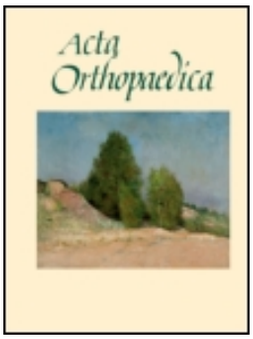

Acta Orthopaedica

ISSN: 1745-3674 (Print) 1745-3682 (Online) Journal homepage: informahealthcare.com/journals/iort20

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To cite this article: Mark T Dillon, Christopher F Ake, Mary F Burke, Anshuman Singh, Edward H Yian, Elizabeth W Paxton & Ronald A Navarro (2015) The Kaiser Permanente Shoulder Arthroplasty Registry, Acta Orthopaedica, 86:3, 286-292, DOI: 10.3109/17453674.2015.1024565

To link to this article: https://doi.org/10.3109/17453674.2015.1024565

The Kaiser Permanente Shoulder Arthroplasty Registry

Results from 6,336 primary shoulder arthroplasties

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Submitted 2014-07-03. Accepted 2014-12-15.

Background and purpose — Shoulder arthroplasty is being performed in the United States with increasing frequency. We describe the medium-term findings from a large integrated healthcare system shoulder arthroplasty registry.

Patients and methods — Shoulder arthroplasty cases registered between January 2005 and June 2013 were included for analysis. The registry included patient characteristics, surgical information, implant data, attrition, and patient outcomes such as surgical site infections, venous thromboembolism, and revision procedures.

Results — During the study period, 6,336 primary cases were registered. Median follow-up time for all primaries was 3.3 years; 461 cases were lost to follow-up by ending of health plan membership. Primary cases were predominantly female (56%) and white (81%), with an average age of 70 years. The most common reason for surgery was osteoarthritis in 60% of cases, followed by acute fracture (17%) and rotator cuff tear arthropathy (15%). In elective shoulder arthroplasty procedures, 200 all-cause revisions (4%) were reported, with glenoid wear being the most common reason.

Interpretation — Most arthroplasties were elective procedures: over half performed for osteoarthritis. Glenoid wear was the most common reason for revision of primary shoulder arthroplasty in elective cases.

In the period 2000 through 2010, over 200,000 shoulder arthroplasties were performed in the USA for osteoarthritis (Trofa et al. 2014). With the increasing use of shoulder arthroplasty (SA) over the past decade (Kim et al. 2011) and projections that future growth rates of SA may exceed those of hip and knee arthroplasty (Day et al. 2010), the need to track the outcomes of SA is becoming increasingly important.

Arthroplasty registries provide an important mechanism for tracking surgical outcomes. In the fields of total hip arthroplasty and total knee arthroplasty, registries have demonstrated their importance in monitoring revisions, complications, and mortality, identifying outlier prostheses, and improving quality of care (Graves et al. 2004, Herberts and Malchau 2000, de Steiger et al. 2013, Paxton et al. 2010). SA registries have also provided critical information about demographics, survival, and outlier implants, though there have been considerably fewer publications from the younger national SA registries than from the more established hip and knee registries (Clitherow et al. 2014, Young et al. 2013, Rasmussen et al. 2012a, Rasmussen et al. 2014a and b, Fevang et al. 2009, Fevang et al. 2013). The lack of a national US registry emphasizes the need to use existing US registries to conduct international comparisons of SA patients, implants, surgical techniques, and outcomes. We present the medium-term findings of a large integrated healthcare system SA registry.

Material and methods

Data collection procedures and participants

Kaiser Permanente is a large integrated healthcare system based in California, USA. In 2001, Kaiser Permanente started a total joint replacement registry, focusing on a minimal dataset and revision surgery as the endpoint. Its success led to the formation of other registries, including the Kaiser Permanente Shoulder Arthroplasty Registry (KPSAR) (Paxton et al. 2012).

Starting in April 2010, surgeons have collected intraoperative information on paper forms to send to the registry. This information on paper is validated and supplemented with information from the institution's electronic medical records (EMRs) using electronic algorithms and queries. Cases from

DOI 10.3109/17453674.2015.1024565

January 2005 through March 2010 have been incorporated into the registry by retrospective review of EMR information.

Registry data components

Patient factors captured by the registry include age, sex, race, diagnosis, BMI, American Society of Anaesthesiologists' (ASA) score, and medical comorbidities. Surgical factors recorded in the registry include the type of procedure performed (total shoulder arthroplasty (TSA), humeral head resurfacing (HHR), reverse total shoulder arthroplasty (RSA), hemiarthroplasty (HEMI)), implanted components, fixation, surgical approach, bone graft, subscapularis repair, anesthesia, blood loss, operative time, and length of stay. Surgeon characteristics captured include fellowship status and calculated annual case volume. Hospital annual volume is also included.

The registry captures a number of postoperative complications. Data on death (30- and 90-day mortality) are obtained from an administrative database that monitors the institution's membership and information about use of the service. International Classification of Disease, Ninth Revision, Clinical Modification codes (ICD-9-CM) (Buck 2010) are used to identify suspected complications; all such cases are audited through chart review by clinical content experts to determine if they meet pre-established criteria. These outcomes include deep infection (following National Healthcare Safety Network/Centers for Disease Control guidelines (Horan et al. 2008) with extended surveillance time for the lifetime of the implant), deep vein thrombosis and pulmonary embolism (DVT/PE) monitored within 90 days of surgery (using the Agency for Healthcare Research and Quality Inpatient Quality Indicators Algorithm (Department of Health and Human Services 2007)), and implant revision. Revisions, defined here as any procedure after the registered index arthroplasty involving the addition, removal or replacement of at least 1 implanted component, are captured together with reasons for revision and validated by chart review. HHR procedures and reverse total shoulder procedures are distinguished from other procedures, and patients with a history of fracture are identified through details on the operative paper forms. Missing data concerning identification of the patient or surgeon, procedure type with laterality, and primary diagnosis are reviewed and coded using chart review methodology for comprehensive data and 100% capture.

Attrition of the cohort is monitored using the membership files of the integrated healthcare system that this registry covers. Biannual reports monitoring both termination of membership in the health plan and mortality in the enrolled cohort are obtained from the institution and integrated with the registry. For this study, attrition is defined as a patient ending his/her health plan membership or dying before the end of June 2013.

Study design

SA cases between January 2005 and June 2013 were included for analysis. This study examined primary procedures from 2 of 6 regions in the healthcare system (Southern California and Northern California) with a combined patient population of well over 7 million members (Kaiser Permanente 2014). The population covered by Kaiser Permanente has been shown to be representative (Karter et al. 2002, Khatod et al. 2008, Koebnick et al. 2012) of the 37 million inhabitants of the state of California (United States Census Bureau 2015). While 6 regions participated in the registry during the study period, the other 4 regions (Hawaii, Pacific Northwest, Mid-Atlantic, Colorado) each represent much smaller case volumes and also later entry into the registry. The final study sample includes data from 32 medical centers and 263 participating surgeons, all in California.

All biological glenoid resurfacing procedures were excluded from the study. Individuals with primary diagnoses of cancer and/or infection were also excluded. Patients who had surgery secondary to acute fracture were evaluated separately from those undergoing elective surgery, as it was felt that trauma patients may represent a different patient demographic.

For this study, we developed a hierarchy to apply to cases with more than 1 diagnosis listed for the index procedure, in order to identify the primary diagnosis (i.e. the principal reason to be reported). All index cases with multiple diagnoses were reviewed by a registry surgeon to ensure the clinical accuracy of the primary diagnosis hierarchy. In contrast, more than 1 reason for revision could be reported for study purposes (for example, rotator cuff tear and glenoid component loosening).

Ethics

Institutional review board approval was obtained prior to the inception of the registry (Kaiser Permanente Southern California Institutional Review Board, study 5527).

Results

Demographics

6,336 cases met the inclusion criteria (Table 1), comprising 2,179 HEMIs (34%), 191 HHRs (3%), 940 RSAs (15%), and 3,026 TSAs (48%). Female members comprised 56% of all cases, and the mean overall age was 70 years. HHR patients were younger on average (mean 59 years) whereas RSA patients were generally older (mean 75 years). Whites represented 81% of all cases. Mean BMI of all cases was 30. On average, cases had 3.3 years of follow-up. Overall, 461 cases (7%) were lost to follow-up before the end of the study period, due to termination of membership in the health plan. Of the 6,336 cases altogether, 5,291 (84%) were elective, made up of 1,218 HEMIs (23%), 191 HHRs (4%), 868 RSAs (16%), and 3,014 TSAs (57%). There were 1,045 acute fracture cases, which included 961 HEMIs (92%), 72 RSAs (7%), and 12 TSAs (1%).

Table 1. Demographics for primary shoulder arthroplasty. All rows are number or percentage unless otherwise specified

	Total sample n = 6,336		HEMI n = 2,179		HHR n = 191		RSA n = 940		TSA n = 3,026		Elective n = 5,291		Fracture n = 1,045	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gender														
Missing	29	0.5	3	0.1	0	0	6	0.6	20	0.7	28	0.5	1	0.1
Male	2,747	43	817	38	115	60	302	32	1,513	50	2,498	47	249	24
Female	3,560	56	1,359	62	76	40	632	67	1,493	49	2,765	52	795	76
Mean age (SD), years	70	11	68	12	59	12	75	7.6	69	9.1	69	10	71	12
Race														
Asian/Pacific islander	154	2.4	55	2.5	4	2.1	28	3.0	67	2.2	118	2.2	36	3.4
Black	299	4.7	93	4.3	19	10	40	4.3	147	4.9	274	5.2	25	2.4
Native American	16	0.3	10	0.5	0	0.0	1	0.1	5	0.2	10	0.2	6	0.6
Missing	55	0.9	16	0.7	1	0.5	5	0.5	33	1.1	49	0.9	6	0.6
White	5,154	81	1,753	81	147	77	737	78	2,517	83	4,321	82	833	80
Hispanic	606	9.6	229	10.5	20	11	125	13	232	7.7	480	9.1	126	12
Other	52	0.8	23	1.1	0	0	4	0.4	25	0.8	39	0.7	13	1.2
Mean BMI (SD)	30	6.5	30	7.2	31	7.0	29	5.8	30	6.1	30	6.2	30	7.8
BMI category														
< 30	3,551	56	1,222	56	96	50	622	66	1,611	53	2,971	56	580	56
≥ 30 and < 35	1,485	23	479	22	50	26	189	20	767	25	1,254	24	231	22
≥ 35	1,208	19	441	20	45	24	120	13	602	20	990	19	218	21
Missing	92	1.5	37	1.7	0	0.0	9	1.0	46	1.5	76	1.4	16	1.5
ASA category														
1 or 2	3,106	49	1,066	49	107	56	372	40	1,561	52	2,670	51	436	42
≥ 3	2,675	42	948	44	65	34	467	50	1,195	40	2,153	41	522	50
Missing	555	8.8	165	7.6	19	10	101	11	270	8.9	468	8.9	87	8.3
Mean follow-up (SD), days	1,196	838	1,398	846	1,348	789	856	708	1,147	832	1,187	839	1,245	833
Membership termination														
No termination	5,875	93	1,974	91	165	86	899	96	2,837	94	4,927	93	948	91
Termination	461	7.3	205	9.4	26	14	41	4.4	189	6.3	364	6.9	97	9.3

Primary diagnoses

The principal diagnosis was osteoarthritis in 60% of all cases, including 94% of TSAs (Table 2). Fracture was the principal diagnosis for 17% of all cases: 44% of HEMIs, 8% of RSAs, and 0.4% of TSAs. In 15% of all cases rotator cuff arthropathy (RCA) was the principal diagnosis, including 85% of RSAs, 13% of HHRs, and 6% of HEMIs. Overall, osteonecrosis applied to 2.6% of cases, with rheumatoid arthritis assigned to only 1.4% of cases.

Table 2. Primary diagnosis for shoulder arthroplasty

	Total sample n = 6,336		HEMI n = 2,179		HHR n = 191		RSA n = 940		TSA n = 3,026	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Osteoarthritis	3790	60	818	38	130	68	6	0.6	2836	94
Proximal humerus fracture	1045	17	961	44	0	0	72	7.7	12	0.4
Rotator cuff arthropathy	949	15	129	5.9	25	13	795	85	0	0
Osteonecrosis – avascular necrosis	167	2.6	91	4.2	21	11	3	0.3	52	1.7
Rheumatoid arthritis	89	1.4	32	1.5	1	0.5	0	0.0	56	1.9
Failed ORIF	73	1.2	45	2.1	2	1.1	17	1.8	9	0.3
Non-union	49	0.8	32	1.5	0	0.0	12	1.3	5	0.2
Malunion	48	0.8	25	1.2	2	1.1	9	1.0	12	0.4
Posttraumatic arthritis	46	0.7	16	0.7	3	1.6	0	0.0	27	0.9
Rotator cuff tear	34	0.5	10	0.5	1	0.5	23	2.5	0	0.0
Chronic dislocation	22	0.4	15	0.7	3	1.6	3	0.3	1	0.0
Non-rheumatoid inflammatory arthritis	16	0.3	5	0.2	1	0.5	0	0.0	10	0.3
Capsulorrhaphy arthropathy	11	0.2	3	0.1	2	1.1	0	0.0	6	0.2
Other	6	0.1	3	0.1	1	0.5	2	0.2	0	0.0

Outcomes

There were 200 all-cause revisions in the elective patient population (4%) (Table 3). The most common reason was glenoid arthritis wear in 53 cases (27%). Among the HEMI revisions, glenoid wear was a reason for revision in 52% of cases, and it was a reason for revision in 78% of HHR revisions. In the elective procedures (Table 4), there were 56 instances of deep infection (1.1%); these occurred more commonly among RSAs (2.4%). Similarly, there were 25 DVTs (0.5%) and 20

Table 3. Reasons for revision after elective primary shoulder arthroplasty. One procedure could have several reasons for revision

	Total n = 200 n (%)	HEMI n = 75 n	HHR n = 18 n	RSA n = 44 n	TSA n = 63 n
Glenoid wear	53 27	39	14	0	0
Deep infection	40 20	6	1	15	18
Instability	36 18	8	1	16	11
Rotator cuff tear	33 17	10	1	0	22
Glenoid component failure	26 13	0	0	6	20
Humeral component loosening	12 6	9	0	1	2
Painful HEMI with cuff dysfunction	11 6	11	0	0	0
Malposition	11 6	4	1	1	5
Periprosthetic fracture	3 2	1	0	1	1
Other	9 5	1	1	5	2

Table 4. Outcomes after elective primary shoulder arthroplasty

n (%)	Total n = 5,291 n (%)	HEMI n = 1,218 n (%)	HHR n = 191 n (%)	RSA n = 868 n (%)	TSA n = 3,014
Deep infection	56 1.1	13 1.1	1 0.5	21 2.4	21 0.7
DVT	25 0.5	4 0.3	1 0.5	5 0.6	15 0.5
PE	20 0.4	0 0.0	1 0.5	6 0.7	13 0.4
Revision for any reason	200 3.8	75 6.2	18 9.4	44 5.1	63 2.1
Revision (aseptic)	160 3.0	69 5.7	17 8.9	29 3.3	45 1.5
Death (30 days)	9 0.2	1 0.1	0 0.0	2 0.2	6 0.2
Death (90 days)	16 0.3	3 0.3	0 0.0	3 0.4	10 0.3

Table 5. Reasons for revision after primary shoulder arthroplasty for acute fracture. One procedure could have several reasons for revision

	Total n = 31 n	HEMI n = 30 n	RSA n = 1 n
Deep infection	11	11	0
Instability	7	6	1
Glenoid wear	5	5	0
Rotator cuff tear	5	5	0
Humeral component loosening	3	3	0
Other	4	3	1

Table 6. Outcomes after primary shoulder arthroplasty for acute fracture

	Total n = 1,045 n (%)	HEMI n = 961 n (%)	RSA n = 72 n
Deep infection	15 1.4	15 1.6	0
DVT	8 0.8	6 0.6	2
PE	10 1.0	10 1.0	0
Revision for any reason	31 3.0	30 3.1	1
Revision (aseptic)	20 1.9	19 2.0	1
Death (30 days)	11 1.1	10 1.0	1
Death (90 days)	17 1.6	16 1.7	1

PEs (0.4%). The 90-day mortality rate in the elective patient population was 0.3%.

There were 31 all-cause revisions in fracture patients (Table 5), resulting in a revision rate of 3%. The most common reason for revision was deep infection (11 revisions), while instability was the second most common reason for revision in fracture patients. In acute fracture cases (Table 6), there were 15 instances of deep infection (1.4%) and all of these occurred in HEMI patients. There were 8 DVTs (0.8%), 6 of which occurred in HEMI patients (0.6%). The 90-day mortality rate was 1.6%.

Discussion

To our knowledge, this study covering the Kaiser Permanente population residing in California is one of the largest ever to be published from a shoulder arthroplasty registry. Four-fifths of the patients who received SA were whites. In comparison, Jain et al. (2006) noted that roughly nine-tenths of patients undergoing SA in the USA from 1990 through 2000 were of white race. It is unknown whether our data represent improved access to SA by minority populations or whether this difference simply represents the diversity of our patient population

in California. The average age of patients in our study is comparable to that in other studies examining the US population (Jain et al. 2006, Adams et al. 2006) and to those based on studies from other national shoulder replacement registries (Rasmussen et al. 2012a, Fevang et al. 2013, Young et al. 2013, Clitherow et al. 2014).

Similarly to other studies examining US based populations (Adams et al. 2006, Jain et al. 2006, Day et al. 2010, Kim et al. 2011), we found that the majority of patients undergoing SA are females (56%). However, this difference may be lessening with time. A study by Adams et al. (2006) examining the incidence of SA in Olmstead County, Minnesota between 1976 and 2000 contained over 65% female patients. Jain et al. (2006) reported on 12,758 patients from Nationwide Inpatient Sample databases from between 1990 and 2000. From 1990–1993, 66% of the patients were female, as compared to 63% from 1994–1997 and 57% from 1998–2000. It is interesting to note, however, that patient populations outside of the USA continue to show that a high percentage of female patients undergo shoulder replacement. In 2012, the Danish registry published its early findings and reported that 70% of primary SAs were performed on women (Rasmussen et al. 2012a), while a recent study from Norway found that 85% of patients undergoing RSA were female (Fevang et al. 2013).

Few studies have evaluated SA and obesity (Li et al. 2013, Griffin et al. 2014). In our cohort, 19% of the patients had a BMI of 35 or more. In their recent study, Griffin et al. (2014) noted that 7.5% of patients undergoing shoulder replacement in the USA are obese, with 1.8% being categorized as morbidly obese (BMI of 40 or over).

As with our findings, other reports from within the USA have shown osteoarthritis to be the most common reason for shoulder replacement (Adams et al. 2006, Jain et al. 2006, Kim et al. 2011). The percentage of cases with osteoarthritis as the primary diagnosis appears to be increasing. Jain et al. (2006) noted that osteoarthritis was the primary diagnosis in 57% of cases during the period 1990–1993, increasing to 71% during 1998–2000.

TSA was the most commonly performed procedure in our study. The procedures performed on 48% of the cases in the KPSAR were TSA, and osteoarthritis was the primary diagnosis in 94% of these cases. HEMI was performed in 34% of cases, with fracture being the most common reason in 44% of cases, followed by osteoarthritis in 38% of cases. Using the Nationwide Inpatient Sample, Kim et al. (2011) reported that osteoarthritis was the most common diagnosis for both HEMI (43% of cases) and TSA (77% of cases) between 1993 and 2008. During this period, Kim et al. also demonstrated that while the annual rate of HEMIs increased, the rate of TSAs increased at a much higher rate. However, it should be noted that due to the fact that TSA and RSA cannot be distinguished using ICD-9-CM codes, much of this increase in the incidence of TSAs was judged to be due to approval of the RSA by the United States Food and Drug Administration during the study period.

Interestingly, our registry showed much more frequent use of TSA than some registries have reported in the international literature, such as in Norway, where, after examining 1,825 SA patients, only 69 TSAs were performed (Fevang et al. 2009). Likewise, the Danish Shoulder Arthroplasty Registry reported that TSA was used in only 3% of the cases (Rasmussen et al. 2012a). It should be noted that the major indication for SA in the Danish registry was displaced proximal humerus fracture (54%), as compared to only 17% in the present study. These findings suggest that the indications for elective arthroplasty procedures differ in various parts of the world. This may lead to future collaboration to compare the use of SA globally.

Our all-cause revision rate for elective SA was 4%, with the most common reason for revision being glenoid wear following HEMI or HHR (27% of all revisions). Looking specifically at elective HEMI, the revision rate was 6% with glenoid wear as the reason for revision in 52% of cases, while the revision rate following TSA in particular was only 2%. Previous studies from the KPSAR have examined the effect of age on early to medium-term revision rates, and have found that patients less than 60 years of age receiving a HEMI had an almost 5 times higher risk of revision than those patients who received TSA (Dillon et al. 2013).

Our overall infection rate was 1.1% for elective cases and 1.4% for traumatic cases, though not all deep infections led to formal revisions. A recent study from our registry revealed that males have a more than 2.5 times greater risk of infection, and the risk of infection decreases 5% with every 1 year of additional age (Richards et al. 2014). We have also examined our rates of venous thromboembolism, with an early paper suggesting a trend of increased DVT/PE in patients undergoing arthroplasty for trauma (Navarro et al. 2013), a trend that appears to be supported by our most recent data.

The major strength of the present study is the quality of the data. The registry collects data from over 90% of surgeons in the health system, and participation is increasing at a steady rate every year. With a high rate of participation among many surgeons across several medical centers, our findings can be generalized to larger community-based populations more accurately than results from studies consisting of cases from few surgeons at a single institution.

All the data are actively monitored on a case-by-case basis and go through a systematic quality-control process each quarter to ensure that there is a high level of integrity of the data, and to reduce information bias. Quality-control processes include an integrated set of queries, programming, and chart review methodology to catch outliers, to validate data, and to capture missing values. To maintain clinical accuracy, registry surgeons lead efforts to develop and validate data-cleaning procedures. As the registry matures, we continually evaluate our collection methods in order to better refine our data. Chart review is performed, and a new diagnosis or reason for revision can be assigned if it more accurately reflects the data.

One weakness of the present study may be the lack of outcome scores. It should be noted that there is no consensus regarding the use of patient-reported outcomes in registries, as demonstrated in a recent review of the national shoulder replacement registries by Rasmussen et al. (2012b). All 7 registries used implant survival as the primary outcome, but only 5 used or plan to use outcome measures. Only the Swedish registry obtains baseline scores, and only at certain participating centers, with the UK also planning to obtain preoperative scores. (Starting in July 2010, the KPSAR began collecting VAS pain and VAS function scores preoperatively). Furthermore, even when the decision is made to obtain patient-reported outcomes, achieving adequate patient participation can be challenging (Polk et al. 2013, Fevang et al. 2013). The Danish registry recently noted that only 65% of patients initially returned their follow-up evaluations, with follow-up telephone calls or mailings being required to improve response rates (Polk et al. 2013).

Admittedly, using implant survival alone fails to capture patients with underperforming SAs who simply decline revision surgery. A recent study examining the outcomes of SA following proximal humerus non-unions noted that 12 patients out of 67 in the study underwent reoperation. However, 24 other patients had unsatisfactory outcomes but declined revision surgery. As a result, the authors advised that "caution should be exercised when using survivorship analysis as a prognostic indicator of outcome" (Duquin et al. 2012).

In summary, we have presented the current findings from the Kaiser Permanente Shoulder Arthroplasty Registry. We hope that with time, we will be able to better examine implant survivorship and factors influencing revision for individual reasons, such as glenoid component failure. Future directions include more specific examinations of unique patient populations, such as those undergoing SA for fracture or for elective purposes.

MD: conception of the study, interpretation of data, and manuscript preparation. CA: statistical analysis and manuscript preparation. MB: data processing and manuscript preparation. AS and EY: interpretation of data and manuscript preparation. EP: conception of the study and manuscript preparation. RN: conception of study and interpretation of data.

No competing interests declared.

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