Early results and future challenges of the Danish Fracture Database

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ABSTRACT

INTRODUCTION: The Danish Fracture Database (DFDB) was established in 2011 to establish nationwide prospective quality assessment of all fracture-related surgery. In this paper, we describe the DFDB’s setup, present preliminary data from the first annual report and discuss its future potential.

MATERIAL AND METHODS: The DFDB collaboration includes 13 hospitals and covers a population of 3.7 million. Data registration is performed online by the surgeon following surgery, and it includes patient-, trauma- and surgery-related data. Primary procedures, reoperations and planned secondary procedures are registered. Indication for reoperation is also recorded. The reoperation rate and the one-year mortality are the primary indicators of quality.

RESULTS: Approximately 10,000 fracture-related surgical procedures were registered in the database at the time of presentation of the first annual DFDB report (currently 15,000). 85% of all procedures were performed on adult fractures and 15% on paediatric fractures. Proximal femur (33%), distal radius (15%) and malleolar fractures (12%) were the three most common primary adult fractures. Pain and discomfort from orthopaedic hardware, infection and failure of osteosynthesis were the three most common indications for reoperation and accounted for 34%, 14% and 13%, respectively.

CONCLUSION: The DFDB is an online database for registration of fracture-related surgery that allows for basic quality assessment of surgical fracture treatment and large-scale observational research by registering primary surgery, reoperations and planned secondary procedures.

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The current annual fracture incidence in Denmark is unknown; however, studies from England suggest an annual fracture incidence of up to 3.6% [1]. Extrapolated to the Danish population, this incidence would result in approximately 200,000 fractures. Over 30% of all patients with fractures require admission to the hospital [2], which making fractures an important public health concern. In the United States, the annual economic burden associated with caring for osteoporosis-related fractures alone is estimated at $17 billion [3]. Despite this, very few data exist on fracture epidemiology and fracture-related surgery in particular.

Most of the current knowledge and recommendations on surgical treatment of fractures stem from retrospective cohort studies and prospective randomised controlled trials (RCT); and while these scientific sources of data are extremely valuable, observational research, such as registry data, should be viewed as complementary to RCTs as data from such research plays an essential role in providing the basis for evidence-based treatment in all medical fields [4, 5]. Orthopaedic surgeons worldwide do agree on a gold standard for surgical treatment for some types of fractures. Many controversies therefore remain which produces regional variations in surgical fracture treatment, and because of the lack of consensus on what is the optimal approach [6, 7], the surgeon’s preference often determines which approach is chosen.

To accommodate the need for basic quality assessment of treatment and large-scale observational research, several hip fracture registries have emerged in recent years [8]. However, to our knowledge, only few national registries exist that cover other types of fracture-related surgery.

The Danish Fracture Database (DFDB) was established in 2011 to establish nationwide prospective quality assessment of all fracture-related surgery. Our goal was to create a registry allowing us to evaluate the outcome of surgical fracture treatment, to identify potential risk factors for reoperation and, finally, to provide a foundation for implant monitoring, all on a nationwide scale.

In this paper, we describe the DFDB’s setup, present preliminary data from its first annual report and discuss its future potential.

MATERIAL AND METHODS

Development and regulation

The DFDB was developed in 2011 as a quality-monitoring tool for fracture-related surgery. The first pilot phase was a three-month period counting the participation of the Department of Orthopaedic Surgery, Hvidovre Hospital, Denmark, and the Department of Orthopaedic Surgery, Odense University Hospital, Denmark [9]. After having been piloted, the database was fully introduced at the two departments. Participation in the DFDB collaboration was voluntary, and several other hospitals...
RESULTS

General demographics
Approximately 10,000 fracture-surgery-related surgical procedures were performed in the database at the time of presentation of the first annual DFDB report. A total of 85% of all procedures were performed on adult fractures and 15% on paediatric fractures. The reoperation burden (percentage of reoperations from all registered procedures) was higher for adult fractures (10%) than for paediatric fractures (5%). Removal of orthopaedic hardware due to pain or discomfort accounted for 3% of all registered procedures.

The anatomical distribution of primary surgery on adult fractures is presented in Figure 1. Proximal femur (33%), distal radius (15%) and malleolar fractures (12%) were the three most common primary fractures and accounted for over half of all adult primary surgeries. The forearm (58%), the humerus (23%) and the lower leg (8%) were the three most common paediatric fracture sites.

Reoperations
The four most common anatomical locations for reoperations were the proximal femur (30%), the distal radius (6%), the tibial shaft (6%) and the malleoli (12%). The recorded indications for reoperation of the proximal femur, the tibial shaft and the malleoli fractures are summarised in Figure 2. Pain and discomfort from orthopaedic hardware, infection and failure of orthopaedic implants were the most common indications for reoperation and accounted for 34%, 14% and 13%, respectively.

Surgical delay
We defined surgical delay as the time from radiological diagnosis to the initiation of surgery. Surgical delay for adult and paediatric fractures is presented in Figure 3. Close to 50% of adult fractures and 70% of paediatric fractures were operated within 24, 48, 72 etc. hours after radiological diagnosis. Similarly, 75% of the malleolar fractures and 57% of the distal radius fractures were operated within 48 hours.

Complete and data quality
We have performed and published a validated and completeness analysis of the data [9] shortly after the implementation of the database, and we found a 83% completeness for all types of data entry, with 88% completeness for primary fracture surgery and 77% for reoperation, respectively. Patient- and trauma-related data were 82-100% valid, while surgery-related data were valid in 89-99% of the cases.

Trial registration: not relevant.

FIGURE 1
Anatomical distribution of primary fracture surgeries in adults. Percentages in each anatomical region are presented. Total n = 7,578.

FIGURE 2
Distribution of indications for reoperation for the three most commonly reoperated surgical sites: proximal femur, tibial shaft and malleoli—presented as percentages of all reoperations at the specific surgical site.

FIGURE 3
Surgical delay for adult fractures (A) and paediatric fractures (B), presented as number of procedures performed within 24, 48, 72 etc. hours after radiological diagnosis.
Finally, we present Kaplan-Meier survival plots for the most common adult primary fracture surgeries showing survival until first reoperation. We recorded 94.5%, 96.5% and 93.8% one-year survival rates for malleolar, proximal femur and distal radius fractures, respectively.

It is important to stress that these findings are preliminary, and definite conclusions should follow the completion of the entire database. We performed and published a validation study showing 88% completeness for primary surgeries and 77% completeness for reoperations [9] for the two first-referrer departments, and continuous monitoring of the completeness of the data for the entire database is therefore warranted. Such monitoring will be implemented in the future based on surgical codes from the Danish National Patient Registry (DNPR). Currently, the short follow-up for the registered primary procedures as well as reoperations is most likely underestimated. The reason why we have chosen to present them, well aware of this error, is that we want to demonstrate the potential for analysis and presentation of the data in the DFDB.

We believe that the DFDB has two major strengths. First, the online method of data collection allows customization of output, which makes it possible to investigate very specific events and populations, for example when examining the level of supervision depending on the time of surgery [14]. Second, the DFDB allows for collection of data on a large scale, which allows evaluation of very rare events such as pathological or open fractures – something that is difficult to do in prospective randomized trials [15].

Studies based on registry data play a crucial role in providing guidance for evidential medical therapy, supplementing the knowledge we gather from RCTs and other high-level evidence trials. Anthroplasty registries are often used as examples of observational research that have greatly contributed to advances in orthopaedic surgery; their importance has been underlined by the existence of substantially lower anthropology revision rates in countries with such registries compared with countries without these registries [14]. The same trend in registry-based research is seen in other medical fields around the world [17]. Unfortunately, at present observational, registry-based data are lacking in the field of fracture-related surgery.

To our knowledge, The DFDB is one of the few registries that cover all types of fracture-related surgery. We believe that it will provide us with valuable epidemiological knowledge on fracture-related surgery and also help in identifying potential risk factors for reoperations. In recent years, there has been considerable focus on the need for increased regulation when introducing new medical implants as well as for implant monitoring – in particular the recall of the ASR prosthesis [18] as well as the Poly Implant Prothese (PIP) [19]. This year, changes were made in EU regulatory provisions. These changes introduced stricter rules on implant approval; however, continued monitoring of such monitoring of orthopaedic implants is currently not possible.

We believe that the DFDB could provide a solution meeting the requirements for such monitoring as it allows for prospective scanning of orthopaedic implants used for fracture-related surgery and linking of these to the patient and the specific procedure.

CONCLUSION
In this paper, we presented the setup for systematic registration of fracture-related surgery through the DFDB. We presented preliminary one-year data, including patient demographics, anatomical distribution of primary procedures as well as reoperations and surgical delay for various types of procedures. Finally, we demonstrated the potential for survival analysis for various types of fracture-related surgical procedures with first reoperation as end point.

DISCUSSION
In this paper, we present the setup and preliminary data from the DFDB. Currently, 13 hospitals participate in the DFDB collaboration, covering a population of 3.7 million, which constitutes nearly 65% of the entire Danish population.

Not surprisingly, we found proximal femoral and distal radial fractures to be the largest groups of primary surgeries as well as reoperations in adults, whereas forearm fractures were the most commonly registered fractures in children [1].

Pain and discomfort due to hardware was generally the most common indication for reoperation, followed by infection and failure of osteosynthesis. When investigating surgical delay, we found that 72% of all adult fractures were operated within 48 hours, which is consistent with previous findings [2, 11].

We believe that this could be an important factor, particularly for the outcome following specific types of fractures [12, 13].

performed 20% of the primary procedures and 37% of the reoperations. When investigating the level of supervision, we found that 23% of the surgeries performed by residents were unsupervised.

Survival until first reoperation
We performed Kaplan-Meier survival analysis for primary procedures as well as reoperations. When investigating the level of supervision, we found that 72% of all adult fractures were operated within 48 hours. We believe that this could be an important factor, particularly for the outcome following specific types of fractures [12, 13].