e.g. high/low energy, fall, traffic accident) and fracture-related information (e.g. open/closed, classification according to the Arbeitsgemeinschaft Osteosynthese) as well as the result of the completed patient-centred outcome questionnaire in the register.

In total, we received valid questionnaires from 2237 patients for all anatomical regions (shoulder, elbow, wrist, pelvis, hip, knee, ankle and foot). Of proximal humerus fractures 359 patients returned a correctly completed patient-centered outcome questionnaire (MSQ) after a mean follow-up of 54 months SD 36 months. According to the Neer classification²⁸ the mean MSQ was 82 points SD 14 in type II, 84 points SD 15 in type III and 69 points SD 23 in type IV fractures.

After obtaining these promising results our aim is to develop a prospective patient-centred fracture register for both surgical and non-surgical treatment. In the future all patients in Germany with a specific tracer diagnosis will be asked to complete the relevant joint-specific questionnaire after three, six and 12 months and thereafter once a year. All obtained data will be recorded in the patient-centred fracture register.

To summarise, our aim was to evaluate the feasibility of a patient-centred fracture register in Germany that covers fractures of all types, regardless of treatment. After the completion of this proof-of-concept study the register

data will be recorded prospectively. The obtained data should supply physicians and researchers with population-based data that add to the body of knowledge on the treatment of fractures. The register will be able to present both the results of fracture treatment and valuable epidemiologic data.

AUTHOR INFORMATION

Department of Trauma Surgery, Klinikum rechts der Isar, Technical University of Munich, Germany.

Correspondence should be sent to: Peter Biberthaler, Department of Trauma Surgery, Klinikum rechts der Isar, Technical University of Munich, Ismaningerstrasse 22, 81675 Munich, Germany.
Email: peter.biberthaler@mri.tum.de

ICMJE CONFLICT OF INTEREST STATEMENT

None declared.

FUNDING

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

LICENCE

© 2017 The author(s)

This article is distributed under the terms of the Creative Commons Attribution-Non Commercial 4.0 International (CC BY-NC 4.0) licence (<https://creativecommons.org/licenses/by-nc/4.0/>) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed.

REFERENCES

- Duan X, Zhong G, Cen S, Huang F, Xiang Z. Plating versus intramedullary pin or conservative treatment for midshaft fracture of clavicle: a meta-analysis of randomized controlled trials. *J Shoulder Elbow Surg* 2011;20:1008–1015.
- Gardner MJ, Streubel PN, McCormick JJ, et al. Surgeon practices regarding operative treatment of posterior malleolus fractures. *Foot Ankle Int* 2011;32:385–393.
- Lee SY, Teoh PJ, Camm CF, Agha RA. Compliance of randomized controlled trials in trauma surgery with the CONSORT statement. *J Trauma Acute Care Surg* 2013;75:562–572.
- Bestehorn K. Medical registries. *Med Klin (Munich)* 2005;100:722–728. (In German)
- Boyer P, Boutron I, Ravaud P. Scientific production and impact of national registers: the example of orthopaedic national registers. *Osteoarthritis Cartilage* 2011;19:858–863.
- Rawlins M. De testimonio: on the evidence for decisions about the use of therapeutic interventions. *Lancet* 2008;372:2152–2161.
- Wennergren D, Ekholm C, Sandelin A, Möller M. The Swedish fracture register: 103,000 fractures registered. *BMC Musculoskelet Disord* 2015;16:338.
- Bergdahl C, Ekholm C, Wennergren D, Nilsson F, Möller M. Epidemiology and patho-anatomical pattern of 2,011 humeral fractures: data from the Swedish Fracture Register. *BMC Musculoskelet Disord* 2016;17:159.
- Leonardsson O, Rolfson O, Hommel A, et al. Patient-reported outcome after displaced femoral neck fracture: a national survey of 4467 patients. *J Bone Joint Surg [Am]* 2013;95:1693–1699.
- Gjertsen JE, Engesaeter LB, Furnes O, et al. The Norwegian Hip Fracture Register: experiences after the first 2 years and 15,576 reported operations. *Acta Orthop* 2008;79:583–593.
- Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37:53–72.
- Matre K, Havelin LI, Gjertsen JE, et al. Sliding hip screw versus IM nail in reverse oblique trochanteric and subtrochanteric fractures. A study of 2716 patients in the Norwegian Hip Fracture Register. *Injury* 2013;44:735–742.
- Gromov K, Brix M, Kallemose T, Troelsen A. Early results and future challenges of the Danish Fracture Database. *Dan Med J* 2014;61:A4851.
- Andersen MJ, Gromov K, Brix M, Troelsen A, Danish Fracture Database collaborators. The Danish Fracture Database can monitor quality of fracture-related surgery, surgeons' experience level and extent of supervision. *Dan Med J* 2014;61:A4839.
- Kostuj T, Klady B, Hoffmann R. Registries of the German Society for Orthopaedics and Trauma: overview and perspectives of the DGU and DGOOC registries. *Unfallchirurg* 2016;119:463–468.
- Burkhardt M, Nienaber U, Holstein JH, et al. Trauma registry record linkage: methodological approach to benefit from complementary data using the example of the German Pelvic Injury Register and the TraumaRegister DGU(®). *BMC Med Res Methodol* 2013;13:30.
- Pizanis A, Pohlemann T, Burkhardt M, Aghayev E, Holstein JH. Emergency stabilization of the pelvic ring: clinical comparison between three different techniques. *Injury* 2013;44:1760–1764.
- Zwingmann J, Südkamp NP, König B, et al. Intra- and postoperative complications of navigated and conventional techniques in percutaneous iliosacral screw fixation after pelvic fractures: Results from the German Pelvic Trauma Registry. *Injury* 2013;44:1765–1772.
- Holstein JH, Pizanis A, Köhler D, Pohlemann T, Working Group Quality of Life After Pelvic Fractures. What are predictors for patients' quality of life after pelvic ring fractures? *Clin Orthop Relat Res* 2013;471:2841–2845.
- Stephan K, Huber S, Häberle S, et al. Spinal cord injury—incidence, prognosis, and outcome: an analysis of the TraumaRegister DGU. *Spine J* 2015;15:1994–2001.
- Weber CD, Horst K, Lefering R, et al. Major trauma in winter sports: an international trauma database analysis. *Eur J Trauma Emerg Surg* 2016;42:741–747.
- Zacher MT, Kanz KG, Hanschen M, et al. Association between volume of severely injured patients and mortality in German trauma hospitals. *Br J Surg* 2015;102:1213–1219.
- Capuano L, Poulain S, Hardy P, et al. No correlation between physicians administered elbow rating systems and patient's satisfaction. *J Sports Med Phys Fitness* 2011;51:255–259.
- Schmidutz F, Beirer M, Braunstein V, et al. The Munich Shoulder Questionnaire (MSQ): development and validation of an effective patient-reported tool for outcome measurement and patient safety in shoulder surgery. *Patient Saf Surg* 2012;6:9.
- Beirer M, Friese H, Lenich A, et al. The Elbow Self-Assessment Score (ESAS): development and validation of a new patient-reported outcome measurement tool for elbow disorders. *Knee Surg Sports Traumatol Arthrosc* 2017;25:2230–2236.
- Beirer M, Serly J, Vester H, et al. The Munich Wrist Questionnaire (MWQ) – development and validation of a new patient-reported outcome measurement tool for wrist disorders. *BMC Musculoskelet Disord* 2016;17:167.
- Beirer M, Fiedler N, Huber S, et al. The Munich Knee Questionnaire: Development and Validation of a New Patient-Reported Outcome Measurement Tool for Knee Disorders. *Arthroscopy* 2015;31:1522–1529.
- Neer CS 2nd. Displaced proximal humeral fractures. I. Classification and evaluation. *J Bone Joint Surg [Am]* 1970;52:1077–1089.