

Analysis of the Completeness of Reoperation Registration in
the Swedish Fracture Register at Sahlgrenska University
Hospital during 2011

Master thesis in Medicine

Ada Kapetanovic

Supervisor: Michael Möller

Institute of Clinical Sciences, Department of Orthopaedics



UNIVERSITY OF GOTHENBURG

Programme in Medicine
Gothenburg, Sweden 2015

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Abstract

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Ada Kapetanovic, 2015

Supervisor: Michael Möller, MD, PhD

Institute of Clinical Sciences, Department of Orthopaedics, The Sahlgrenska Academy at University of Gothenburg

Gothenburg, Sweden

Keywords: *orthopaedics, registry, fracture, reoperation*

Background: The difficulty of carrying out randomized controlled studies in the area of trauma orthopaedics has resulted in a limited level of evidence rate in the field. The Swedish Fracture Register (SFR) was founded with the goal of acquiring knowledge about the epidemiology and treatment of fractures in Sweden. In order to be able to draw proper conclusions from our data, we need to ensure its validity. The validity of registered data can be assessed in two steps; by analyzing the completeness of data, and by analyzing the validity of the included variables.

The reoperation rate is one of the outcome measurements in the SFR. Failure to report revision procedures has emerged as a common problem in registers evaluating surgical treatment. The Danish Fracture Database reported a completeness of 77% regarding reoperations during their first year.

It is difficult for the registries to retrospectively control if correct registration of reoperations has been carried out. With this in mind, this validation study was performed.

Objective: To evaluate the completeness of reoperation registration in the Swedish Fracture Register at the Department of Orthopaedics, Sahlgrenska University Hospital in Gothenburg and Mölndal, Sweden.

Methods: All patients treated for a fracture of the humerus and tibia at the Sahlgrenska University Hospital (SU) in 2011 were included. Base data was collected from the SFR for all the registered variables such as fracture classification, date of injury, code of primary treatment (according to ICD-10) and date and code for secondary treatment. This register data was compared to information in the medical charts and the coding/information in the surgery planning systems.

Results: In total, 896 fractures of the humerus and tibia were treated at SU during the given time frame. 122 reoperations were performed. 57 of these were registered in the SFR. This results in a completeness of 47%. The majority of the missed registrations regarded removal of osteosynthesis material (36%, n=55).

Conclusion: As expected, a considerable number of reoperations that were not registered in the SFR were identified. Consistent with the findings of the Danish Fracture Database, removal of osteosynthesis material is the most common procedure not to be registered.

Implications: Regular validation studies are important to ensure high data quality. A high completeness regarding revision surgery is essential for the usefulness of the register data for

research and quality control. Prospectively, more validation studies need to be performed to ensure high validity of all used variables.

Background

Fractures are a common cause of disability in all age groups. The incidence rate of fractures in the adult population of Sweden can be approximated to 192 fractures per 10,000 person-years (1). The total economic burden due to fractures is unknown and difficult to calculate, but the costs of osteoporosis-related fractures is estimated to make up 3% of total health care costs in Sweden. (2) Several studies have reported an increasing fracture incidence. This has been attributed to increased life expectancy and the corresponding increase in the prevalence of osteoporosis (1, 3). Due to Sweden's aging population, the fracture burden is likely to increase even more. It has been estimated that the costs due to osteoporosis will have risen by 56% by the year 2050. (2) Therefore, it is important to determine which methods of treatment are the most effective, both from a medical and from a health economical perspective.

Randomized controlled studies are difficult to carry out in the field of trauma orthopaedics, thus there are few of this kind. There are several reasons for this - it is difficult to obtain informed consent in the acute setting, patients are due to age or other reasons unable to participate in long term follow up, and both the choice of treatment and the intervention itself needs to be performed quickly. Accordingly, only 11% of published articles in orthopaedic journals carry the highest level of evidence. (4)

Consequently, as data about fracture treatment is limited, the choice of intervention is largely based on experience and local tradition. There is a large variation in the method of treatment among different centers, even for the common fractures that orthopaedic surgeons see on a regular basis. Ankle fractures, which are one of the most common fractures in adults of all

ages (5), provide an illustrative example of this statement. A Cochrane review from 2012 has concluded that there is not enough evidence to establish if conservative or surgical treatment results in better outcomes from a long-term perspective (6). American figures report a wide span in the proportion of surgically treated ankle fractures, ranging between 14 to 72%. (7) The same conclusion is drawn in a Cochrane review about proximal humerus fractures, another common type of fracture. (8)

One way of studying outcomes from the different approaches applied in orthopaedic surgery is through patient registries. Both national and regional arthroplasty registers are widespread throughout the world. All residents of Sweden are assigned their own personal identification number. This system makes way for a unique opportunity of creating national quality registers. National registers for knee and hip arthroplasty in Sweden were established in the late nineteen-seventies and have made significant contributions to the development in the field. There are now several corresponding registers across the world. The use of registries as an evaluation tool is not nearly as widespread in trauma orthopaedics. Specific registers covering hip fractures exist in Sweden, Norway and United Kingdom among many others. A nationwide register of surgically treated fractures has recently been established in Denmark. (9) However, to our knowledge there are no national registers covering all fractures regardless of treatment.

With the aim of acquiring knowledge about the epidemiology and treatment of fractures in Sweden, The Swedish Fracture Register (Svenska Frakturregistret, SFR) was founded. It includes all fractures, irrespective of anatomic localisation or treatment of choice. It was first implemented in 2011 at Sahlgrenska University Hospital in Göteborg and Mölndal. The first year only fractures of the humerus and tibia were registered, but gradually the register spread

to include more fractures and hospitals. At the time of writing, SFR covers approximately half of the clinics that are treating fractures in Sweden. The SFR measures outcome in two dimensions – revision surgery and patient reported outcome measures. (10) Prospectively, the data of SFR will serve as a foundation that enables further evaluation of our methods and their effectiveness.

The patient reported outcome measures are collected through two questionnaires. The EQ-5D monitors general health related quality of life, taking five aspects into account; mobility, self-care, usual activities, pain/discomfort and anxiety/depression (11). Short Musculoskeletal Functional Assessment (SMFA) , reviews the patients' level of disability and discomfort due to the particular injury. (12) The questionnaires are sent out twice; shortly after injury and one year later. The first time, patients are asked to assess their health status prior to injury. Both questionnaires are previously tested on a Swedish population (13, 12).

There are many advantages with research based on register data. With pre-existing data, no time- and resource-consuming data collection is necessary. The sample size is large, which enables study of less common diagnoses and procedures. The data collection and the analyses are performed separately, which diminishes the risk of bias. (15) However, absence of data can influence the results and, consequently, lead to inaccurate conclusions. (16)

The number of reoperations performed is an indication of the efficiency of a given surgical intervention. A reoperation is defined as a procedure that was not part of the original treatment plan and could not be foreseen at the start of treatment. Planned procedures such as extraction of external fixation and subsequent internal fixation of a fracture or secondary suture after fasciotomy are thus classified as planned follow-up procedures.

Not only do reoperations increase the risk of general adverse events associated with surgery, such as venous thromboembolism, infection and mortality (14) but also lead to poorer functional outcome, longer convalescence and increased expenditures.

In order to be able to draw proper conclusions from our data, we need to ensure its validity. The validity of registered data can be assessed in two steps; by analyzing the completeness of data, and by analyzing the validity of the included variables. The completeness of is defined as the proportion of the true number of occurred cases or procedures that have actually been included in the given register. (15)

Failure to report revision procedures has emerged as a common problem in registers evaluating surgical treatment. The Danish Fracture Database has reported 77% completeness of reoperations, The Swedish Total Hip Arthroplasty Register 78%, and the Swedish Knee Arthroplasty Register 80%. The corresponding numbers for primary operations are 88%, 98% and 97%, respectively. (17-19).

It is likely that we have the same weakness in the SFR, and the purpose of this validation study was to determine whether this was the case.

Material and methods

All fractures of the humerus and tibia that occurred between January 1 and December 31, 2011 and were registered in the SFR at the Sahlgrenska University Hospital (SU) in Gothenburg and Mölndal (n=896) were included. The fractures were identified in the SFR using the International Classification of Diseases, Tenth Revision (ICD-10) diagnostic codes S.42.1-S42.4 (humerus) and S82.1-S82.8 (tibia). As the SFR is linked to the population

database of The Swedish Tax Agency, *Skatteverket*, only individuals holding a Swedish personal identity number, *personnummer*, can be registered. Hence, visitors and temporary residents are not included. As the purpose of the SFR is to review fracture treatment in Sweden, Swedish residents treated for such fractures abroad were excluded. Approval from the Regional Ethical Review Board in Gothenburg and from the head of the Department of Orthopaedics at Sahlgrenska University Hospital was received before start.

Data from SFR was obtained regarding the following variables: fracture classification according to ICD-10, date of injury, cause of injury (ICD-10 code), date of primary treatment, method of primary treatment (ICD-10 code), method of secondary treatment (if applicable) and indication for secondary treatment.

In the SFR secondary treatment can be classified as: planned follow-up procedures, surgery after that non-surgical treatment is abandoned at an early stage or reoperation/operation in a late stage. Late stage is here defined as at least two weeks after primary non-surgical treatment. These types of surgical treatments are in the SFR equalized with a reoperation, as they denote an unsuccessful non-surgical treatment. The indication for reoperation is described with one out of seven options; non-union, malunion, infection, changed treatment plan, change of diagnosis, wrongly placed implant and “other reasons”.

The medical charts of the included patients were scrutinized with regard to the variables above, with the purpose of identifying reoperations that were not registered in the SFR. In addition, the information entered in the hospital's surgery planning system was reviewed. Here, information about time of treatment and ICD-codes can be found. All surgical

procedures defined as reoperations using the criteria above were put down and subsequently used to analyze the completeness of reoperation registration.

The statistical analysis was made using Microsoft Excel 2013 (Microsoft Corporation, Redmond, WA, United States).

Ethical considerations

This study is based on analysis of previously collected information from the SFR and medical charts. Informed consent is obtained from the registered individuals prior to inclusion in the SFR, and withdrawal of consent can be carried out at any time. We judge that the scientific value of our study counteracts the very small risk of violation of the integrity the included individuals. The research objects do not benefit directly from taking part in the study. However, the knowledge that the study might generate is considered large since it can provide information that leads to new and deepened knowledge about fracture treatment. This can lead to improved care for patients with fractures and a more effective use of our resources. We do not believe that any ethical problems might arise as a result of this study. As previously stated, the study was approved by The Regional Ethical Review Board.

Results

In total, 896 fractures were registered in the SFR at SU during 2011. 657 (73%) were fractures of the humerus and 239 (27%) of the tibia. 324 of the total number of fractures were treated surgically as the primary treatment option, and 40 fractures were treated surgically after non-surgical treatment had been abandoned at an early stage. 57 reoperations or reoperations in a late stage were registered. After studying the medical charts and the administrative system, an additional 65 reoperations or reoperations in a late stage were identified. This results in a total number of 122 reoperations, and thus a completeness of

47%. The majority (56%, n=70) of secondary surgeries were performed due to “other reasons”, followed by nonunion (19%, n=24) and infection (12%, n=15). The most common reoperation not to be registered was removal of osteosynthesis material (n=36), constituting 55% of the missed registrations. The majority of missed registrations, 55% (n=36), constituted removal of osteosynthesis material due to “other reasons”. Removal of osteosynthesis material was also the most common reoperation to be performed (n=63). The indication for these procedures was stated as “other reasons” in 78% of cases (n=49). The average time from primary procedure to reoperation was 286 days (standard deviation 271, median 197).

Humerus fractures

Out of 657 humerus fractures, the majority (72%, n=470) affected female patients. Humerus fractures occurred at a similar age in both female and male patients (mean age 67 years and 62 years respectively). As shown in Table 1, similar proportions of female and male patients underwent reoperations, and comparable proportions of reoperations were registered in both sexes. The most common reoperation not to be registered was removal of osteosynthesis material (n=14), constituting 52% of the missed registrations. The number of reoperations where osteosynthesis material was removed but not registered was higher in females (56% versus 44% in males).

Table 1. Humerus fractures

	All patients	Female	Male
Number of fractures	657	470 (71,5%)	180 (28,5%)
Average age at the time of injury, mean and (median), years	67,0 (68,0)	67,0 (68,0)	62,3 (64,0)
Number of reoperated patients	50 (7,61%)	33 (7,02%)	17 (9,09%)
Number of reoperations performed	59	37	22
Number of reoperations registered	32 (54,2%)	19 (51,4%)	13 (59,1%)
Number of reoperations not registered	27 (45,8%)	18 (48,7%)	9 (40,8%)

Number of reoperations where osteosynthesis material was removed and registered	14	9	5
Number of reoperations where osteosynthesis material was removed but not registered	14 (51,9%)	10 (55,6%)	4 (44,4%)

Tibia fractures

Among patients with tibia fractures, 125 (52%) occurred in females and 114 (48%) in males. The mean age at injury was 55 years for female patients and 50 years for male. As shown in Table 2, the proportion of reoperated patients were slightly higher in males; 25% compared to 17% in females. The proportion of registered reoperations was lower in females; 28% compared to 47% in males. The most common reoperation not to be registered was removal of osteosynthesis material (n=22), constituting 58% of the missed registrations. The number of reoperations where osteosynthesis material was removed but not registered was higher in females (67% versus 50% in males).

Table 2. Tibia fractures

	All patients	Female	Male
Number of fractures	239	125 (52,3%)	114 (47,7%)
Average age at the time of injury, mean and (median), years	54,7 (55,0%)	54,8 (55,0%)	50,0 (51,0)
Number of reoperated patients	49 (20,5%)	21 (16,8%)	28 (24,6%)
Number of reoperations performed	63	25	38
Number of reoperations registered	25 (39,7%)	7 (28,0%)	18 (47,4%)
Number of reoperations not registered	38 (60,3%)	18 (72,0%)	20 (52,6%)
Number of reoperations where osteosynthesis material was removed and registered	13	4	9
Number of reoperations where osteosynthesis material was removed but not registered	22 (57,9%)	12 (66,7%)	10 (50,0%)

Discussion

As expected, we found a considerable number of reoperations that were not registered in the SFR. It is difficult to detect missing registrations, and it appears difficult to remember that the reoperations should be included. In this study, we present lower figures than the Danish Fracture Database (DFDB). (9) However, only surgically treated fractures are included in the

DFDB. This might increase awareness of the fact that secondary procedures are to be included as well. Furthermore, the DFDB included all types of fractures in their validation study, irrespective of anatomical localisation. Therefore, the figures are not fully comparable.

Although our results provide an indication about how well registration is carried out, they are not necessarily generalizable to the rest of the participating clinics. Since SFR was first started at SU, both the commitment to registration and the awareness of its importance might be higher than in other hospitals. On the contrary, using early data might influence the results negatively as registering has not yet become a habitual task. To ensure the longest follow up time possible, the data used in this study was collected during the register's first year in use. At the time of writing, four years have passed. It is likely that registering fractures is now done routinely and that completeness has improved. Even so, it is important to continuously perform validation studies. A high completeness and validity is essential for the ability of using the data of SFR for quality control and research purposes. Additionally, validation studies provide a means for quality control of the register itself and its user friendliness. Common errors in registration indicate that improvements need to be performed in terms of instructions or register design.

There are few studies regarding the reoperation rate after fracture surgery. The papers published on the subject typically focus on readmitted patients. Consequently, reoperations that do not require readmission, such as removal of osteosynthesis material, are not included. (20, 21) Furthermore, many studies are confined to subtypes of fractures treated with specific methods, such as locking plate fixation (22, 23) or shoulder arthroplasty (23) for complex fractures of the proximal humerus. Therefore, the incidence of reoperations from this study is difficult to

compare with other available data. English figures report a reoperation rate of 1.9% after primary procedures for orthopaedic trauma. The corresponding number for ankle fractures was 8.9% (24).

Consistent with our findings, the Danish Fracture Database found removal of osteosynthesis material to be the most common reoperation, constituting 34% of all performed secondary surgeries during the study period. The indication was in these cases pain and discomfort, a variable not used in SFR. This may have affected the results since our figures include removal of osteosynthesis material regardless of indication. Infection was the second most common indication for reoperation in the DFDB (14%), with “failure of osteosynthesis” close behind (13%).

Removal of osteosynthesis material was both the most common revision procedure to be performed, and the most common procedure not to be registered. These procedures are often performed on an outpatient basis and are considered routine procedures. It appears easier to remember to register procedures performed under extraordinary circumstances. This indicates that it is important to continually strive for registering to become a natural part of clinical practice, just like primary fracture registration has become at the emergency department.

Although the aim of this study was not to investigate the epidemiology of humerus and tibia fractures, we noticed that there were some differences in regard to age and sex. It is well known that most humerus fractures occur proximally in older women with osteoporosis (1, 5). This explains why 72% of all humerus fractures in our material occurred in women with a mean age of 67 years. Another finding is that the number of reoperations that were registered was somewhat lower in females, both in the humerus and the tibia group. One can speculate

about the reasons behind this difference. Since the number of events in this study was limited, it is impossible to draw any conclusions from our figures.

In conclusion, regular validation studies are important to ensure high data quality. A high completeness regarding revision surgery is essential for the usefulness of the register data for research and quality control. Prospectively, more validation studies need to be performed to ensure high validity of all used variables. Further studies are also needed to investigate the possible difference in reoperation registration between sexes.

Populärvetenskaplig sammanfattning på svenska

Benbrott, *frakturer*, är en vanlig orsak till funktionshinder i alla åldrar. Den totala kostnaden för samhället är okänd och svår att beräkna, men kostnaderna för benbrott hos enbart bensköra personer har uppskattats till 3 % av de totala hälso- och sjukvårdskostnaderna i Sverige. Benskörhet, osteoporos, är vanligare med högre ålder. Eftersom befolkningen blir allt äldre kommer även andelen bensköra att öka. Man har uppskattat att kostnaderna för osteoporos kommer att öka med 56 % fram till 2050.

Det finns förhållandevis få vetenskapliga studier om hur man bäst behandlar frakturer, och behandlingen är framför allt baserad på erfarenhet. Kartläggningar har visat att det finns stora skillnader i hur samma fraktur behandlas på olika sjukhus, både inom landet och i världen.

För att öka vår kunskap om frakturbehandling i Sverige startades 2011 Svenska Frakturregistret, SFR, 2011. I detta registreras patienter som har fått en fraktur. Information samlas om frakturens egenskaper, orsaken till denna och hur den behandlats. Målet är att i framtiden inkludera alla frakturer i landet. På detta sätt får vi en stor mängd data som sedan

kan användas till att utvärdera frakturbehandling i Sverige. Patientregister har länge används inom olika medicinska områden, exempelvis cancer och ledproteskirurgi, men SFR är det första registret i världen där alla frakturer registreras oavsett på vilken plats i skelettet de skett.

En reoperation innebär att man på grund av missnöje med resultatet efter en första operation behövt operera ytterligare en gång. Antalet utförda reoperationer är därför ett mått på hur effektiv en viss operationsmetod är.

För att kunna utvärdera hur bra våra behandlingsmetoder är, är det viktigt att data i SFR är så kompletta som möjligt, dvs. att alla frakturer och behandlingar som sker faktiskt registreras. Om data är inkompleta finns en risk att felaktiga slutsatser dras. Därför genomfördes denna studie, där vi gick igenom hur många av alla de reoperationer som utförts som finns med i vårt register. Det visade sig att enbart 48 % av alla genomförda reoperationer registreras i SFR. För att kunna utnyttja SFR på bästa sätt måste mer arbete måste läggas ned på att motivera klinikerna till registrering.

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