Comparison of Community-Based ACL Reconstruction Registries in the U.S. and Norway

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Introduction: Joint registries have demonstrated value as a resource for the study of large numbers of patients, providing the opportunity to study rare occurrences and identify early failures of surgical procedures. Anterior cruciate ligament (ACL) reconstruction registries have been established in Norway and the U.S. In this study, we compared the preoperative characteristics of the Norwegian National Knee Ligament Registry (NKLR) and the Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry (KP ACLRR) cohorts.

Methods: A cross-sectional comparison of the NKLR and KP ACLRR cohorts registered between 2005 and 2010 was performed. Aggregate level data including preoperative patient characteristics, mechanisms of injury, preoperative Knee Injury and Osteoarthritis Outcome Score (KOOS), intraoperative findings, and adjusted revision rates were shared between the two registries, and a descriptive analysis was conducted.

Results: During the study period, 10,468 primary ACL reconstructions were entered in the NKLR and 10,394, in the KP ACLRR. The age at the time of surgery was similar between the two cohorts (twenty-seven years in the NKLR versus twenty-eight years in the KP ACLRR), although the KP ACLRR had a higher proportion of males (65% versus 58%, $p < 0.001$). The revision rate per follow-up year was 0.9% in the NKLR and 1.5% in the KP ACLRR. Soccer was the most common mechanism of injury in both registries (40.0% in the NKLR and 26.6% in the KP ACLRR). The preoperative KOOS was statistically different, but the difference was not clinically relevant (defined as a change of >10 points). A higher prevalence of meniscal tears was seen in the KP ACLRR (61% versus 49%, $p < 0.001$).

Conclusions: Baseline findings are so congruent between the NKLR and the KP ACLRR cohorts that comparisons between these two registries will likely provide information to the orthopaedic community that can be generalized.

Implant device registries, like disease registries[1], can greatly contribute to the scientific community[2-4]. Registries can provide continuous surveillance of the implant performance for recalls or complications and can be used to assess patient-reported outcomes over time. Within orthopaedics, hip and knee arthroplasty registries have a thirty-year history of contributions to scientific knowledge. Anterior cruciate ligament (ACL) reconstruction is one of the most studied procedures in orthopaedics, but there are many unanswered questions that cannot be easily evaluated with randomized controlled trials or meta-analyses.

Currently, the largest community-based knee ligament reconstruction registries in the world are located in Scandinavia[5] and the U.S.[6,7]. These registries were initiated in the mid-2000s and have similar follow-up protocols. Early reports from ligament registries have focused on the description of the ACL reconstruction population[5,6], description of the associations between the time from the injury to surgery and concurrent injuries[8], revision and reoperation procedures[9-11], and risk factors associated with complications[12].

Comparison of the Scandinavian registries' populations has already shown homogeneity of patient characteristics and incidence of overall reconstructions, but the heterogeneity of other variables, such as graft selection, thromboembolism prophylaxis, hospital encounter types (inpatient versus outpatient), and incidence of certain age-specific reconstruction[5],

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has not been well described. These similarities and differences provide the framework for future analysis of registry data, and ensure that results from independent and regionalized registries may be generalized. A comparison of the largest community-based ACL reconstruction registry in the U.S. and other existing registries has not been done. Possible collaborations among countries and registries may be beneficial for surveillance of registered grafts and implantable devices, risk factor assessment for complications in this population, and providing answers to specific research questions about small effect sizes, rare events, or specific subpopulations.

The purpose of this study was to compare the registered cohorts of the Norwegian National Knee Ligament Registry (NKLR) and Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry (KP ACLRR) with regard to baseline demographics, preoperative patient-reported outcomes, activities when injured, and concurrent injuries at the time of surgery. This study will serve as a baseline for understanding the differences and similarities between these two culturally and geographically different populations, and we will evaluate how this can be best incorporated into clinically useful prospective collaboration.

Methods

Internal Review Board and Regional Committee for Medical Research Ethics approval was obtained before this study was performed.

Data Sources

The NKLR was started in 2004, and by December 2010 11,217 cases had been registered. The NKLR covers the population of Norway (4.9 million people) and collects information at fifty-seven hospitals or surgery centers. It has reported high participation, with >85% voluntary participation since 2006[13].

TABLE I Population Demographics and Characteristics

	NKLR		KP ACLRR		
	N	% (95% Confidence Interval)	N	% (95% Confidence Interval)	P Value
Total registered cases	11,217	100	11,050	100	—
Primary ops. (included in analysis)	10,468	93.3 (92.8-93.8)	10,394	94.1 (93.6-94.6)	—
Revisions (total number of revisions in registry)	749	6.7 (4.9-8.5)	656	5.9 (4.1-7.7)	0.023
Revisions (of primary ops. in registry)	284	2.7 (0.8-4.6)	163	1.6 (0-3.5)	<0.001
Average follow-up time (range, years)	3.1	0-6.6	1.1	0-5	
Revision rate adjusted for person-years at risk	32,438	0.9 (0.8-1.0)	11,192	1.5 (1.2-1.7)	<0.001
Operative side, right	5336	51.0 (49.7-52.3)	5062	48.7 (47.3-50.1)	<0.001
Contralateral knee normal	8041	76.8 (75.9-77.7)	6140	59.1 (57.9-60.3)	<0.001
Prior surgery to index knee	—	—	544	5.2 (3.3-7.1)	—
Males	6016	57.5 (56.3-58.7)	6702	64.5 (63.4-65.6)	<0.001
Females	4452	42.5 (41.0-44.0)	3692	35.5 (34.0-37.0)	<0.001
Time to reconstruction (non-missing data)	9983	95.4	5530	53.0	—
	Median	SD	Median	SD	P Value
Time to reconstruction, months	8	41.23	5.0	36.7	<0.001*
Age at time of surgery, years	27.0	10.5	27.8	11.4	<0.001*
Age at time of injury, years	25.0	14.3	-	-	-
BMI, kg/m^2	24.7	3.6	26.2	5.0	<0.001*
Race	N	%	N	%	P Value
Asian	—	—	1052	10.1	—
Black	—	—	675	6.5	—
White	—	—	5629	54.2	—
Hispanic	—	—	849	8.2	—
Native American	—	—	117	1.1	—
Other	—	—	882	8.5	—
Unknown	—	—	1190	11.5	—

*P value based on means comparison. Data not shown.

The KP ACLRR covers 8.6 million members and collects information at forty-two district hospitals and surgery centers throughout eight U.S. geographical regions. From its implementation in 2005 to December 2010, at least 12,900 cases had been registered. The registry reports at least 90% compliance in 2010.

Data Collection

Data collection for the NKLR has been described previously[13]. In brief, this is a paper-based registry with anonymous contribution by surgeons from all of Norway. The patient's social security number is used as the unique identifier of the patient by the registry. The KP ACLRR also collects information at the time of surgery using paper forms, and its database is enhanced with electronic health-record data, which covers the whole population enrolled within the Kaiser Permanente integrated health-care system. The patient's electronic medical record number is the unique identifier used by this registry.

Primary ACL reconstruction cases registered in the NKLR from January 2005 to December 2010 and in the KP ACLRR from February 2005 to June 2010 were used in this analysis. The registries were used to identify patient characteristics, injury pathology at the time of the ACL reconstruction, preoperative knee-related patient-reported outcomes (measured with the Knee Injury and Osteoarthritis Outcome Score [KOOS]), knee function (measured with one question item, scored 1 to 10, with 1 being the lowest and 10 the highest), and activities at the time of injury. The time intervals for the collection of some of the information regarding activities at the time of injury and patient-reported outcomes differed between the registries and therefore different denominators are being compared.

Statistical Analysis

Aggregate level data were shared between registries. Tabulated data with volumes, proportions, means, medians, and standard deviations in Excel spreadsheets (Microsoft, Redmond, Washington) completed by both registries were circulated among registry leads. Chi-square and Fisher exact tests were applied to compare categorical variables, and independent t tests were used to compare continuous variables. Sensitivity analyses were carried out when data were missing for certain variables being compared. SAS (version 9.1.3; SAS Institute, Cary, North Carolina) was used to analyze the data, with $p < 0.05$ as the statistical threshold.

Results

During the study period, 11,217 ACL reconstructions were registered in the NKLR; 10,468 (93.3%) were primary reconstructions and 749 (6.7%) were revisions. In the KP ACLRR, 11,050 cases were registered, with 10,394 (94.0%) primary reconstructions and 656 (5.9%) revisions. The median ages of the cohorts were statistically different but clinically similar, with the median age in the NKLR being 27.0 years old and that in the KP ACLRR being 27.8 years old. The NKLR had a higher proportion of registered females (42.5% versus 35.5%, $p < 0.001$) and a lower median body-mass index (BMI) (24.7 versus 26.2 kg/m^2) than the KP ACLRR. The average duration of follow-up of the cohort was 3.1 years in the NKLR and 1.1 year in the KP ACLRR. The revision rate, adjusted for person-years at risk, was 0.9% (95% confidence interval [CI], 0.8% to 1.0%) in the NKLR and 1.5% (95% CI, 1.2% to 1.7%) in the KP ACLRR. See Table I for patient characteristics and procedure description.

Table II shows the activities at the time of the injury that led to the primary ACL reconstruction. The activities at the time of injury differed between the cohorts. The most common activity at the time of injury in the NKLR was soccer (40.0% of all cases), followed by skiing (16.4%) and team handball (14.6%). In the KP ACLRR cohort, the most common activity at the time of injury was soccer (26.6%), followed by basketball (17.1%) and skiing (9.1%). The "other" category (23.7%) in the KP ACLRR included falls (19.5% of the activities in the "other" category), volleyball (9.3%), dance injuries (8.8%), and skateboard accidents (4.3%). The KP ACLRR information is limited to cases recorded between July 2008 and June 2010. A significant proportion of KP ACLRR cases did not have the activity at the time of injury reported. A sensitivity analysis was carried out to determine whether the cases with injury information were

TABLE II Patient-Reported Activities When Patient Injured

	NKLR (N = 10,468)		KP ACLRR* (N = 6251)		
	N	% (95% Confidence Interval)	N	% (95% Confidence Interval)	P Value
American football	15	0.1 (0.0-1.7)	403	11.3 (8.2-14.4)	<0.001
Basketball	123	1.2 (0.0-3.1)	610	17.1 (14.1-20.1)	<0.001
Handball	1527	14.6 (12.8-16.4)	0	0	—
Soccer	4187	40.0 (38.5-41.5)	946	26.6 (23.8-29.4)	<0.001
Baseball	1	0.0 (0.0-0.0)	108	3.0 (0.0-6.3)	<0.001
Skiing	1719	16.4 (14.6-18.2)	324	9.1 (6.0-12.2)	<0.001
Martial arts	195	1.9 (0.0-3.8)	122	3.4 (0.2-6.6)	<0.001
Other	1923	18.4 (16.6-20.1)	843	23.7 (20.8-26.6)	<0.001
Motor-vehicle accident	318	3.0 (1.1-4.9)	156	4.4 (1.2-7.6)	<0.001
Work injury	269	2.6 (0.7-4.5)	51	1.4 (0.0-4.6)	<0.001
Not reported	191	1.8 (0.0-3.7)	2688	53.0 (51.1-54.9)	—

*KP ACLRR limited dataset: data point implemented in July 2008. KP ACLRR proportions for all sports are based on N = 3563, cases with data, as these proportions are most representative of the distribution of sports.

TABLE III Preoperative Patient Reported Outcomes*

	NKLR (N = 10,959)			KP ACLRR† (N = 1140)			
	N	Mean	SD	N	Mean	SD	P Value
KOOS: symptoms	8967	71.9	17.8	801	68.2	18.5	<0.001
KOOS: pain	8905	73.4	18.4	798	70.9	18.8	<0.001
KOOS: function in activity of daily living	8881	81.7	18.6	793	80.4	18.0	0.052
KOOS: function in sport and recreation	8826	41.8	26.9	758	46.8	28.6	<0.001
KOOS: knee-related quality of life	8907	34.3	18.2	796	31.1	20.5	<0.001
Knee function: prior to injury	—	—	—	637	9.1	2.1	—
Knee function: current	—	—	—	634	4.7	2.3	—

*KOOS = Knee Injury and Osteoarthritis Outcome Score; SD = standard deviation. †KP ACLRR limited dataset: three locations only, data point implemented in July 2008.

different from the cases without injury information, and no differences in revision rates, operative side, or sex were found.

The preoperative KOOS for the registry cohorts are shown in Table III. In all subscales of the KOOS (symptoms, pain, function in activity of daily living, function in sport and recreation, and knee-related quality of life), the cohorts had clinically similar average scores (no more than a 10-point difference). The average knee function score prior to injury (9.1, standard deviation [SD] = 2.1) and the current knee function score (4.7, SD = 2.3) in the KP ACLRR patients are also reported. Only a limited sample of patients had a KOOS recorded in the KP ACLRR (approximately 65% to 70% of patients, depending on KOOS subscale).

Table IV shows the concurrent injuries and intraoperative findings in each cohort. In the NKLR, 38.2% of the cohort had an isolated ACL injury, a rate that is significantly higher than that in the KP ACLRR (31.5%) ($p < 0.001$). The NKLR had a higher proportion of concurrent injuries to the posterior cruciate ligament (1.8% versus 0.9%), medial collateral ligament (6.1% versus 2.2%), and posterolateral corner (1.0% versus 0.5%) than the KP ACLRR (all $p < 0.001$). A higher proportion of KP ACLRR cases had meniscal pathology at the time of surgery (61.3% versus 48.5%, $p < 0.001$) and higher proportions of medial meniscal tears (40.3% versus 30.6%, $p < 0.001$), lateral meniscal tears (36.7% versus 24.1%, $p < 0.001$), and tears of both menisci (15.7% versus 9.3%, $p < 0.001$). A significantly

TABLE IV Concurrent Injuries and Intraoperative Findings*

	NKLR (N = 10,468)		KP ACLRR (N = 10,394)		
	N	% (95% Confidence Interval)	N	% (95% Confidence Interval)	P Value
Open physis	—	—	246	2.8† (0.7-4.9)	
Isolated ACL tear	3996	38.2 (36.7-39.7)	3271	31.5 (29.9-33.1)	<0.001
PCL injury	188	1.8 (0.0-3.7)	89	0.9 (0.0-2.9)	<0.001
MCL injury	642	6.1 (4.2-8.0)	224	2.2 (0.3-4.1)	<0.001
LCL injury	147	1.4 (0.0-3.3)	—	—	—
Posterolateral corner injury	108	1.0 (0.0-2.9)	52	0.5 (0.0-2.4)	<0.001
Other injury	44	0.4 (0.0-2.3)	93	0.9 (0.0-2.8)	<0.001
Meniscal pathology	5081	48.5 (47.1-49.9)	6370	61.3 (60.1-62.5)	<0.001
Medial meniscal tear	3208	30.6 (29.0-32.2)	4184	40.3 (38.8-41.8)	<0.001
Lateral meniscal tear	2520	24.1 (22.4-25.8)	3818	36.7 (35.2-38.2)	<0.001
Both menisci injured	971	9.3 (7.5-11.1)	1632	15.7 (13.9-17.5)	<0.001
Articular cartilage injury	2636	25.2 (23.5-26.9)	2414	23.2 (21.5-24.9)	<0.001
Meniscal and cartilage injury	1604	15.3 (13.5-17.1)	1801	17.3 (15.6-19.0)	<0.001

*PCL = posterior cruciate ligament; MCL = medial collateral ligament; and LCL = lateral collateral ligament. †Proportion is based on N = 8929. Data are missing for 1465 (14.1%) of cases.

higher proportion of articular cartilage injuries was reported by the NKLR (25.2% versus 23.2%, $p < 0.001$).

Discussion

Registries have demonstrated value as a resource for studying large numbers of patients, providing the opportunity to study rare occurrences and identify early failures. ACL reconstruction registries have been established in Norway, Sweden, Denmark, and the U.S. These registries may help shed light on factors associated with successes and failures of ACL reconstruction. Comparative studies of registry cohorts could provide insights into similarities and differences in patient characteristics, graft/implant usage, intraoperative procedures, and surgical outcomes. In order to compare findings between registries, it is imperative to understand the similarities and differences in patient demographics and patient characteristics within each cohort.

In the present study, we identified a number of similarities between the NKLR and the KP ACLRR. The two registries are of similar size and collect data in a similar fashion. Each registry is community-based, with multiple surgeons from multiple facilities contributing data. Greater than 85% of all ACL reconstruction cases performed within the respective patient populations have now been collected, which gives a representative data set for analysis and comparison. We also tried to determine the clinically relevant differences and similarities between the registry cohorts. The median ages of the patients were very similar, and the age distribution seemed parallel between the registries. Sex, however, was found to be differently distributed between cohorts, with a higher proportion of males in the KP ACLRR than in the NKLR (64.5% versus 57.5%). The greater percentage of females in the NKLR may be due to differences between the two cohorts with regard to the type of activities in which females typically participate or the numbers of females who engage in activities associated with a higher risk of ACL injury. Another interesting significant difference between the cohorts is the higher BMI seen in the KP ACLRR, which was at least 1.5 units higher than that in the NKLR cohort. While this could be attributed to the different racial distribution of these cohorts, it is most likely reflective of the overall populations of Norway and the U.S. We also found notable differences in the type of activities being performed at the time of injury. Although soccer was the most common sport at the time of injury in both registries, it accounted for 40% of the injuries in the NKLR and only 26.6% in the KP ACLRR. Team handball accounted for 14.6% of the cases in the NKLR but no cases in the KP ACLRR; likewise, basketball and American football combined accounted for 28.4% of the injuries in the KP ACLRR cohort and only 1.3% of those the NKLR cohort. This mirrors the athletic activity in the two countries. Team handball is a popular sport in Europe; American football is not played in Norway, and basketball is a small sport in the Scandinavian countries. Another characteristic that differed significantly between the cohorts was the adjusted revision rate, which was higher in the KP ACLRR than in the NKLR cohort. This difference was observed despite the similar revision burden of the populations (5.9% versus 6.7%) and is an area of interest for future studies on these registries.

Another area of difference was found in the associated injuries at the time of surgery; 48.5% of the NKLR patients compared with 61.3% of the KP ACLRR patients exhibited meniscal pathology at the time of surgery. It is known that an increased time to surgery increases the odds that meniscal pathology will be found at the time of surgery[8], but the time to surgery was shorter in the KP ACLRR cohort (five months versus eight months). It is possible that the difference in activity at the time of injury or sex differences may play a role in the injuries noted at the time of surgery. This highlights the importance of adjusting future analyses for sex and time to surgery when studying the impact of concurrent injuries on the outcomes of ligament reconstruction surgery.

We found the cohorts to be similar with regard to the preoperative KOOS in all domains (symptoms, pain, function in activity of daily living, function in sport and recreation, and knee-related quality of life). Although the overall numbers are statistically different, they are not clinically relevant. A clinically relevant difference is considered to be a change in score of ≥10 points, and all scores for the two groups were within 5 points of each other[14].

In a previous study by Magnussen et al., comparing the NKLR with the Multicenter Orthopaedic Outcomes Network (MOON), a number of differences were reported[15]. In that study, 713 patients from the seven academic centers comprising the MOON group were compared with 4928 patients from the NKLR. Differences were noted in age, sex, activity at the time of injury, time to surgery, preoperative KOOS symptoms score, and associated meniscal and cartilage injury at the time of surgery. Interestingly, the MOON group had a higher percentage of females (48%) and also a shorter time to surgery (2.4 months). Despite these differences, the incidence of meniscal injury was similar between the American cohorts (65% in the MOON and 61.3% in the KP ACLRR [as reported in our study]). This may be related to the sport at the time of injury, as both American registries had a large proportion of injuries sustained in basketball and American football. The fact that the KP ACLRR and the NKLR cohorts have more similarities than do the MOON group and the NKLR may be due to the fact that both the KP ACLRR and the NKLR are community-based registries encompassing a broad cross section of the population while the MOON group comprises ACL specialty surgeons at academic centers. It is possible that the surgeons participating in the MOON study may also see younger patients who are more eager to return to sports, which may account for the shorter time to surgery.

There are a number of limitations with any cohort comparison such as this study. Not all data in either registry were collected on all patients. In some cases, data collection implementation occurred at different times during the study, but sensitivity analysis did not show any bias as a result. The registry data set is limited to information that can be readily and reliably collected at the time of surgery; therefore, some important detailed information such as activity level prior to surgery is not available. There are racial differences between the two cohorts, with the NKLR comprising a fairly homogeneous population (race data are not currently collected by the NKLR

registry, but population statistics show a very homogeneous population constitution), whereas the KP ACLRR is comparatively racially diverse. If race is found in future studies to play a role in any of the outcomes of ACL reconstructive surgery, adjustments of the data will be needed. Different philosophies in treating ACL tears may also play a role in some of the differences noted. In Norway, a greater emphasis has been placed on injury prevention programs, especially for high-risk female athletes. Nonoperative treatment of ACL tears may also be more common in Norway. Since we do not have accurate data on the overall incidence of ACL injuries in the general populations, the impact of these differences cannot be determined at this time.

The strength of the registries lies in the number of patients who can be evaluated. The NKLR and the KP ACLRR have each enrolled over 11,000 patients. Similar data collection methods are employed with similar data elements along with routine follow-up, which allows for more reliable comparison between the two registries. Registry data are also based on a community-based sample and include information from all surgeons within the catchment area of the registry; these include both high and low-volume surgeons as well as knee ligament specialists and general orthopaedic surgeons.

Conclusion

The baseline findings are so congruent between the Norwegian Knee Ligament Registry and the Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry cohorts that comparisons between these two registries will likely provide information that can be generalized to the international orthopaedic community. ■

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