Data-driven improvement of hip fracture care

Würdemann, F.S.

GENERAL DISCUSSION

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This thesis aims to identify determinants for the quality of hip fracture care and to improve the measurement of the quality of care provided, using data from the first five years of the Dutch Hip Fracture Audit (DHFA). Evidence, practice, and the measurement thereof are inevitably connected: it is a vicious cycle in which gained evidence is put into practice, then practice is measured, leading to new evidence on how and where to improve the quality of care.

THE POWER OF REGISTRY DATA IN PROVIDING TRUSTWORTHY AND GENERALIZABLE EVIDENCE

In the introduction of this thesis, the 'end-result theory' of dr. Ernest Amory Codman dating from around 1910, was explained: follow up on the treatment of patients to evaluate whether a treatment was successful, and if not, analyzing the process and using gained insights as a starting point for improvement of care in future patients. [1, 2] This can be seen as the first conceptualization of Evidence-based medicine related to the quality of care. However, it was not until a century later, in the early 1990s, that the term 'Evidence-based medicine' was first mentioned by Guyatt et al. [3] They proposed to evaluate and acquire a better empirical basis for the practice of medicine by introducing Evidence-based medicine.

Evidence-based medicine acknowledges a role for all empirical evidence Codman suggested. However, it is characterized by a grading structure for classifying evidence. In this structure, (randomized) trials are rated the highest level of evidence, followed by observational studies. [4] Where the consideration of trials as the highest level of evidence in pharmaceutical research can be defended, the generalization of this hierarchy in evidence to other medical fields must be questioned. This applies especially to emergency surgery fields like trauma surgery; there is often no time for an inclusion and randomization process in acute trauma surgical research. [5] Provided that observational studies are well executed, their quality of evidence can be considered equal to randomized controlled trials. [5, 6] Besides, observational studies frequently have several benefits compared to trials, which will be discussed in the following paragraphs. The main limitation of observational studies would be a bias, primarily due to confounding. However, confounding can be largely corrected for by using adequate statistical techniques. And when residual confounding is likely, the bias can be acknowledged when interpreting results. [7] Hence unsurprisingly, the interest in observational studies,

especially those based on orthopedic registries, has increased. This increase is illustrated by the fact that the observational literature in the field of arthroplasties has an average yearly growth rate of 28%. [8]

The study presented in Chapter 3 exemplifies several benefits that observational studies may have over randomized controlled trials. This study searched for an answer to the question about 'the unsolved' fracture: why the failure rate of femoral neck fractures remains high despite renewed techniques. [9–11] Taking reoperation as an outcome parameter, the postoperative clinical consequences of rotational torque in a sliding hip screw was determined. The most obvious way to determine if the failure in left and right-sided hip screws is clinically relevant, and caused by the rotation side of the torque of the screw, would have been to start a clinical trial with different-sided torqued screws. One arm of the study would get a right-sided torqued screw inserted, the other arm a left-sided torqued screw, and the outcome measure would be reoperation. However, such formats for trials are costly, time-consuming, and, especially in acute orthopedic trauma surgery, prone to ethical dilemmas. [8, 12, 13] Also, most trials do not represent heterogeneous real-world patient populations. [7,8] Although earlier studies showed biomechanical differences in left- and right-sided hip fractures, this was still a theoretical explanation for treatment failure in femoral neck fractures. [16, 17] Therefore, it would not justify to start a trial considering the abovementioned disadvantages. Analyzing a biomechanical principle using registry data might not seem logical because the databases (the DHFA and the FAITH trial database) did not include any scans or x-rays. However, when a specific theory is assumed to apply to a clinical effect or outcome registered in a database, it is possible to use registry data to determine whether it is worth further investigation without having to deal with the drawbacks of clinical trials. In this case, the theory was that the biomechanical properties of the clockwise torqued screw are related to implant failure. The results of our observational study in Chapter 3 showed no statistically significant difference in implant failure rate in left- versus right-sided sliding hip screws. Thereby the available observational data enabled us to disprove the aforementioned biomechanical theory.

Since registry datasets usually provide large numbers of observations, they allow for complex analyses, even on low-incidence problems. The study in Chapter 2 showed an analysis of the hospital volume-outcome relationship, with volume as a continuous parameter. An extensive review of separate studies covering over 2 million patients on the effect of annual hospital volume on outcomes was published earlier. [18] However, it was limited in determining the association between hospital volume and outcomes, likely due to the variety in volume cut-off used in all studies included in the meta-analysis. [18] The large number of patients from a vast number of hospitals registered in the DHFA in the past few years enabled us to treat hospital volume as a continuous parameter in our analysis. Thereby the limitations of using volume thresholds and directing the centralization debate were overcome. We found no clinically relevant effect of hospital volume on turnaround times and mortality. Small annual

hospital volumes or volumes larger than 367 led to a decreased provision of orthogeriatric co-treatment. The literal power of large datasets is also shown in Chapter 3. Although the incidence of implant failure is clinically relevant, the exact numbers are small, and therefore multivariate analysis of associated factors is often hindered. The large amount of DHFA data (although supplemented with another dataset as the DHFA was still in the implementation phase at that time) allowed us to answer the research question of this study on a relatively low-incidence problem.

Hence, observational studies can contribute substantially to the available evidence and find determinants for quality of care. They may even be preferred over randomized trials, especially in acute trauma surgery, like for hip fracture patients. The studies in Chapters 1-3 together exemplify how registry-based studies can contribute to the evidence on which hip fracture surgeons would like to base their practice.

PRACTICING EVIDENCE-BASED MEDICINE AND THE USE OF CLINICAL AUDITS

Clinical auditing is a tool to obtain practice-based evidence, as shown in the former paragraphs, but simultaneously may promote the practice of evidence-based medicine. In the Netherlands, two different types of surgically trained specialists treat patients with hip fractures, which is quite a unique situation. In Chapter 4, only a few clinically relevant differences in patient characteristics and hospital processes were found between all surgeon groups. This indicates that different types of surgeons treat similar hip fracture patient populations. Consequently, the assumption could be made that the outcomes of care for hip fracture patients should be comparable for all surgeon types. However, they make different treatment choices. We have found that guideline adherence of trauma- and non-trauma-certified orthopedic and general surgeons regarding implant choice differed significantly. The finding of variation in guideline adherence regardless of the surgeon's background is not new, nor is it unique, but can be assumed to be of considerable importance. [19, 20] Firstly, high guideline adherence assures better outcomes. [21, 22] And secondly, diminishing practice variation is a key aspect of improving the quality of care through clinical auditing. Wouters et al. stated: 'Evaluation of differences in guideline adherence between hospitals can reveal the reasons behind the differences in outcome and identify best practices with better outcomes.'[23]

However, there must be a reason why not all surgeons practice the same evidence-based medicine. In Chapter 4, guideline adherence was used as a proxy for better outcomes. Before reducing practice variation, it would be desirable to assure the clinical applicability of the current Dutch guidelines by analyzing outcomes such as implant-related complications, reoperations, and functional outcomes. Especially as there seems to be a knowledge gap in what the best implant choice might be, there are options that seem equally preferable. [20, 24] The guideline adherence in the treatment of trochanteric AO-A1 fractures was low overall,

which we have explained to be an effect of the guideline not being one hundred percent conclusive on the best choice of implant. The analysis of outcomes of chosen implant types can be derived from registry data; in this the Norwegian hip fracture audit sets an example that the DHFA should follow [25–27] thereby linking registry-based evidence and practice.

When there is agreement on the guideline, the next step would be to strive to reduce practice variation. I believe there is a task for the professional bodies to reduce practice variation in implant choice in hip fracture surgery between surgeons. The DHFA should facilitate this task as professional bodies of both trauma and orthopedic surgeons are represented in the clinical audit board of the DHFA: the Nederlandse Vereniging voor Traumachirurgie (NVT) and the Nederlandse Orthopaedische Vereniging (NOV). The DHFA should introduce quality indicators on guideline adherence regarding implant choice to stimulate surgeons to reflect on their practice.

MEASUREMENT OF PRACTICE THROUGH CLINICAL AUDITING: THE MATURATION OF THE DHFA

Clinical auditing has been shown to improve the quality of care in numerous health care domains. [28–30] However, this effect does not occur directly after the start of a registry. As explained in the general introduction of this thesis, the maturity of a clinical audit has implications for the quality indicators that can be measured and the research that can be performed using the registry's data. Chapters 5, 6, and 7 are about the maturation of the DHFA. Between 2019 and 2022, the DHFA almost entirely developed from a phase 2 registry into a phase 3 registry (Figure 1 in the General Introduction).

In 2020 linkage between the Dutch Vektis data institute, which collects data from health insurance reimbursements, and DHFA datasets led to the availability of dates of death for 95% of the patients registered within the DHFA. This linkage allowed new analyses to find associations between structure or process indicators and mortality, a solid outcome parameter. The need for case-mix correction arose, and in Chapter 5, a case-mix model was developed, enabling a fair comparison of mortality rates between hospitals. Thus far, this quality indicator was only used for internal feedback to participating hospitals to compare themselves with the national benchmark, and the hospitals' results were not corrected for case-mix. However, now that we have a case-mix correction model, mortality can be used as a comparative outcome measure for benchmarking to identify outlier hospitals in the Netherlands.

Phase 3 of the maturation model of the DICA entails the development of new quality indicators. Chapter 6 describes the analysis of potential new variables and found that Serum Haemoglobin at admittance, polypharmacy and screening questions for delirium have a statistically significant association with outcomes currently measured within the DHFA. Adding

these variables to the registry dataset would allow even better case-mix correction of outcome parameters in the DHFA such as mortality. It may also serve to find new leads for improvement of care and thereby develop new structure- and process quality indicators.

Comparing the maturation of hip fracture registries, it seems the DHFA develops equally well as other nationwide hip fracture registries. Apart from case completeness and data quality, little is written about the maturation of hip fracture audits. Especially little is written about the implementation of (new) quality indicators and the trend in scores on existing quality indicators over time, troubling international comparison of the maturation of the DHFA. However, some insights can be deduced from inspiring annual reports of hip fracture registries and several comparative reviews. [31–33]

THE LIMITATIONS OF WHAT WE CAN DO WITH THE DHFA - THE NEED FOR OUTCOME INFORMATION

All studies presented in Part I of this thesis share one limitation: the data was not validated, and data availability, especially on outcomes, was limited. In Chapter 2, we were only able to analyze the effect of hospital volume on the outcome parameter mortality; the quality of data of other outcome measures was insufficient. In Chapter 3, guideline adherence was chosen as a proxy for outcomes, while analyzing complications, reoperations, or functional outcomes would have been more desirable. In Chapter 4, we analyzed reoperations as an outcome parameter. However, at that time, the dataset was not as large as it is now. The analysis of reoperations in Chapter 4 was only possible by collaborating with the FAITH trial researchers, and analyses were performed on a combined dataset. In Chapter 7, recent data quality is presented, showing a deficit, primarily in the completeness of functional outcomes. This paucity (but also between-hospital variation) in data quality has large consequences: not only for research purposes but also for fair comparisons of hospital performance as it leads to bias in outcome measurement and benchmarking.

For this reason, we cannot say the DHFA has completely passed phase 2 of the registry maturity model. To answer more substantive questions on hip fracture care and expand the use of available data for benchmarking to increase the audit's value, the DHFA needs *more outcome data of better quality, while at the same time paying attention to lowering the burden of registration.* Several projects have already been initiated within the DHFA to realize these aims in the coming years.

FUTURE PERSPECTIVES

Improving the effort-benefit balance of registration

In order to lower the burden of registration, a project was initiated by the DHFA. In this project an expert panel with members of all scientific societies involved in hip fracture care (orthopaedic and general (trauma) surgery, geriatrics, internal medicine and nursing home medicine) defined the nationwide clinical pathway of hip fracture patients. This clinical pathway consists of information that is supposed to be recorded in a structured and day-by-day manner: from admittance to discharge and eventually follow-up, focusing on 'reusing' readily available parameters from the systems. The DHFA variables are also included in this clinical pathway. Implementation of this so-called 'Electronic Patient File Pathway for Hip Fracture Patients' is to follow and will lead to an easy, timely, uniform, and accurate registration. An automated upload of the DHFA data out of the electronic patient file into the DHFA is the ultimate goal, hopefully being achieved in the coming years.

Besides lowering the burden of registration, we could also increase the benefits of complete registration to regain more balance in effort versus benefits, for example, by enabling hospital-specific data fields to be built into the registry to encourage local research, which Rikshöft already carried out. [34] I believe the clinician's personal incentive is key to improving registration, and the option to perform local research with the entered data would likely increase this incentive to register.

Other parties with an incentive to register, or accommodate registration, could be found in commercial parties such as implant producers. For example, by providing financial means and in return, receiving information on the complications of their implants. Logically, competing financial interests should be strictly regulated and prevented. Another registry, the Dutch Breast Implant Registry (DBIR), also accommodated by the Dutch Institute for Clinical Auditing (DICA), recently set up an implant catalog to use alongside their clinical registration. Publications on its effect are still to be expected. In hip fracture surgery, implants are also used. Thus, more detailed registration of implant types, models, or serial numbers, could be beneficial to identify implants that cause complications. Possibilities for collaboration with the Dutch Orthopedic Implant Registry (LROI), which already registers details of arthroplasties, or with implant suppliers, could be explored.

Improving data on outcomes

Data validation is necessary to improve data quality of outcome parameters such as complications and functional outcomes. Only when valid outcomes are available their relation with processes can be analyzed, and outlier hospitals can be identified and stimulated to improve their care. The DICA initiated a data validation project. The first results were

promising: the accuracy of entered clinical data is high; however, the completeness still needs to be tested. This data-verification project is only possible by linking datasets, and this is where the DHFA could gain ground. This beholds especially for complications (mainly implant-related) and other outcomes such as residency at three months after fracture. Linkage with healthcare reimbursements or other trustworthy data sources would be the leading solution to improve and supplement the outcome data in the DHFA dataset without increasing the burden of registration. Linkage with trustworthy datasets may even diminish the need for registration of specific parameters when these are readily available.

Prevention is better than cure

The comparative analysis of parameters registered in other hip fracture registries made in Chapter 6 showed that most other registries have a more pronounced focus on risk assessment than the DHFA. In the 5-years analysis in Chapter 7, we identified two cornerstones in need of attention: ortho-geriatric co-treatment and adequate screening and treatment of osteoporosis. Both can be seen as - or result in - risk diminishing measures. The new variables identified in Chapter 6 on risk screening for delirium can also help identify those patients in need of delirium preventive measures and are therefore risk assessment parameters. Another addition following the new Dutch osteoporosis guidelines (still to be published) could be risk screening for falling. A combined 'risk assessment' quality indicator could probably be developed, and secondarily indicators on whether 'preventive measures' are taken.

Towards patient-centered care (at lower costs)

The best treatment and outcome, however, are patient-dependent. There is a need for insights into what matters most to the patient. For this reason, a feasibility study on Patient-Reported Outcome Measures (PROMS) is initiated by the Dutch Society of Clinical Geriatricians (NVKG). The aim is to determine whether measurement of PROMS in this aged patient population is feasible. The fact that other registries are using PROMS does suggest so. [35] Tailoring the treatment to the patient is a current topic; the recently published FRAIL hip study shed light on the outcomes of nonoperative management of proximal femoral fractures in institutionalized frail older patients with a limited life expectancy. This study found that for these patients, using shared decision making, non-operative management is a viable option. [36] I suspect future guidelines might also advise to refrain from surgical treatment in specific patient categories. Shared decision-making on whether to operate could also be included as a process quality indicator in the DHFA.

Eventually, once the DHFA data and health care reimbursements data are linked, the DHFA will mature into phase 4 of the maturity model of the DICA. In that case, one could work towards value-based healthcare: striving to maximize health outcomes for the patient while lowering health care costs.

Maximizing the effective use of the available data

I believe there are three possibilities to further optimize the use of a clinical audit registry for improving the quality of care provided: Proof, peers, and motivation. The first, proof, can be assured by the DHFA; by providing valid data, statistical outliers can be identified based on valid quality indicators. Second, peers can be found on different levels: local, regional or international. We could use the data of the collaborative trauma regions in the Netherlands for regional benchmarking. An example is the new dashboard of the DICA, allowing hospitals to compare their results on a regional basis, which is now implemented in two trauma regions in the Netherlands. But also, national 'mirror-sessions' in which best performing hospitals share their practices may be initiated. Hip fracture registries also could collaborate more across borders than they do now, to promote international benchmarking and to share insights. Especially the younger registries could learn from more mature registries. And lastly: Motivation. Motivation needs to come from the caregivers and institutions and requires an open attitude. Hopefully, the insights in evidence, the measurements, and the practice discussed in this thesis will motivate to utilize the DHFA and thereby improve the quality of hip fracture care provided in the Netherlands.

CONCLUSION

The key question that started off the studies gathered in this thesis was: did the DHFA data *give rise to* improvements in hip fracture care?

From this thesis, I would like to conclude it did. In Part I, the marginal effects of hospital volume and implant side on hip fracture care and outcomes are described. Furthermore, the different choices made by surgeons with different backgrounds indicate there is practice variation, thus a potential for improvement. These studies add to the available evidence for practicing evidence-based medicine.

From Part II, a second conclusion on improvements made can be drawn: that of the DHFA itself. The DHFA is rapidly maturating and has achieved case completeness similar to other national hip fracture registries. In just over five years, between 2016 and 2022, over 60,000 patients from 68 hospitals were registered in the DHFA, indicating an almost full nationwide coverage and thus successful implementation. Meanwhile, data completeness has improved, enabling the identification of outlier hospitals on (case-mix corrected) valid quality indicators.

Future improvements in the short run include optimization of the effort-benefit balance of the registry by improving data quality on outcomes and lowering the burden of registration. In the long run, the primary focus of the DHFA may shift towards patient-centered and value-based hip fracture care. Meanwhile, the DHFA could maximize the effective use of data: the proof the DHFA delivers can be discussed by surgeons and their peers. With adequate motivation, the quality of care for hip fracture patients can thus be further improved.

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