Validation of the Swedish Knee Arthroplasty Register

A postal survey regarding 30,376 knees operated on between 1975 and 1995

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The Swedish Knee Arthroplasty Register is dependent on the participating clinics regarding accuracy of information. As the register is prospective, and since revision is used as the endpoint in survival analyses, it is important that all revisions of registered primary arthroplasties are reported. To validate the register, we sent a questionnaire to all living patients with 30,796 knees registered as having been operated on from 1975–1995. Of living patients, 99% could be located and 93% answered. We found that one fifth of the revisions had not been reported and that relatively fewer revisions were lost to follow-up during the first decade of the register than in the following years.

To investigate whether the Patient Administrative System (PAS), a database based on ICD coding and run by the Swedish health authorities, could be used to locate missing revisions found by the postal survey, we compared this database with the Swedish Knee Arthroplasty Register. 84% of the missing revisions revealed by the postal survey were found by using this method. Hence after the survey and the use of the PAS to find unreported revisions in deceased and non-responding patients, we estimate that 94% of all revisions are accounted for.

Apart from a generally higher cumulative revision rate, conclusions reported from the Register in recent years regarding survivorship seem to be unaffected by the underreporting.

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The Swedish Knee Arthroplasty Register (SKAR) was started in 1975 (Bauer et al. 1980) and since then, primary knee arthroplasties and their revisions have been reported yearly by the participating clinics to the administrative center at the Department of Orthopedics in Lund. The project is dependent on the participating hospitals regarding accuracy of information and we know that about 20% of the arthroplasties performed in Sweden are not included (Knutson et al. 1994). Because of the vast number of primary operations, an unbiased loss in reports of primary arthroplasties has not been regarded a problem. However, the register is prospective and since revisions are utilized as the endpoint in survival analyses, it is important that revisions of included patients are reported.

The aim of this study was to evaluate the accuracy of the register regarding revisions and subsequently to update it. To accomplish this, we decided to locate all living patients registered in the SKAR and ask by a postal survey if they had been re-operated. Further, we wanted to find out whether the Patient Administrative System (PAS), a database run by the health authorities based on ICD coding, could be used to find missing revisions. If this were the case, the PAS could be used regarding deceased and nonresponding patients, as well as for future updates of the SKAR.

Patients and methods

The SKAR registers patients operated on with knee arthroplasties and records their unique social security number, side operated on, date of operation and implant-related factors. The SKAR defines a revision as addition, exchange or removal of prosthetic components. In the case of a revision, information regarding reason for failure and the type and date of revision are added to the database. Details about the design of the SKAR have been reported (Knutson et al. 1994)

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The Swedish National Census Register (NCR) records persons living in Sweden. This includes their unique social security number, home address, marital status, nationality and date of death, if appropriate.

The Swedish Patient Administrative System (PAS) was started 1964 by the Swedish health authorities mainly for health planning purposes. It involves all hospitals in Sweden since 1987 and registers data regarding hospital admissions. Among this data is the social security number of patients, hospital codes, admission and discharge dates along with several ICD-codes for diagnosis and surgical procedures regarding each admission. There is, however, no detailed information about procedures such as side of operation or implant-related factors.

In June1997, the SKAR had information on 36,901 patients operated on with a knee arthroplasty during the period 1975–1995. Among these, 25,761 patients were registered as living and were located with the assistance of the NCR. Every living patient found was sent a questionnaire. Patients with bilateral operations received two questionnaires, one regarding each side. The patients were informed of the date of the last operation registered in SKAR and the side operated, and asked whether they had subsequently undergone an operation on their knee. In case their answer was yes, they were asked about when and where the operation had been performed.

When a patient reported having been reoperated, we contacted the treating clinic to obtain the medical charts to find out whether the operation was a true revision by our definition.

To estimate how effective the PAS database would be for locating missing revisions not reported to the SKAR, the databases were compared. For each patient, the PAS was searched for a later date of admission for surgery (with an appropriate orthopedic surgical code) than the latest registered date of operation in the SKAR. By comparing the results from the PAS with the missing revisions that had been found by asking the patients, we could evaluate the sensitivity of using the PAS register to find unreported revisions.

Statistics

The chi-square test with a probability level of < 0.05 was considered significant when used to compare groups regarding lost revisions.

The cumulative revision rate (CRR) was calculated with Kaplan-Meyer statistics (SPSS software) and graphs plotted with confidence intervals, calculated by the Wilson quadratic equation with Greenwood and Peto effective sample-size estimates (Dorey et al. 1993). Curves were cut-off when 40 knees remained at risk. The end-point was defined as revision, with addition, exchange or removal of prosthetic components

Table 1. Results of questionnaire regarding 30,796 knees (operated on 1976–1995)

	Knees
Answer	
Died before letter could be answered	420
Not returned	
Patient not found at given address	135
No answer	1,155
Returned	
Returned, no answer regarding reoperation	727
No answer because of general disease	148
Reoperation before end of 1995	1,099
No reoperation before end of 1995	27,112
Total	30,796

Results

36,901 patients were registered as having been operated on with 45,195 knee arthroplasties during 1975–1995. 160 patients could not be located by the NCR because of faulty social security numbers, patients leaving the country, change in identity and unknown reasons. 25,761 patients with 30,796 knees were registered as being alive, and were sent a questionnaire regarding one or both of their knees. 420 questionnaires were returned because the patient had recently died, leaving 30,376 (67%) knee patients to answer. Only 1,290 questionnaires (4%) had not been returned and answers regarding reoperation were received for 28,211 knees (92%) (Table 1).

Among answering patients, 186 knees (0.6%) were said to have been registered as the wrong side. After checking with the treating clinics, this was confirmed in 160 cases, while in 14 cases the clinic stated that the registered side was the side

Table 2. Year of operation and respons

	All patients		Responding patients		
Year	Prim.[a]	Resp.%[b]	T. Rev.[c]	M. Rev.[d]	M.%[e]
1975–1982	7,769	26	138	1	0.7
1983	1,365	36	47	2	4.3
1984	1,589	41	54	4	7.4
1985	1,737	47	69	5	7.2
1986	1,679	51	75	5	6.7
1987	2,167	55	83	16	19.3
1988	2,259	59	110	16	14.5
1989	2,266	62	106	17	16.0
1990	2,743	70	174	27	15.5
1991	3,837	73	183	45	24.6
1992	5,238	77	266	70	26.3
1993	4,578	82	308	54	17.5
1994	4,206	86	309	90	29.1
1995	3,762	89	294	85	28.9
Total	45,195	62.4	2228	437	19.6

[a] Primary operations referes to the total number of primary operations registered during a given year.
[b] Percent responding shows the percentage of primary operations in patients who were alive and answered to the questionnaire.
[c] Total revisions shows knees in responding patients who had had their first revision the year shown.
[d] Missed revisions shows the number of revisions in responding patients who were not reported to SKAR (previously registered as unrevised).
[e] Percent missing revision of all revisions each period.

Table 3. Reported revisions and missed revisions at university, county and local hospitals. (Revised patients who answered the questionnaire)

Type of hospital	Reported revisions		Missed revisions		Total
	No.	Percent	No.	Percent	No.
University	417	87	64	13	481
County	1,085	79	284	21	1,369
Local	289	76	89	24	378
Total	1,791	80	437	20	2,228

Table 4. Type of revision performed in unreported first revisions compared to reported first revisions. (Revised patients who answered the questionnaire)

Type of revision	Reported revisions		Missed revisions		Total
	No.	Percent	No.	Percent	No.
Amputation	8	73	3	27	11
Extraction	74	70	31	30	105
Arthrodesis	39	75	13	25	52
Hinged	19	95	1	5	20
Linked	112	90	12	10	124
TKA	1,013	82	221	18	1,234
Bilat. Uni	16	100	0	0	16
Med. Uni	107	94	7	6	114
Lat. Uni	61	92	5	8	66
Partial exch.	222	76	71	24	293
Patella	120	62	73	38	193
Total	1,791	80	437	20	2,228

operated on. 12 are still uncertain. 57 patients (0.2%) said that they had not been operated on the knee we asked about. In 34 of these cases, the relevant clinics confirmed that no knee arthroplasty had been performed, while in 12 cases they said that a knee arthroplasty had been performed. In 6 cases, the other knee had been operated on; 5 are still uncertain.

1,099 (3.6%) patients said that a reoperation had been performed before the end of 1995. After checking with the clinics, 506 of these were found to be true revisions. 243 were surgical procedures on the knee, but not true revisions by our criteria and in 330 cases, the reoperation referred to by the patient was unrelated to the knee or a misunderstanding of the question. 6 cases were revisions registered as primaries that should not have been included in the base because the primary operation had not been reported earlier. Twenty medical records could not be found.

Of the 506 lost revisions, 69 were revisions in knees that were already registered as revised (one stage of a two-stage exchange arthroplasty, additional revisions in revised knees, etc.) while 437 were revisions in knees previously registered as unrevised.

The reports of the participating clinics reported to the SKAR were more accurate during the first 10 years, but since then the accuracy has declined (Table 2). The university hospitals were better than the smaller units at reporting all types of revisions (Table 3).

The types of revisions most often missed were partial revisions or procedures such as amputations, extraction of the prosthesis and arthrodesis (Table 4). The type of primary operation that did not have its revision reported was most often the TKA (Table 5). Gender had no effect on reporting.

Table 5. Type of primary operation performed in unreported first revisions compared to reported first revisions. (Revised patients who answered the questionnaire)

Type of primary	Reported revisions		Missed revisions		Total
	No.	Percent	No.	Percent	No.
Hinged	23	85	4	15	27
Linked	36	90	4	10	40
TKA	680	76	220	24	900
Med. Uni	803	83	166	17	969
Lat. Uni	119	86	19	14	138
Bilat. Uni	100	82	22	18	122
Patella	30	94	2	6	32
Total	1,791	80	437	20	2,228

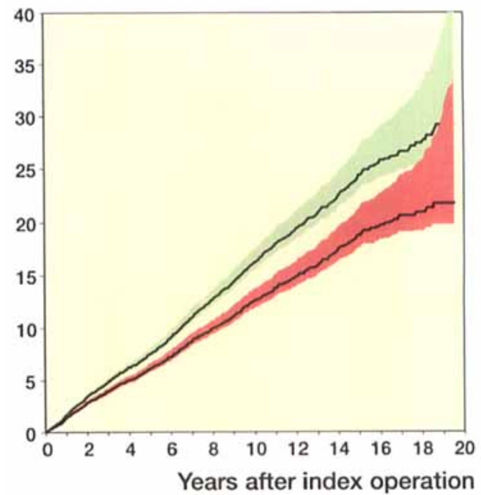

Figure 1. CRR before (red) and after (green) update of the register. All patients who answered the questionnaire. All types of prostheses and all diagnoses 1975–1995. Curves are cut-off when only 40 patients remain at risk.

In revised cases, the mean age at primary operation was 5 years lower than in those not revised. The revised cases, not reported, had a slightly higher mean age than those reported, both at primary operation (65/64) and at revision (70/69).

Missing revisions affect the survival estimate of prosthetic models differently. The distribution is not random since types of prostheses used and revised during the last 10 years are more often not reported than those from the first 10 years. The additional revisions, however, are few in each implant group which makes any statistical evaluation difficult.

To evaluate the effect of the missing revisions on survivorship, the Cumulative Revision Rate (CRR) for all patients who answered our questionnaire was calculated, before and after update (Figure 1). As expected, because of the missing revisions, there was a general increase in CRR after the update.

To evaluate the rationale of using the PAS database to track revisions not reported to the SKAR regarding deceased and nonresponding patients, the PAS was searched for suspected reoperations of the patients who had answered our questionnaire. 1,835 (6.5%) operations were found that could qualify as being a knee operation case at a later date than the last knee operation found in the SKAR. These suspected revisions could, of course, be arthrodeses and amputations unrelated to the index knee, unreported primary arthroplasties on the opposite side as well as operations not qualifying as true revisions. Among the suspected operations were 423 of the 506 known missing revisions (84%) and 381 of the 437 known missing revisions in previously unrevised patients (87%). It thus seemed that a comparison of these two databases was a good way of improving information regarding revisions, and therefore we subsequently checked the 13,580 knees operated on with a knee arthroplasty during 1975–1995 in deceased patients as well as the 2,585 knee cases who did not reply to the questionnaire. The same fraction of missed revisions was found as in the responding patients. After update of the SKAR with the information gained by both the postal survey and the cross-checking of deceased and nonresponding patients, we estimate the number of revisions lost to follow-up at less than 6% (Figure 2).

Discussion

The Swedish Knee Arthroplasty Register was initiated in 1975 by orthopedic specialists in Sweden. Knee arthroplastic surgery was then a newly accepted operative procedure having been done by relatively few units for about 5 years. During the first 10 years of the register, the number of primary operations steadily increased to 1,600 per year (Knutson et al. 1994), while the number of

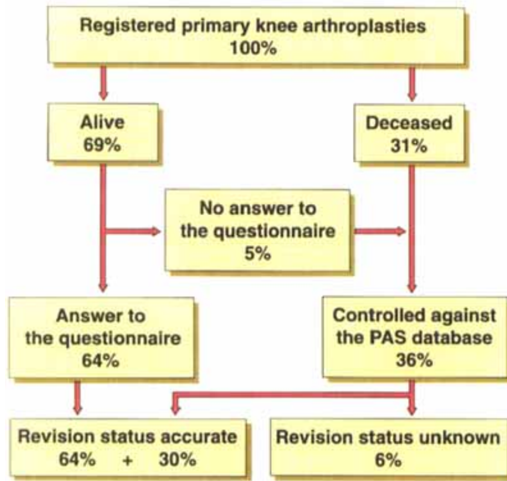

Figure 2. A flow chart that describes how the Swedish Knee Arthroplasty Register was validated with the help of a questionnaire and the PAS database.

reporting units increased from 35 to 50. In the following 10 years, from the mid-1980s, the number of operations increased threefold and the number of reporting units increased to 80. Knee arthroplasty was no longer an exceptional procedure, done in highly specialized units and reserved for a few patients.

There are two national registers in Sweden with access to data regarding patients with knee arthroplasties—the SKAR and the PAS. The SKAR relies on a voluntary contribution from the orthopedic community, is unrelated to monetary reimbursement and is utilized mainly for scientific reasons and to some extent to improving quality control of knee prosthetic surgery. In contrast, the PAS is a mandatory administrative system, that during the last 5 years has been related to monetary reimbursement through ICD diagnosis and procedure registration.

In a recent article (Robertsson et al. 1999a) we found that during the period 1985–1995 the PAS had a 96% match among the operations in the SKAR. As the information to the registers is provided at different levels, on the one hand by administrative departments and on the other by health care staff, a systematic error where no information is provided to both registers seems unlikely. In recent years the PAS has apparently captured a larger number of primary knee arthroplasties and revisions than the voluntary and more comprehensive SKAR. Ideally, the PAS could be expanded to include the information contained in various specialty registers. However, the complexity of such a database is prohibitive because of the different needs of the specialties, changes in medical treatment and in focus of interest. However, it has been discussed (Werkmeister and Ramshaw 1995) whether reimbursement in some way should be linked to delivery of a minimal data set of information for implants regarding type of implant, treatment and complications. Data could be gathered by the health authorities while the specialties decide which data could be requested and analyzed. The implications of our study are that national registers should be augmented by some form of mandatory reporting. However, we do not believe that a general health register can replace the SKAR for gathering relevant data, and especially for evaluating different prosthetic designs and complications.

The value of a national census system such as the NCR is clearly demonstrated by the fact that less than 1% of patients registered in the SKAR were not found.

93% of living patients answered the questionnaire regarding reoperation. This is a high rate of response for a postal survey (Asch and Christakis 1994, McHorney et al. 1994, Plant et al. 1996) and suggests that patients with knee arthroplasty are positive to inquiries regarding the operation and that the procedure has been a major event in their lives.

We found that 20% of revisions had not been reported to the SKAR and that the reporting had declined with time (Table 2). The types of revisions that were forgotten most often concerned amputations, extractions and arthrodeses or relatively minor surgery such as partial or patella revisions (Table 4). The reasons may be that they are more often caused by infections and the patients therefore were not admitted to orthopedic wards, and the minor revisions may have been forgotten.

Of the different types of primary arthroplasty, revisions of TKAs were more often missed than those of UKAs (Table 5). This may be because patients with TKA are more prone to complications (Bengtson and Knutson 1991, Knutson et al. 1994) and more often subject to partial or patellar revisions (Robertsson et al. 1999b). Moreover,

during recent years, some UKA implants have been the focus of attention (Lindstrand et al. 1992, Lewold et al. 1995), which has led to greater scrutiny regarding gathering of reports on revisions.

The decline in reporting revisions many partially be explained by the sharp increase in the number of procedures, which has led to changes in reporting routines, and changed knee arthroplasty from being an uncommon procedure into a routine operation no longer requiring close monitoring and follow-up.

In summary, we found that 1.7% of the responding knee cases previously registered as unrevised had, in fact, been revised, but not reported to the register. This amounted to one fifth of all revisions and resulted in an increased CRR (Figure 1). These numbers remind us of the importance of taking into account patients lost to follow-up when using survival curves for statistical evaluation (Carr et al. 1993, Dorey et al. 1993, Murray et al 1993). However, apart from a generally higher Cumulative Revision Rate, we do not find that, taking the missing revisions into account changes the general conclusions regarding survivorship reported from the SKAR in recent years.

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