
Quality Assurance in Primary Total Knee Arthroplasty

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Abstract: This study aims to compare internal and external documentation methods, to assess differences in complication rates through time and the potential association of patient parameters with morbidity. Data concerning primary knee arthroplasties performed between 2004 and 2014 were prospectively collected. The Pearson's chi-squared test or the Fisher's exact test was used to compare internal with external data and complications documented during 2005-2009 and 2010-2014. The Mann-Whitney U test was used to compare continuous outcomes in the two periods. Furthermore, binary logistic regression analyses were performed with occurrence of surgical complications as dependent variable. The total number of knee arthroplasties was 2100. Postoperative complications were experienced by 212 patients (median age: 72 years) and 30% were male. A significant difference between the internal and external datasets was detected in the "inability to walk at discharge" ($p < 0.0001$) and the "total number of complications" ($p = 0.02$). A significant reduction of the complication rate was observed in the second observation period ($p < 0.0001$). The variables "length of hospital stay" and "duration of operation" independently predicted the occurrence of complications. The observed reduction of complications through time may be attributed to acquired surgical experience and the application of quality assurance measures.

Keywords: Arthroplasty, Replacement, Knee, Quality Assurance, Health Care, Data Collection

1. Introduction

Quality Assurance (QA) intends to analyze processes and outcomes aiming at development and improvement in healthcare. In order to assess quality, the standardized and accurate prospective documentation is a prerequisite. The terms quality assurance and quality management are often used interchangeably, the last term represents not only the assessment but also the promotion of quality. Internal QA aims to self-evaluate, recognize the issues and implement changes. On the contrary, external QA aims to compare similar healthcare institutions.

The quality assurance process aims to develop procedures of measurement and presentation of the quality of care, documentation, technical implementation of data and publication of data in a suitable and readily comprehensible

form. During the process, sensible data such as postoperative complications are set as quality objectives, evaluated and made generally accessible [1].

In Germany all hospitals are obliged to submit detailed data on patients after major joint arthroplasty according to §137 of Part V of the German Social Security Code [2]. Data evaluation was conducted by the Federal Office for Quality Assurance [3] until 2008 and by the AQUA-Institute thereafter [4].

Original studies comparing quality assurance data with internal data in the field of primary knee arthroplasty in the recent literature are lacking to the best of our knowledge. Aim of the present study was to investigate the differences of external and internal documentation after primary total knee arthroplasty, the potential variation of complication rates through time and the potential association between patient parameters and complications.

Table 1. Complications with statistical significant difference between the time periods 2005-2009 and 2010-2014.

Complications	number of patients operated between 2005-2009	total number of patients with complications 2005-2009	number of patients with a specific complication (2005-2009)	number of patients operated between 2010-2014	total number of patients with complication s 2010-2014	number of patients with a specific complication (2010-2014)	two tailed p-value of Fischer's exact test/Pearson's chi-squared test	Odds Ratio and Confidence Intervals
complications (external)			118			21	<0.0001	5.8, 3.6-9.4
complications (internal)			87			14	<0.0001	6.3, 3.5-11.1
hematoma/postoperative hemorrhage (external)			16			2	0.0014	7.6, 1.7-33.1
hematoma/postoperative hemorrhage (internal)			15			2	0.0025	7.1, 1.6-31.2
cardiovascular complications (external)	996	193	16	932	56	2	0.0014	7.6, 1.7-33.1
cardiovascular complications (internal)			16			0	<0.0001	-
reintervention (external)			14			4	0.0322	3.3, 1.1-10.1
other complications (external)			29			4	<0.0001	7.0, 2.4-19.9
other complications (internal)			45			1	<0.0001	44.1, 6.1-320.3

Table 2. Significant results of binary logistic regression analyses (dependent variable: occurrence of complication, independent variables: gender, normalized duration of operation, normalized length of hospital stay and normalized patient age).

Dependent Variable	Independent Variable	Sig.(p<0.05)	Exp.(B)
external fracture	NormSD	0.001	1.024
external prosthesis dislocation	NormLOS	0.003	1.084
internal prosthesis dislocation	NormLOS	0.015	1.116
external postoperative wound infection	NormLOS	0.005	1.084
external hematoma/hemorrhage	NormLOS	0.005	1.077
internal hematoma/hemorrhage	NormLOS	0.032	1.045
external reintervention	NormLOS	0.001	1.091
internal reintervention	NormLOS	0.022	1.057
internal wound healing disorders	NormLOS	0.015	1.066

Abbreviations: Norm Age - normalized age, NormLOS - normalized length of hospital stay, NormSD - normalized duration of operation.

2. Methods

Data on primary knee arthroplasties performed in the Orthopedic Department of a university-affiliated Hospital from 2004 until 2014 were prospectively collected. All surgeries were performed or supervised by one of four senior arthroplasty surgeons. Institutional review board approval was obtained for this study. Data were collected using two methods: internal documentation (institutional data collection forms) and documentation for external quality assurance (electronic form for submission of data). The institutional form was completed at discharge, whereas the external documentation was usually submitted up to 4 week after discharge. According to the part V of the German Social Security Code, German hospitals are obliged to submit these data until the 15th of March of every year. Both documentation forms were completed by an orthopedic surgery resident. The institutional form is available upon request and the aforementioned external documentation form (latest version, 2014) is available online [5]. The persons responsible for evaluating the data were a doctoral candidate (IB) and an orthopaedic surgeon (CK). The internal data and external data were evaluated in the same institution. The

senior arthroplasty surgeon (HH), who performed or supervised a large number of surgical procedures, did not take part in the data evaluation process.

The Pearson's chi-squared test or the Fisher's exact test was used to compare internal with external data (quality assurance) and complications observed during the periods 2005-2009 and 2010-2014. The Fisher's exact test was used when the expected values were below 5. The Mann-Whitney U test was used to compare continuous outcomes (duration of operation, length of hospital stay and patient age). Binary logistic regression analyses were performed in SPSS 22.0 (SPSS Inc., Chicago, Illinois, USA) to investigate the correlation between the independent binary and continuous variables (patient's gender, duration of operation, length of hospital stay and patient age) and the dependent binary variable of occurrence or non-occurrence of a surgical complication (nerve injuries, prosthesis dislocation, fracture, postoperative wound infection, hematoma/postoperative hemorrhage, reintervention, wound healing disorder, skin lesion, duration of operation \geq 124 min, blood consumption $>$ 2 units, vascular lesion). The transformation of continuous variables to normal was conducted through a two-step process in SPSS described by Templeton [6]. Ad hoc binary logistic regression analyses

with American Society of Anesthesiologists (ASA) Score as independent binary variable (ASA 1 or 2 and ASA 3 or 4) were also conducted. The significance threshold was set at 0.05 for all tests.

3. Results

The total number of primary knee arthroplasties was 2100. The median age of patients, who experienced a complication was 72 years (range, 16-89) and 30% were male. A total of 212 patients experienced at least one postoperative complication, after exclusion of patients experiencing postoperatively ambiguously defined

changes in the mobility. The median postoperative length of stay for patients having experienced a complication was 15 days (range, 2-49) and the median duration of operation (time taken until skin closure) was 105 minutes (range, 30-356).

The complication events observed in our internal and external quality assurance dataset are represented in the bar chart of Figure 1. The most frequent complications were duration of operation more than 124 minutes (9.9%, external data), hematoma and postoperative hemorrhage (7.9%, external and 7.3%, internal data), cardiovascular complications (6.9%, external and internal data) and reintervention (6.9%, external and internal data).

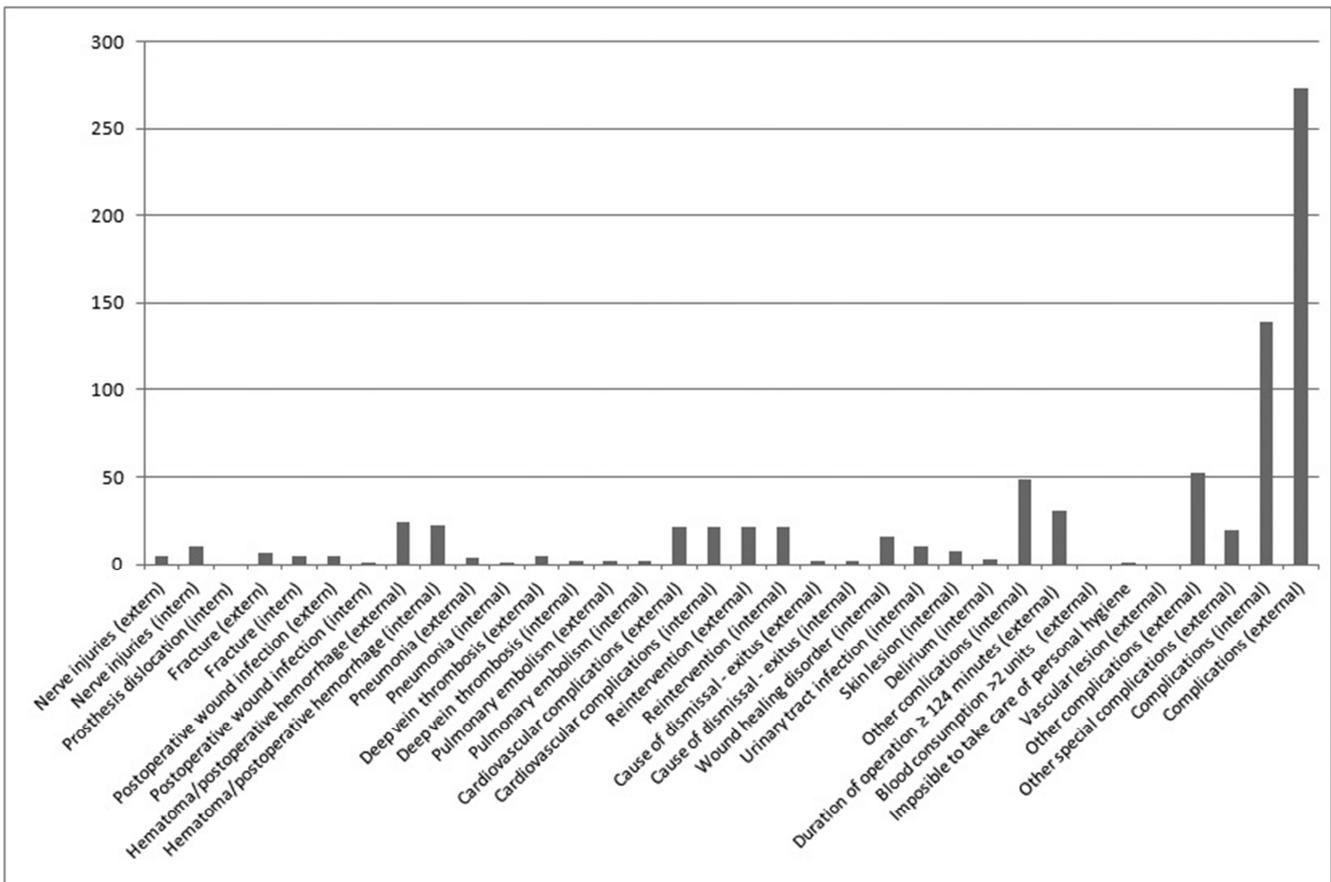


Figure 1. Number of patients that experienced internally or externally documented complications.

A statistical significant difference between the internal and external datasets was detected in the “inability to walk at discharge” ($p < 0.0001$) and the “total number of complications” ($p = 0.02$, OR 0.68, CI 0.48-0.95). A statistical significant reduction of the complication rate was observed during the second period (2010-2014), according to the internally and externally documented “total complication rate” ($p < 0.0001$). Furthermore, a significant difference was found in “hematoma and postoperative hemorrhage” and “cardiovascular complications” ($p < 0.01$) documented through both documentation methods. The number of complications presented in Table 1 produced statistical significant differences between the two time

periods under study. The Mann-Whitney U test identified a significant difference ($p < 0.0001$) in the postoperative length of stay between the two study periods (median of 15 vs. 11 days, for the periods 2005-2009 and 2010-2014 respectively).

Furthermore, binary logistic regression analyses removing insignificant independent variables suggested that the normalized variables „length of hospital stay” and “duration of operation” independently predicted the occurrence of several complications. Table 2 demonstrates significant results of binary logistic regression analyses including the data on primary knee arthroplasties performed from 2004 until 2014.

Finally, the ad hoc binary logistic regression analyses, with ASA score as an extra independent variable predicted the occurrence of cardiovascular complications (externally documented, $p=0.03$).

4. Discussion

The most common documented complications in the present study were reinterventions, fractures and cardiovascular complications. The “inability to walk at discharge” and the “total number of complications” demonstrated a statistically significant difference between external and internal data. Furthermore, a significant reduction of the complication rate was observed during the period 2010-2014 according to internal and external data. The incidences of hematoma and postoperative hemorrhage, cardiovascular complications and reintervention were significantly lower in the second period. The length of hospital stay was significantly shorter, with a reduction of the median length of hospital stay from 15 days (2005-2009) to 11 days (2010-2014). Finally, the length of hospital stay more often predicted the occurrence of a complication, and the ASA score the occurrence of cardiovascular complications (external).

The reduction of complications (2010-2014) may be due to accumulated surgical experience in knee arthroplasty or the familiarity of senior surgeons with specific surgical implants. Furthermore, the lower rate of general complications could be the result of standardization of the processes through the years. The difference in the parameter “inability to walk at discharge” was probably significant due to different definitions of this parameter in the two documentation methods. Inability to walk was more often documented in the external database, when physiotherapist assistance or mobility aids were assigned to a patient.

A recent study [7] described the creation of a task force to examine the reliability of a rating system created by the biggest health insurance company in Germany (AOK). The task force examined the role of patient-specific parameters on the external quality assurance of patients undergoing total knee replacement. Four orthopaedic departments above average and four below average according to the aforementioned patient-specific parameters were identified for the study purposes. The task force found differences between patient groups in the rate of comorbidities, knee extension lag and operations before the knee arthroplasty. A similar analysis could not be conducted in the present study, due to the missing documentation of the mentioned patient-specific parameters.

Several publications examined the role of patient parameters on the morbidity after total knee replacement. In the present study the length of hospital stay, the duration of the operation, and the ASA score were the most influential factors affecting postoperative complications. In the recent bibliography a combination of male gender, with one comorbidity and age more than 70 years (analogous to a

worse ASA score) were predictive factors of worse outcomes [8]. A correlation was also found between the operative time and the infection rate in TKA patients [9], as well as the amount of blood loss [10], and also the tourniquet time and neurologic complications [11]. A systematic review [12] recorded worse function in obese patients undergoing a knee replacement surgery. Diabetes mellitus was associated with an increased rate of complications after knee arthroplasty [13, 14], when combined with obesity [15] and in case of uncontrolled disease [16]. Furthermore, obesity (BMI>50) and younger age are identified in a publication [17] as risk factors. The retrospective study by Berend et al. [18] identified high rate of complications in TKA patients with knee extension lag of 20 degrees or more preoperatively. In the present study, the gender of the patient and the age did not prove to be statistically relevant for the occurrence of a complication. The BMI and the preoperative ROM were not recorded. Furthermore, a recent study [19] described that the median time of venous thromboembolism was three days after knee arthroplasty. Taking into account that venous thromboembolic events after knee arthroplasty occur usually until the end of second postoperative week, we may assume that a great amount of the events have been included in the present work. Finally, a research team found that a potential inclusion of 1 year follow-up data after total knee arthroplasty could change the complication rates significantly [20]. The results of the current study may be also changed in the 1-year follow-up.

Possible explanation for the observed differences between the internal and external documented complications is the fact that the institutional form was completed at discharge, whereas the external documentation was usually submitted up to 4 weeks after discharge. The German hospitals were obliged to submit the external data until the 15th of March of every year. Furthermore, the external complications were precisely defined [21], in contrast to the internal documented complications, which were usually in accordance with the diagnoses of the discharge letter.

The present study has several limitations. Comorbidities, which may have an influence on the surgical outcome [22], were not documented in this study. The differences in the definition of parameters of internal and external data made a comparison often impossible. The data normalization through a two-step process [6] was required for statistical analysis, a back-transformation being thus not possible. Additionally, a medical chart review would be a recognized method to test the internal validity of data.

5. Conclusions

Differences between internally and externally documented complications should be further investigated in combination with a medical chart review. A reduction of complications through time may be due to the increased familiarity of senior surgeons with the surgical techniques or the specific surgical implants and the positive impact of a quality assurance program.

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