The incidence of implant fractures after total hip arthroplasty

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Abstract

Purpose Implant fractures after total hip arthroplasty (THA) are considered as rare in clinical practice. Nevertheless they are relevant complications for patients, physicians, and the public health system leading to high socioeconomic burdens. The aim of this study was to assess the incidence of fractures after THAs in a comparative analysis of clinical studies and worldwide arthroplasty register datasets.

Methods We calculated the pooled incidence of revision operations after fractures of THAs in a comparison of clinical studies published in Medline-listed journals and annual reports of worldwide arthroplasty registers in a structured literature analysis based on a standardised methodology.

Results Included clinical studies (sample-based datasets) were mono-centre trials comprising a cumulative number of approximately 70,000 primary implantations whereas worldwide national arthroplasty register datasets referred to 733,000 primary implantations, i.e. approximately ten times as many as sample-based datasets. In general, sample-based datasets presented higher revision rates than register datasets with a maximum deviation of a 14.5 ratio for ceramic heads, respectively. The incidence of implant fractures in total hip arthroplasty in pooled worldwide arthroplasty register datasets is 304 fractures per 100,000 implants. In other words, one out of 323 patients has to undergo revision surgery due to an implant fracture after THA in their lifetime.

Conclusions Implant fractures in total hip arthroplasty occur in a relevant number of patients. The authors believe that

comprehensive arthroplasty register datasets allow more general evaluations and conclusions on that topic in contrast to clinical studies.

Keywords Total hip arthroplasty · Fracture · Incidence · Register dataset

Introduction

Implant fractures after total hip arthroplasty (THA) are relevant complications for patients, physicians, and the public health system leading to high socioeconomic burdens [1]. They are very distressing for the patients and are leading to technically demanding revision operations [2]. Patients often do not accept these complications as being predestined, which may involve subsequent claims for damages. The event of an implant fracture is generally an unacceptable complication and not reconcilable with satisfactory outcome [3]. Even if implant fractures are commonly considered as rare events, it is worth undertaking every reasonable effort in order to avoid them.

A project funded by the EU Commission [4] included analysis of the development of indicators for medical devices, outcome measurements, market monitoring, and failure management, as well as a comparative analysis of the quality of the relevant register data and clinical studies published. The presented meta-analysis was therefore primarily based on both clinical studies and data from national arthroplasty registers.

As a rule, clinical studies use samples to derive conclusions on the total population (sample-based datasets). However, in case of rare events such as implant fractures there is a particular danger of underpowered studies or case reports being published, which only provide a restricted view of the actual situation.

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As opposed to this, national arthroplasty registers record all operations performed in a country and therefore allow for better representation of the incidence of such events [5–12]. These datasets are thus suitable for the use as reference datasets in assessing a meta-analysis of clinical studies under the aspect of a potential influence by special factors. Therefore, in order to elaborate more differentiated and accurate results, it is essential to describe both register data and information from clinical studies as these two methods of reporting have different strengths and weaknesses [13]. A multitude of publications, for example, in Scandinavia, the region where these quality control systems were developed, have repeatedly underlined the positive impact of national arthroplasty registers and the possibility of complete data collection so that the value of these registers has meanwhile been recognised worldwide [6, 8, 11, 14–19].

However, valid data on implant fractures after THA, as the solid basis for target-oriented efforts, has not been pooled in the scientific literature to date.

In order to address the topic of implant fractures after total hip arthroplasty (THA) it is the objective of this study to conduct a comparative analysis of their pooled incidence using clinical studies, multicentre analysis, and worldwide arthroplasty register data.

Material and methods

A structured literature research was performed searching PubMed for relevant keywords leading to a search algorithm “(implant fracture OR fracture) AND (hip arthroplasty OR hip replacement AND incidence AND study)”. This step was followed by a further manual literature research. The inclusion criteria for consideration in the ensuing detailed analysis were the following: (1) unequivocal description of an implant fracture after primary implantation, (2) revision rate data of the study cohort either presented in the text or unambiguously calculable from the data contained, and (3) English-language publication in Medline-listed, peer-reviewed journals. We excluded biomechanical studies and case reports from this analysis. The trial flow of study identification is illustrated in Fig. 1.

Twenty-three clinical studies (sample-based datasets) could finally be included in this analysis [20–43]. Reference data from national arthroplasty registers were taken from the latest annual reports available for those countries providing workable data. These were Sweden, Finland, New Zealand, Australia, Denmark, England & Wales, and Canada [44–50]. The reports of Australia, New Zealand, and Great Britain contain information on the actual broken components while the remaining registers publish cumulative data.

All datasets were pooled in a standardised way for all data sources. For every parameter, except follow-up times, precise

values were required for inclusion in the study. If no specific follow-up times but follow-up periods were given, a linear distribution of cases was assumed.

The main evaluation criterion was the indicator ‘*Revision Rate*’, a variation of which, ‘*Revisions per 100 observed component years*’, was used for comparative assessment. It was applied in accordance with the Australian National Arthroplasty Register’s definition [46].

The methodology is a variation of a well-established procedure in epidemiology used in a previous publication from 1959 among British physicians to demonstrate the effect of smoking on lung cancer and cardiovascular diseases [51]. By definition there is a risk for revision after arthroplasty from the moment of primary implantation. Individual follow-up periods are collected and compared with observed incidents (i.e. revisions). This allows for direct comparison of different studies and data sources including adjustment for number of cases and follow-up period. A value of one revision per 100 observed component years corresponds to a revision rate of 5 % at five years or a 10 % revision rate at ten years in conventional follow-up studies. To facilitate comparison, the fracture rates per 100,000 implants are indicated in addition even though this calculation disregards the time period up to the occurrence of the incident.

To determine statistical significance, 95 % confidence intervals were calculated according to the Wilson score method without continuity correction. For statistical analyses, SPSS software, version 13.0 for Windows (SPSS, Chicago, IL), was used.

Results

Clinical studies and multicentre analyses

The papers from clinical literature were published from 1975 to 2008, with a considerable portion dealing with fractures of ceramic-on-ceramic bearings since 2000 [26, 29, 39, 41]. Mono-centric clinical studies show a cumulative number of 72,387 cases followed up. In this cohort a total of 230 fractures occurred: 191 fractures among 73,743 cups and 40 fractures among 16,187 head implants.

The only multicentre analysis, a survey performed by the AAHKS (American Association of Hip and Knee Surgeons [52]), comprises 64,483 implantations with 355 documented fractures.

In a comparative analysis the individual studies show great variation as regards the incidence of implant fractures. Stem fracture rates range from 0.2 [31] to 25.71 [25] revisions per 100 observed component years, thus covering a 128.5-fold difference. The results for cups vary between 1.12 revisions per 100 observed component years [39] and not a single one

Fig. 1 Trial flow of study identification

within a study collective of 5,873 cases after a follow-up period of ten years.

For femoral heads the results are in a range from 0.15 [36, 40] up to 2.17 [43] revisions per 100 observed component years and hence encompass a 14.47-fold difference.

Cumulative evaluation of all clinical studies yields an average fracture rate of all arthroplasty components of 0.43 % (CI 0.40–0.47) with reference to the patient's lifetime.

Register datasets

In contrast, the arthroplasty register publications included in this analysis [44–50] involve a cumulative number of 733,036 follow-up cases and 2,227 implant fractures. Thus, the dataset of arthroplasty registers covers about ten times as many primary operations as all clinical studies put together.

The average values of worldwide national arthroplasty registers presenting relevant numbers of cases that were used as a benchmark are characterised by several specifics. The British NJR [49] is a relatively young register. The data presented were collected over the course of one year, but neither do they specify when the primary operation was performed nor whether the respective case has been recorded in the register, which would both be basic requirements for comparative calculations adjusted for survival rates. A similar restriction applies to the register data from Canada.

In the other register datasets components of the cup (i.e. liner and shell) and of the stem, in case of modular systems, are presented as cumulative figures. To allow fair comparison the same procedure was applied to clinical studies.

In a general comparison, New Zealand [45] shows a relatively low implant fracture rate as measured by the total

Table 1 Revisions due to implant fractures in datasets of National Arthroplasty Registers

Register	Data source	Data collection	Follow-up (years)	N Primary THA	N Revisions	N Implant fractures	% Implant fractures at all revisions	% Implant fractures of all primary THA	Failure rate per 100,000 observed component years	Factor difference to mean
Swedish Hip Arthroplasty Register	Annual Report 2006	1979–2006	27	296,015	25,984	407	1.57	0.14	10	0.38
New Zealand Orthopaedic Ass. - National Joint Registry	Eight-year Report	1999–2006	7	42,092	1,034	8	0.77	0.02	5	0.20
Australian Orthopaedic Association - National Joint Registry	Annual Report 2007	1999–2006	7	160,349	23,261	700	3.00	0.44	12.5	4.66
Finnish Arthroplasty Register	The 2006 Implant Yearbook on Orthopaedic Endoprostheses	1997–2006	10	65,062	13,113	262	2.00	0.40	8.1	3.01
Danish Hip Arthroplasty Register	Annual Report 2006	1995–2005	11	75,304	10,381	512	4.93	0.68	12.4	4.62
National Joint Registry for England and Wales	4th Annual Report	2006	1	55,052	5,296	201	3.80	0.37		
Canadian Joint Replacement Registry (CJRR)	Annual Report 2007	2003–2006	4	39,162	3,464	137	4.00	0.35		
Total/average			7.57	733,036	82,533	2,227	2.70	0.30	27	

number of revisions, which, among other things, might be explained by specific documentation standards.

The results of individual countries differ considerably as regards the incidence of implant fractures and the failure rate per 100,000 observed component years, with Sweden [44] showing the smallest proportion of implant fractures. However, even in this country, 1.57 % of all revision operations are performed due to implant fracture.

In Denmark this rate reaches a value of nearly 5 %. These values are further illustrated in Tables 1 and 2.

Comparative analysis

The cumulated comparative implant fractures and their frequencies in studies, multicentre analysis and register datasets are shown in Tables 3, 4 and 5. The average revision rates published in clinical studies exceed the comparative values from registers 3.3-fold and the results of the AAHKS survey 1.8-fold.

Since the average follow-up times are longer in the clinical studies and registers (about 7.5 years) than in the AAHKS survey [52] (five years), fracture incidences appear to be lowest in a calculation adjusted to the follow-up period of the AAHKS survey. They fall 2.3-fold below the comparable value from registers whereas the adjusted values of clinical studies exceed this benchmark 1.5-fold. If the data from different data sources are analysed with respect to individual components, a comparison of the results reveals notable differences. In clinical studies stems exhibit the highest risk of fracture whereas cups are affected least. In registers, by contrast, it is the cup that is affected most frequently while heads fail the least often.

When these differences are quantified and set in relation to the benchmark of register results, the ratio of differences extend up to a factor of 14.5 in the case of ceramic heads.

Table 2 Revision risk after total hip arthroplasty: adjusted average values from National Arthroplasty Registers in Sweden, Finland, Denmark, Great Britain, Australia, New Zealand, and Canada

Reason for revision	Reason for revision in %	Frequency after primary THA in %	Absolute frequency of risk after primary THA in 1/x patients
Aseptic loosening	55,24	7,94	13
Dislocation	11,79	1,69	59
Septic loosening	7,45	1,07	93
Periprosthetic fracture	6,07	0,87	115
Wear	4,18	0,78	128
Pain without other reason	3,74	0,52	193
Implant fractures	2,48	0,31	323

Table 3 Cumulated fracture rate in different datasets

Dataset	N Observed implants	N Documented fractures	Fracture rate per 100,000 implants	Failure rate per 100,000 observed component years	CI
Registers	733,036	2,227	304	38.50	38.41–38.58
AAHKS survey	64,483	355	550	16.71	16.66–16.76
Clinical studies	34,436	353	1,025	60.02	59.97–60.07

Except for the cup implant, the fracture rates are generally overestimated in clinical studies. Even if the results of the structured AAHKS survey [52] as a multicentric data collection do not deviate as strongly as monocentric studies, the deviations are considerable yet, with the range extending up to 11-fold.

Discussion

It was the objective of this study to conduct a comparative analysis of the pooled incidence of fractures of total hip arthroplasty (THA) using clinical studies, multicentre analysis, and worldwide arthroplasty register data.

We found that the incidence of implant fractures after total hip arthroplasty in pooled worldwide arthroplasty register datasets is 304 fractures per 100,000 implants. Furthermore, one out of 323 patients has to undergo revision surgery due to an implant fracture after THA in their lifetime.

Calculations based on worldwide register reports concerning reasons for revisions in relation to the patient's lifetime show that, despite all achievements of modern joint arthroplasty, a considerable proportion of patients must still reckon with revision surgery [4, 53–56]. In detail, one out of 13 patients has to be revised due to aseptic implant loosening after THA implantation and one out of 93 patients in consequence of a septic complication.

The more in-depth analysis of this investigation revealed that one patient out of 323 is affected by an implant fracture during his lifetime and must therefore undergo revision surgery. The authors believe that this overview indicates that in spite of all the advances in the field of arthroplasty, it makes

sense to undertake activities to increase quality and avoid complications.

These results may not be in line with subjective estimates. However, it is extremely difficult for individuals to keep track of these long periods of time and the multitude of patients and it seems that the problem of implant fractures is often underestimated in subjective awareness [1, 2].

Clinical studies absolutely serve an important purpose in terms of indicators for potential product failure of individual implants [20–43]. However, they are of very limited value when it comes to global statements since they do not allow for valid conclusions about the relevance of observations [5].

Surveys such as the one conducted by the AAHKS [52] show lower deviations from worldwide register data than clinical studies but nevertheless exhibit relevant differences up to 11-fold.

Even the manufacturers' post-marketing surveillance appears to be unable to ensure a comprehensive overview of the actual fracture rates [4]. In fact, even in the case of unambiguous situations such as ceramic head fractures, one of the world's leading manufacturers publishes incidences, but the actual rate is supposed to be three times higher [41]. However, not all arthroplasty registers report which part of the prosthesis has fractured and therefore for other components such data are not present at all in the literature yet.

According to worldwide register data the fracture rate for ceramic heads is five times higher than reported to the manufacturer. It should be questioned whether uncertainties of 300 or 500 % represent a suitable basis for decision-making. Further uncertainties with respect to data compliance are unfortunately not well reported in all worldwide registers. Only the Swedish register [44] exactly describes not only

Table 4 Fracture rate by components and different datasets reported as the percentage of implant fractures in relation to the patient's lifetime

Dataset	Stem (%)	Head (%)	Cup (%)
Registers	0.12	0.02	0.22
AAHKS survey	0.27	0.22	0.29
Clinical studies	0.77	0.29	0.13

Table 5 Deviations of the fracture rate published in different datasets from the average value of worldwide arthroplasty register datasets

Dataset	Stem	Ceramic head	Cup
Registers	1.00	1.00	1.00
AAHKS survey	2.25	11.00	1.32
Clinical studies	6.42	14.5	0.59

AAHKS American Association of Hip and Knee Surgeons, CI confidence interval

which hospital arrives at its single revision rate but also further the percentage of complete reporting of each single hospital.

At the same time one should, however, take into account that manufacturers—due to reasons of data protection—are not in a position to set up registers and are therefore dependent on reports from the surgeons [4]. In comparison, publications but also scientific discussions most frequently deal with ceramic component fractures, which may be due to the complexity of the revision operations required after such events [41].

Accurate evaluations and target-oriented activities for quality improvement require valid data as a basis for decision-making. We believe that on a large scale, clinical studies but also surveys and post-marketing surveillance measures adopted by the manufacturers appear to serve this purpose only to a limited extent.

However, meta-analyses of arthroplasty register datasets have several limitations. For example, the publications available from annual registers always report summaries of these databases. This fact and the differences in evaluation and publication procedures entail restrictions for data analyses. For example, not all reports mention the implants or components concerned, which is reasonable for a general report since other factors, such as the indication for surgery or individual procedures, have an impact on the incidence of failures. Moreover, internal procedures of individual national registers, for example, the definition of which events are to be documented as implant fracture, can have an influence on the results. It would therefore be helpful to standardise definitions and evaluation procedures. Another limitation of our comparative analysis is that registers record all revision operations, i.e. including also those due to traumatic reasons. In addition arthroplasty registers report incidences of implant fractures without distinguishing between different models, (cementation) techniques, or the fractured part of the prostheses. We believe that this information would add further knowledge to the topic but unfortunately have no option to conclusively report on different models. Next, the data compliance is only sufficiently reported by the Swedish register leading to an uncertainty of a possible bias [44] and it would be of great value if every register would provide data on its data completeness.

We want to underline the following limitations and benefits of this analysis. Namely, register datasets do not further differentiate between cross-linked versus standard polyethylene and do not differentiate between the first and the third generation of monolith zirconia ceramic heads. Therefore, adequate subgroup analysis was not possible in this paper. The presented work has the following benefits, that since the implant fracture rates published in clinical studies are mostly higher than the comparative values from registers, the adjustment of register data would even increase these differences and therefore the meaning of this manuscript. In view of the

great differences, for example, in the case of stems or ceramic heads, this effect appears to be negligible even if it is not exactly calculable. However, not all registers report on the rate of fractures in ceramic on ceramic total hip arthroplasty and therefore a more detailed comparison is not possible. In all datasets the values calculated with respect to fracture rate also include historical components. Recent progress in material techniques and processing, for instance, in the field of ceramic materials, are thus only insufficiently reflected in the average values presented. In addition, it must be stated that register datasets have the highest value for the cross-sectional and longitudinal analyses of rare events such as implant fractures. Clinical studies, but also surveys to a considerable extent, seem to be influenced by various confounders, which may lead to underreporting of negative events such as implant fractures. Last, we want to state that this study serves as the scientific background to answer our patients, that one out of 329 patients suffers from a fracture of her or his hip arthroplasty implant.

Conclusion

Sample-based datasets presented higher revision rates than register datasets with a maximum deviation of a 14.5 ratio for ceramic heads, respectively. The incidence of implant fractures in total hip arthroplasty in pooled worldwide arthroplasty register datasets is 304 fractures per 100,000 implants. The authors believe that comprehensive arthroplasty register datasets allow more general evaluations and conclusions on that topic in contrast to clinical studies.

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