

Lessons Learned From Managing a Prospective, Private Practice Joint Replacement Registry

A 25-year Experience

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Abstract

Background In 1984, we developed a private practice joint replacement registry (JRR) to prospectively follow patients undergoing THA and TKA to assess clinical and radiographic outcomes, complications, and implant survival. Little has been reported in the literature regarding management of this type of database, and it is unclear whether and how the information can be useful for addressing longer-term questions.

Questions/purposes We answered the following questions: (1) What is the rate of followup for THA and TKA in

our JRR? (2) What factors affect followup? (3) How successful is this JRR model in capturing data and what areas of improvement are identified? And (4) what costs are associated with maintaining this JRR?

Methods We collected clinical data on all 12,047 patients having primary THA and TKA since 1984. Clinical and radiographic data were collected at routine followup intervals and entered into a prospective database. We searched this database to assess the rate of successful followup and data collection and to compare the effect of patient variables on followup. Costs related to database management were evaluated.

Results Followup was poor at every time interval after surgery, with a tendency for worsening over time. Patients with a complication and those younger than 70 years tended to followup with greater frequency. There were difficulties with data capture and substantial expenses related to managing the database.

Conclusions Our findings highlight the difficulties in managing a JRR. Followup is poor and data collection is often incomplete. Newer technologies that allow easier tracking of patients and facilitate data capture may streamline this process and control costs.

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at New Mexico Orthopaedics, Center for Joint Replacement, Albuquerque, NM, USA.

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Introduction

Institutional [4, 11] and private practice [2] databases have been developed to assist in outcome studies. These registries have collected a wide spectrum of data points from basic Level I data to very comprehensive levels of data [2, 5, 11, 12]. However, relatively little has been written to describe the management of this type of database [1, 2, 5, 12]. Previous investigations have demonstrated difficulty with maintaining current clinical information when

followup relied on return visits, with improved maintenance of current information when direct contact was made or questionnaires were sent to patients [2, 4]. However, we are not aware of any reports that have detailed the rate of successful data capture or have described causes for incomplete data or solutions for improving data capture for a private practice JRR.

In 1984, we developed a private practice JRR to prospectively follow patients undergoing THA and TKA to assess clinical and radiographic outcomes, complications, and implant survival. However, it is unclear whether and to what degree these sorts of databases can be used to address important questions regarding the treatment of these patients.

In this investigation, we sought to expand the available knowledge regarding management of this type of database by answering the following questions: (1) What is the rate of followup for THA and TKA in our JRR? (2) What factors (age, sex, BMI, complications, time from surgery) affect followup? (3) How successful is this JRR model in capturing data and what areas of improvement are identified? And (4) what costs are associated with maintaining this JRR?

Materials and Methods

All primary and revision THAs and TKAs performed at the New Mexico Center for Joint Replacement Surgery since 1984 have been entered into the registry. In 1984, there was one contributing surgeon; in 2012, there are five contributing surgeons. As of September 1, 2011, the contents of the JRR were 4752 primary THAs, 7295 primary TKA, 867 revision THAs, and 352 revision TKAs. Bilateral cases were entered as two separate entries. For this study, we evaluated clinical data on all 12,047 patients having primary THA and TKA since 1984.

Data collection preoperatively and postoperatively was based on manually populated paper forms scanned into the database (Appendix 1–5; supplemental materials are available with the online version of CORR®). Subjective data forms were completed by the patient alone without any assistance from surgeon, fellow, or physician assistant. The objective data forms were completed by surgeon, fellow, or physician assistant at the time of evaluation. All intraoperative data including surgical technique description and implant identification were entered directly into the database in real time during the surgical procedure. Comprehensive radiographic interpretation was performed by one skilled research director within 1 week of the examination and the resulting data entered directly into the database. This research director had been trained to evaluate TKA and THA radiographs for alignment, osteolysis,

radiolucencies, component migration, and component positioning and has 10 years of experience evaluating radiographs. Data were stored using the Patient Analysis and Tracking System (PATS®; Axis Clinical Software Inc, Portland, OR, USA). The philosophy has always been to collect any potentially useful data points (age, sex, underlying disease, past medical history, Knee Society Score [KSS] or Harris hip score [HHS], SF-12, operative findings and techniques, complications [Appendix 6; supplemental materials are available with the online version of CORR®], followup scoring, and radiographic findings). It is therefore a comprehensive data point collection model. Before the development of the KSS in 1989 [6], data collected on patients with TKA included only radiographic and clinical followup data (ROM, stability, and a subjective account of patient-perceived function).

The routine scheduled postoperative visits coinciding with an entry into the database included 6 months and 1, 2, 5, 7, 10, 15, 20, and 25 years. Patients were instructed verbally and given a written reminder to followup at the intervals noted above by their operative surgeon and no routine attempt was made to contact patients who had missed a scheduled appointment or had failed to schedule a routine appointment. Every 2 years, the database was crossreferenced with the Social Security Death Index [15] to identify those patients who had died. In cases of death or if a joint was revised, the followup of that joint arthroplasty was finalized at latest followup.

A followup visit was accomplished if the patient returned for followup and the appropriate forms were completed by patient and surgeon. For complete accumulation of data, the forms had to be successfully scanned into the database and radiographs taken and reviewed. We queried the database for primary TKAs and THAs at each of the followup intervals beginning at 2 years. Those with and without successful followup were recorded. We evaluated specific factors affecting compliance, including number of patients lost to death at each followup interval, age at time of procedure, sex, duration of followup, and occurrence of a complication.

Age at the time of surgery has been included as a data point since 1984, but the database could not be queried in such a way as to determine the rate of followup based on patient age at the time of the followup visit. However, age at the time of surgery could be used to identify a group of patients based on age and those patients followed at each interval to assess for followup. We grouped patients by age at the time of surgery into the following six groups: younger than 40 years, 41 to 50 years, 51 to 60 years, 61 to 70 years, 71 to 80 years, and older than 80 years. In addition, height and weight have been included as data points, but BMI was not included as an independent and searchable entry until 2007. For this reason, BMI could not

be used to compare followup between groups since 1984 and could only be assessed for all patients with primary THA and TKA eligible for 2-year followup for a surgery date of 2007 and later. We grouped those patients by BMI into the following two groups: BMI of greater than 30 and BMI of lower than 30.

The evaluation of the data also focused on incomplete data. Unless all questions were answered with an accurately filled bubble on forms completed by both patient and surgeon, there would be no HHS or KSS recorded for that interval. We queried the database separately for the scores generated by the patient (SF-12, HHS function score, KSS function score) and those scores generated by the surgeon (HHS physical examination, KSS physical examination).

We identified the costs to maintain the JRR including paying a research coordinator, database contract maintenance, data forms and entry, capital purchases, and every other year querying of the Social Security Death Index. Areas for cost reduction were evaluated.

We used the chi-square test to compare followup between the sexes and the presence and absence of a complication. When the frequency was too small, we used Fisher’s exact test in place of the chi-square test. The chi-square test was also used to compare followup between the two BMI groups. We compared the rate of followup among the age groups at each followup interval using Tukey’s test (R software; R Foundation for Statistical Computing, Vienna, Austria).

Results

Patients with THA demonstrated overall poor followup, with rates declining with time from the index procedure (Table 1). The largest decrease in the THA group occurred between 7 and 10 years after surgery when the compliance rate decreased from 45.3% to 36.1% (Table 2). At 2 years, women followed up more reliably (p = 0.001) than men. At all other intervals, there were no differences (Table 2). At every interval except 15 years and later, the complication rate was higher (p < 0.001) among those who followed up than among those who did not (Table 3). Patients with THA having a BMI of greater than 30 (n = 575) had followup (27.3% versus 29.1%, p = 0.64) and complication (3.5% versus 3.1%, p = 0.94) rates at 2 years similar to those of patients with a BMI of lower than 30 (n = 289). Patients with TKA also demonstrated overall poor followup, with rates declining with time (Table 1). In the TKA group, the largest decrease occurred between 2 and 5 years after surgery when the compliance rate decreased from 52.5% to 41.6% (Table 2). Women followed up with higher compliance than men at 2, 5, 7, and 10 years (Table 2). At every followup interval except

Table 1. Comparison of followup and complications rates between TKAs and THAs at each followup interval

Type of surgery	2 years		5 years		7 years		10 years		15 years		20 years		25 years	
	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)	Followup rate (%)	Complication rate (%)
THA	60	17	51.5	22.3	45.3	25.5	36.1	30.4	32.6	30	10	42.1	5.2	60
TKA	52.5	11.2	41.6	16.1	32.9	18.6	24.4	24.8	16.5	30.8	1.2	50	0	0

Table 2. Followup of male and female patients after THA and TKA

Followup (years)	Number of patients with followup		p value
	Female	Male	
THA			
2	1796 (62%)	1074 (57%)	0.001
5	1017 (52%)	642 (51%)	0.93
7	710 (45%)	451 (45%)	0.98
10	420 (37%)	242 (34%)	0.25
15	215 (34%)	118 (31%)	0.48
20	20 (9%)	18 (11%)	0.52
25	2 (4%)	3 (7%)	0.65
TKA			
2	2553 (56%)	1275 (47%)	< 0.001
5	1134 (44%)	623 (39%)	0.001
7	658 (35%)	348 (30%)	0.01
10	298 (26%)	133 (21%)	0.02
15	93 (18%)	40 (15%)	0.34
20	2 (2%)	0 (0%)	1
25	0 (0%)	0 (0%)	1

Table 3. Followup of patients after THA comparing complication rates in those who returned for followup and those who did not

Followup (years)	Number of patients with followup (complication rate)	Number of patients without followup (complication rate)	p value
2	2870 (17%)	1882 (9.6%)	< 0.001
5	1656 (22%)	1555 (11%)	< 0.001
7	1161 (25%)	1402 (17%)	< 0.001
10	662 (30%)	1173 (22%)	0.001
15	333 (30%)	688 (27%)	0.35
20	38 (42%)	341 (30%)	0.16

Table 4. Followup of patients after TKA comparing complication rates in those who returned for followup and those who did not

Followup (years)	Number of patients with followup (complication rate)	Number of patients without followup (complication rate)	p value
2	3828 (11%)	3467 (5%)	< 0.001
5	1757 (16%)	2463 (10%)	< 0.001
7	1006 (19%)	2049 (14%)	0.001
10	431 (25%)	1337 (19%)	0.008
15	133 (31%)	672 (32%)	0.82
20	2 (50%)	159 (36%)	0.7

15 years and later, the complication rate was higher ($p < 0.05$) among those who followed up than among those who did not (Table 4). Patients with TKA having a

BMI of greater than 30 ($n = 898$) followed up at a lower rate (24.7% versus 27.0%, $p = 0.29$) and had a higher complication rate (3.8% versus 1.7%, $p = 0.009$) at 2 years than patients with a BMI of less than 30 ($n = 896$). When grouped by age, there were similar rates of followup at each interval for every group but a tendency toward poorer followup at every interval for those patients 71 to 80 years of age and those older than 80 years of age (this was noted for both THA and TKA) (Table 5). The sample sizes at 20 and 25 years for TKA and 25 years for THA were too small to be evaluated statistically. Similar to the overall THA and TKA groups, there was more compliant followup in those patients who had suffered a complication. Compared to patients with TKA, patients with THA had a higher compliance rate at each interval. Patients with THA had a higher rate of complications (14.1%) than patients with TKA (8.4%), which may explain their higher compliance rate (Table 1).

The percentage of patients with current followup data in a specific study or an entire JRR is obviously affected by the number of patients lost to death. The magnitude of this potential loss of followup increased with time (Table 6). The largest loss occurred between 10 and 15 years after both THA and TKA when the percentage of patients lost to death increased from 37.9% to 54.6% and from 38.5% to 56.9%, respectively. The search of the Social Security Death Index allows for those patients who have died to be identified and the followup on that patient's joint(s) to be concluded. However, no cause of death can be ascertained and it cannot be known whether death was related to the procedure.

Two additional challenges were identified in this investigation: (1) incomplete or inaccurate data and (2) costs. The details of these two challenges are probably specific to our system but may apply to other situations. Our manually populated, scanned paper forms allowed the patient or provider to skip or miss questions. Any blank question resulted in the inability to create a score for that evaluation. Therefore, no KSSs or HHSs could be calculated in 35.7% of preoperative scores and 46.1% of postoperative scores due to incomplete or unscannable forms. Patients were responsible for 85% of incomplete forms while providers were responsible for 15%.

There were numerous costs associated with maintaining the database (Table 7). These included paying an experienced radiographic technologist for radiographic interpretation and coordination of data harvest and entry, the annual contract for database maintenance, the actual paper forms, any capital purchase, and searching the Social Security Death Index every other year. These costs averaged \$85,000 to \$90,000/year (Table 7).

Table 5. Followup rates of patients after THA and TKA grouped by age

Followup (years)	Followup rate (%)											
	< 40 years		41–50 years		51–60 years		61–70 years		71–80 years		> 80 years	
	THA	TKA	THA	TKA	THA	TKA	THA	TKA	THA	TKA	THA	TKA
2	68	54	63	51	63	48	66	54	59	49	40	38
5	60	52	57	41	60	44	58	48	45	39	19	24
7	56	49	56	31	55	38	54	41	34	29	12	18
10	50	41	50	30	49	34	43	34	21	16	3	10
15	45	54	46	27	49	29	33	25	15	9	1	0
20	15	0	16	20	15	0	10	0	1	3	NA	NA
25	13	0	12	0	0	0	9	0	0	0	NA	NA

NA = not applicable.

Table 6. Number of patients lost to followup due to death at each followup interval

Type of surgery	Number of patients lost to followup due to death						
	2 years	5 years	7 years	10 years	15 years	20 years	25 years
THA	1055 (22%)	992 (31%)	925 (36%)	696 (37.9%)	557 (54.6%)	212 (55.9%)	49 (50.5%)
TKA	1217 (16.7%)	1096 (26%)	987 (32.3%)	680 (38.5%)	458 (56.9%)	102 (63.4%)	2 (40%)

The percentage in parentheses represents the proportion of the entire group eligible for followup at that interval.

Table 7. Yearly costs to operate our joint replacement registry

Cost	Amount (US dollars)
Research coordinator (radiographic interpretation, orchestrates data harvest)	\$60,000
Annual database maintenance contract	\$12,000
Paper forms	\$5,000
Data forms scanning	\$6,000
Capital purchases	\$3,000–\$5,000
Social Security Death Index search every other year	\$3,000
Total	\$86,000–\$91,000

Discussion

A private practice JRR was developed to prospectively follow patients undergoing THA and TKA to assess clinical and radiographic outcomes, complications, and implant survival. Little has been reported in the literature regarding management of this type of database and we sought to expand the available knowledge by answering the following questions: (1) What is the rate of followup for THA and TKA in our JRR? (2) What factors (age, sex, BMI, complications, time from surgery) affect followup? (3) How successful is this JRR model in capturing data and what areas of improvement are identified? And (4) what costs are associated with maintaining this JRR?

The primary limitation of this study is that it represents a retrospective evaluation of a prospective database. However, we had a large number of patients and all were initially entered, and the database extended over a long period of time. Second, the database has evolved over time, with the data point of BMI being added later, making this variable incomplete. When evaluating the 2-year followup of those with a BMI of greater than 30 and those with a BMI of less than 30, we noted the followup rates of those groups (26% and 28%, respectively) were less than the 2-year followup rates for both THA and TKA (60% and 52%, respectively). As previously noted, BMI was included as an independently searchable variable in 2007; thus, these patients represent a recent snapshot of 2-year followup for both TKA and THA. Third, the low followup rate in these patients is less than the 2-year followup rate seen over the course of the history of this database. It is not known whether this represents a change in followup tendencies among patients and further investigation will be required to determine whether this continues and what variables contribute. Fourth, there was poor followup across all patient groups. While a limitation in the potential value of the database, this is not necessarily a limitation of the study since one of the goals of this investigation was to determine rates of followup. Finally, in addition to the measurable and annually repeating costs associated with the database (Table 7), there are likely unmeasured costs such as the unreimbursed time required to fill out forms, possibly resulting in fewer patients seen.

As noted above, followup in patients with TKA and THA was poor in our JRR. The most important factor in encouraging patients to be compliant in their followup is the presence of a complication. This could be related to the psychologic impact of the complication and a desire for closer surveillance of the joint on the part of the patient or the surgeon. However, female sex and index procedure of THA also favored compliance with followup. Patients with a BMI of greater than 30 demonstrated a higher complication rate in the TKA group. Otherwise, there was no difference in followup or complication rate between patients with a BMI of greater or less than 30. Age of greater than 70 years at the time of the procedure was associated with lower followup rates. Previous studies [1, 2, 13] have noted better rates of followup among patients with the following characteristics: female sex, white race, residence closer than 50 miles from the followup location, younger age, better preoperative HHS for gait, bilateral TKA, revision surgery, and when reminded to followup with telephone calls. Berry et al. [2] reported followup approaching 95% when office visits were combined with mailed questionnaires and radiographs. There was no discussion about the completeness of the questionnaires or the adequacy of the outside films in that investigation. Clohisy et al. [4] reported followup for patients with TKA and THA to be 61% and 36% at 1 and 2 years, respectively. Aleem et al. [1] reported followup in patients with TKA to be 78% and 37% at 1 and 2 years, respectively. These rates of followup are comparable to those noted in the current investigation (Table 1).

The challenge of keeping patients current with their suggested followup is great. At most followup intervals, the number of patients who are not current exceeds 50%. The longer a patient has not come in for evaluation, the more difficult it is to perform the evaluation. For example, to make all patients with primary THA current at 10 years after surgery would involve attempting to contact 63.9% of the total available or 1173 patients. If those patients could be contacted, it would take 30 clinical days at 40 patients/day to see these patients. It would be most effective to attempt to contact them as early as possible once an appointment has been missed as this improves followup compliance [4]. Improvements may be made at each followup by contacting patients by mail, email, or telephone and consideration should be given to employing mailed questionnaires and radiographs [2]. Newer electronic medical record (EMR) systems may allow for automated email reminders to be sent to patients due for followup. Previous investigation has shown improved followup compliance when attempts to contact patients are made while others have questioned the value of an office followup visit when compared to a mailed questionnaire [1, 4]. The benefits of regular followup include regular joint evaluation and possible avoidance of more costly revision in the event of joint failure and collection of

current and complete data allowing more comprehensive evaluation of implants and surgical techniques [8–10, 14]. The appropriate interval for regular followup, whether appropriate followup requires a visit to the surgeon or followup by other means, and the costs associated to maintain followup are controversial and beyond the scope of this study [2, 3, 7, 13, 14, 16].

The issue of incomplete or inaccurate data is a difficult challenge. The system in this study employed manually populated paper forms. If any questions were skipped, the form was rendered unreadable and no score was recorded in the database. The large number of forms that patients must complete, especially if more than one joint arthroplasty is being evaluated, contributes to the magnitude of this problem in this patient population. Moreover, older patients might not clearly understand questions, such as differentiating hip pain from back pain. As noted above, incomplete forms were attributed to patients 85% of the time while to staff 15%. As a result of this investigation, more attention has been given to ensuring patient forms are complete before leaving the clinic. This will need to be evaluated going forward to see whether there is improvement in the rate of form completion. In addition, new technologies (internet-based or kiosk-type data entry stations) that require a response to each question could be employed. This new type of collection system may result in substantial hardware, software, or personnel costs and some older or less affluent patients may not as readily adopt new technologies. With new federal mandates and more EMR systems to be installed, consideration should be given to how these new EMRs can facilitate accurate data capture [11, 12]. With most practices experiencing increasing overhead costs compared to revenues, the cost of a research database that does not produce a revenue stream may be challenging. The costs will be dependent on the software/hardware system of collection and the extent of data collection. After initial costs, new technologies may eliminate other costs. If the JRR is an integrated part of the practice EMR and/or practice information system, additional cost reductions may occur. We have estimated the costs for fully converting our manually populated, scanned paper forms to a fully electronic system at \$30,000 to \$50,000. This estimate includes only that of making the database electronic and not that of establishing a practice-wide EMR. We are currently implementing a practice-wide EMR system and will look to integrate the JRR into the EMR in the future.

In conclusion, followup among patients with primary THA and TKA is poor. The factor most associated with followup is the presence of a complication associated with a patient's procedure. Poor followup, difficulties with data capture, and high annual expenses render managing a prospective JRR difficult. Implementation of new technologies may improve these areas and should be considered as EMRs are adopted.

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