The Swedish National Anterior Cruciate Ligament Register

A Report on Baseline Variables and Outcomes of Surgery for Almost 18,000 Patients

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Background: The Swedish National Anterior Cruciate Ligament Register provides an opportunity for quality surveillance and research.

Purpose: The primary objective was to recognize factors associated with a poorer outcome at an early stage.

Study Design: Case series; Level of evidence, 4.

Methods: Registrations are made using a web-based protocol with 2 parts: a patient-based section with self-reported outcome scores and a surgeon-based section, where factors such as cause of injury, previous surgery, time between injury and reconstruction, graft selection, fixation technique, and concomitant injuries are reported. The self-reported outcome scores are registered preoperatively and at 1, 2, and 5 years.

Results: Approximately 90% of all anterior cruciate ligament (ACL) reconstructions performed annually in Sweden are reported in the register. Registrations during the period 2005-2010 were included (n = 17,794). After excluding multiligament reconstructions and reoperations, the male:female ratio was 57.5:42.5 for both primary (n = 15,387) and revision (n = 964) surgery. The cause of injury was soccer in approximately half the male patients and in one third of the female patients. All subscales of the Knee injury and Osteoarthritis Outcome Score (KOOS) were significantly improved 1, 2, and 5 years postoperatively in patients undergoing primary reconstructions. In terms of the KOOS, revisions did significantly less well than primary reconstructions on all follow-up occasions, and smokers fared significantly less well than nonsmokers both preoperatively and at 2 years. Patients who had concomitant meniscal or chondral injuries at reconstruction did significantly less well preoperatively and at 1 year in terms of most KOOS subscales compared with patients with no such injuries. At 5 years, a significant difference was only found in terms of the sport/recreation subscale. Double-bundle reconstructions revealed no significant differences in terms of all the KOOS subscales at 2 years compared with single-bundle reconstructions (114 double-bundle vs 5109 single-bundle). During a 5-year period, 9.1% (contralateral, 5.0%; revision, 4.1%) of the patients underwent a contralateral ACL reconstruction or revision reconstruction of the index knee. The corresponding figure for 15- to 18-year-old female soccer players was 22.0%.

Conclusion: Primary ACL reconstruction significantly improves all the subscales of the KOOS. Young female soccer players run a major risk of reinjuring their ACL or injuring the contralateral ACL; revision ACL reconstructions do less well than primary reconstructions, and smokers do less well than nonsmokers.

Keywords: anterior cruciate ligament; reconstruction; revision; register; KOOS; smokers

Today, national quality registers are being used in a number of medical specialties. This applies in particular in Scandinavia, where the Hip and Knee Arthroplasty Registers are 2 examples.6,16 The purpose of the hip and knee replacement registers is primarily to detect inferior implants at an early stage in order to abandon them. This is best accomplished through register studies involving a large number of patients. Until recently, there were no national registers for monitoring the functional outcome of knee ligament surgery, especially anterior cruciate ligament (ACL) reconstructions. Based on the evidence from the joint replacement registers, it can be presumed that a nationwide ACL register is of value. The primary goal should always be to try to answer questions using randomized controlled trials; however, this is not always possible.1 Large cohorts are valuable for the early identification of procedures and devices that result in early failure and thereby inferior functional outcome. Moreover,
large cohorts can be used to identify prognostic factors. These factors can then be correlated with both good and poor outcomes. The Swedish National ACL Register (www.aclregister.nu) was initiated in January 2005 and comprises patients undergoing ACL reconstructions, ACL revisions, or reoperations for other reasons. The register covers more than 90% of all ACL procedures performed annually in Sweden. The aim of the study was to report the baseline variables and the patient-based outcomes up to December 2010.

MATERIALS AND METHODS

The register is a general database that utilizes a web-based protocol. Age and gender are registered automatically based on the Swedish social security number. The protocol consists of 2 parts. The patient section includes the Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS is knee specific and covers knee-related quality of life (QOL) and function in sport and recreation (sport/rec), for example. The patient section is reported using the web-based protocol before the reconstruction as well as 1, 2, and 5 years after surgery. The web-based protocol includes several drop-down menus. If any answer is left out, the protocol warns that an answer is missing before registration is possible. The second section is surgeon based, where factors such as activity at injury, time from injury to reconstruction, graft selection, and fixation techniques are registered. Previous surgery on the reconstructed knee, the contralateral knee, and all concomitant injuries are also registered. All surgical procedures performed on the injured knee, including meniscal surgery (resection or repair) and treatment for chondral lesions, are reported. Revisions and reoperations for other reasons are registered as separate entries in the database and correlated with the primary ACL reconstruction procedure. The database complies with the Swedish legislation relating to data security, which means that a nonauthorized person can never gain access to the data.

Statistical Methods

Means ± standard deviations are reported for all the KOOS subscales. The Mann-Whitney U test is used to compare the KOOS values between subgroups, the Wilcoxon signed-rank test is used for the within-group comparisons, and the χ² test is used for dichotomous comparisons. The statistical significance was set at P < .05.

RESULTS

Up to 2010, 17,794 unique registrations had been included in the register. In the present study, 1443 registrations were excluded because they were multiligament reconstructions or reoperations other than revision ACL reconstructions. Primary or revision ACL reconstruction was performed on 16,351 patients for whom preoperative and perioperative demographic data were available and KOOS evaluations were available for 10,473 patients (64% of possible patients) preoperatively, 7493 patients (58% of possible patients) at 1 year, 5580 patients (49% of possible patients) at 2 years, and 1452 patients (40% of possible patients) at 5 years. Information with regard to smoking was included in the register from the year 2009 and was available for 4466 patients (4173 nonsmokers; 293 smokers). Double-bundle reconstructions were performed in 493 patients.

The male:female ratio was 57.5:42.5 in both primary (n = 15,387) and revision (n = 964) reconstructions. The

Figure 1. Time in months (mean) from injury to reconstruction during the years 2005-2010.

Figure 2. Use of hamstring tendon (HT) and patellar tendon (PT) autografts: proportions during the years 2005-2010.
The mean age at primary reconstruction was 25.3 ± 10.4 and 27.8 ± 9.2 years for female and male patients, respectively; the corresponding age at revision reconstruction was 26.2 ± 9.0 and 29.0 ± 8.4 years, respectively. The cause of injury was soccer in 48.7% of the male patients and in 35.8% of the female patients; floorball was the cause of injury in 9.5% of the male patients and alpine skiing in 16.1% of female patients. The time interval from injury to reconstruction for the period 2005-2010 is shown in Figure 1. In 2005, 81.8% of the primary reconstructions were performed using a hamstring tendon autograft, while in 2010, the corresponding figure was 96.1% (Figure 2). In 2005, a cortical button was used for fixation on the femoral side in 9.6% of the patients, while transfixation pins were used in 59.8%. On the tibial side, the fixation was performed using a metal or absorbable interference screw in 40.8% of the patients. In 2010, a cortical button was used for fixation on the femoral side in 58.9% of the patients, while transfixation pins were used in 18.7%. On the tibial side, the fixation was performed using a metal or absorbable interference screw in 53.6% of the patients.

Clinical Outcomes

All subscales of the KOOS were significantly improved at 1, 2, and 5 years postoperatively for primary reconstructions \((P < .001)\) (Figure 3). For revision reconstructions, all subscales of the KOOS were significantly improved at 1 and 2 years \((P < .05)\), apart from symptoms at 2 years \((P = .07)\) (Figure 4). At 5 years, only the sport/rec and knee-related QOL subscales were significantly improved compared with the preoperative values for the revisions \((P < .002)\). In terms of the KOOS, revisions had a significantly lower knee-related QOL than primary reconstructions before reconstruction \((P < .001)\). At all follow-up occasions, revisions fared significantly worse in terms of all the KOOS subscales compared with primary reconstructions \((P < .001)\) (Figures 3 and 4). At the time of primary reconstruction, 53.9% of the patients had 1 or more concomitant intra-articular injuries (meniscal: medial 25.2%, lateral 21.4%; chondral: 28.0%). The corresponding number for revision reconstructions was 59.4% \((P < .001)\). In terms of primary ACL reconstructions with associated intra-articular injuries, these patients did significantly less well preoperatively \((P < .001)\) and at 1 year in terms of all the KOOS subscales \((P < .035)\), except for pain at 1 year \((P = .15)\), compared with patients with no such injuries. At 5 years, a significant difference was only found

**Figure 3.** Knee injury and Osteoarthritis Outcome Score (KOOS; means ± standard deviations) for primary anterior cruciate ligament reconstructions preoperatively (Preop) and at 1, 2, and 5 years. ADL, activities of daily living; Rec, recreation; QOL, quality of life.

**Figure 4.** Knee injury and Osteoarthritis Outcome Score (KOOS; means ± standard deviations) for revision anterior cruciate ligament reconstructions preoperatively (Preop) and at 1, 2, and 5 years. ADL, activities of daily living; Rec, recreation; QOL, quality of life.
in terms of the sport/rec subscale ($P < .01$) (Figure 5). Preoperatively, double-bundle reconstructions had significantly lower values than single-bundle reconstructions in terms of all the KOOS subscales ($P < .04$), except for knee-related QOL. At 1 and 2 years, no significant differences were found, except for the sport/rec subscale at 1 year, which was significantly better for the single-bundle reconstructions ($P = .031$) (Figure 6). Smokers fared significantly less well than nonsmokers in terms of all the KOOS subscales preoperatively ($P < .001$) and at 2 years ($P < .01$) (Figure 7). At 1 year, a significant difference was only found in terms of activities of daily living (ADL) ($P = .0017$). During a 5-year period, 9.1% (contralateral, 5.0% [n = 106]; revision, 4.1% [n = 88]) of the patients included in 2005 underwent a contralateral ACL reconstruction or revision surgery of the index knee. The corresponding number for the group of 15- to 18-year-old female soccer players was 22.0% (contralateral, 10.2% [n = 12]; revision, 11.8% [n = 14]) ($P < .001$ vs all patients). For the group of 15- to 18-year-old male soccer players, the number was 9.8% (contralateral, 4.4% [n = 4]; revision, 5.4% [n = 5]) ($P = .02$ vs corresponding female subgroup).

DISCUSSION

To our knowledge, this is currently the largest study reporting the results after ACL reconstruction that has been published. The principal findings were that the overall results, in terms of the KOOS, after primary ACL reconstruction were satisfactory. The KOOS is a knee-specific, patient-related outcome measure validated for both the short- and long-term follow-ups of ACL reconstructions, meniscectomies, and posttraumatic osteoarthritis.20,21 The most sensitive subscales are sport/rec and knee-related QOL, and the least sensitive subscale is ADL, at least in terms of ACL-related problems. It has been suggested that 8 to 10 points represent a clinically relevant change in the KOOS over time.19 In the present study, the largest changes over time were seen in the subscales of sport/rec and knee-related QOL for both primary ACL reconstructions and revisions. In terms of absolute KOOS, as well as changes over time, they are similar to what has been reported from other Scandinavian register studies.5,14,15 In the present study, patients undergoing revision surgery had significantly poorer knee-related QOL than primary reconstructions before reconstruction. At all follow-up occasions, revisions fared significantly less well in terms of all the KOOS subscales compared with primary reconstructions. This finding is in line with previous studies reporting inferior results after revision surgery.13,14,27 In the present study, in terms of the sport/rec subscale, the difference between primary and revision reconstructions was approximately 15 points at 1 year, and it appeared to remain similar over time. Another interesting finding was that patients undergoing revisions displayed no significant improvements in terms of the subscales of symptoms, pain, and ADL at 5 years compared with the preoperative values. These results emphasize that it is important to provide information related to prognosis preoperatively for patients undergoing revision surgery.

The number of ACL reconstructions using a patellar tendon autograft is gradually decreasing in Sweden. In 2010, 96.1% of primary reconstructions were performed using a hamstring tendon autograft. The main reason for this is probably that a number of randomized studies have shown comparable results between these 2 graft types, apart from donor-site morbidity and anterior knee problems, which are more frequent after using a patellar tendon autograft.3,4,11,12 Moreover, the most common fixation method on the femoral side has changed from transfixation pins to cortical button fixation, probably as a result of the concept of anatomic ACL reconstruction, which involves drilling the femoral tunnel through the anteromedial (AM) portal. Using the AM portal technique, fixation is not as feasible using transfixation pins.
More than half the patients had 1 or more concomitant intra-articular injuries. The patients who underwent primary ACL reconstruction and had associated meniscal/cartilage injuries fared significantly less well preoperatively and at 1 year in terms of most KOOS subscales compared with patients without such injuries. At 5 years, a significant difference was only found in terms of the sport/rec subscale. However, the differences for all subscales preoperatively were relatively small (Figure 5). The present study can be compared with the study by Hjermundrud et al,17 who compared 30 patients with full-thickness cartilage lesions with a matched control group comprising 59 patients without cartilage injuries from the Norwegian National Knee Ligament Register. The authors’ most important findings were that a full-thickness cartilage injury did not lead to reduced knee function in ACL-deficient knees preoperatively, as evaluated by the KOOS. In the present study, the differences were also small for all subscales at 1 year, possibly representing a clinically nonrelevant difference. However, with concomitant intra-articular injuries, the risk of developing osteoarthritis over time is higher, especially if a meniscectomy is performed.18 The development of osteoarthritic changes could be one possible explanation for the statistically significant difference at 5 years with regard to function in the sport/rec subscale. However, a longer follow-up is needed to confirm a significant deterioration over time.

The relatively long time period from injury to surgery could have affected the reported outcome, as this has been shown to correlate to an increased number of meniscal and cartilage lesions at reconstruction.5 The reason for this lengthy interval is probably that in Sweden, many patients traditionally follow a rehabilitation protocol before the decision of ACL reconstruction is made for those patients who fail the conservative program.

During a 5-year period, 9.1% of the patients included in 2005 reported a contralateral ACL reconstruction or revision surgery on the index knee. The true incidence of graft failure or contralateral ACL injury is not known, as the register only includes performed reconstructions or revisions and obviously the number of failed ACL reconstructions and contralateral ACL injuries is higher. However, the definition of a failed ACL reconstruction and how to detect a failed ACL reconstruction vary between studies. Consequently, comparing studies is challenging. Salmon et al22 reported a 6% incidence of graft rupture or rupture of the normal ACL on the contralateral side after 5 years of follow-up. The same researchers reported a risk of as much as 30% of either rupture of the graft or the normal contralateral ACL in a cohort followed for 15 years.8 One major finding in the present study is that 22.0% of the 15- to 18-year-old female soccer players reported a revision or contralateral ACL reconstruction during a 5-year period, which was significantly more than the corresponding age-matched male subgroup reported. In line with the findings in the present study, earlier studies have reported higher risks of graft rupture or contralateral ACL injury with a return to high-level sports, especially pivoting sports, and with younger age.8,22,34,35 Some earlier studies have reported no difference in subsequent ACL injuries based on gender,8,22 whereas Shelbourne et al24 reported a higher incidence of subsequent ACL injuries in female patients, mostly in terms of a higher incidence of contralateral ACL injury. In the systematic review by Sward et al,25 the authors found strong evidence for sex being a risk factor for ACL injury in pivoting sports but no evidence that female patients overall are more susceptible to suffer a contralateral ACL injury. The findings in the present study show that female patients under 18 years of age returning to soccer constitute a subgroup with a significantly higher risk of subsequent ACL injuries.

Double-bundle reconstructions revealed no significant differences in terms of almost all the KOOS subscales compared with single-bundle reconstructions at both 1 and 2 years. One possible confounding factor is that patients undergoing double-bundle reconstructions had significantly lower KOOS preoperatively than patients undergoing single-bundle reconstructions. The reasons for these findings are unclear, especially as the differences in the KOOS are small. However, one possible explanation is a selection bias, as the surgeon may have preferred performing double-bundle reconstructions in patients describing more severe limitations. In overall terms, the present study is in line with previous studies that report a reduction in knee laxity but no major difference in patient-related outcome measures after double-bundle reconstruction compared with single-bundle reconstruction.23 However, like several previous studies, the Swedish National ACL Register includes no information on tunnel placement, and it is consequently impossible to further characterize the reconstructions as anatomic or nonanatomic. Moreover, these results also include the learning curve of several different surgeons across the country as the double-bundle procedure was introduced.

Smoking is associated with impaired wound healing26 and has been shown to be the single most important risk factor for the development of complications after arthroplasty of the hip and knee.17 Moreover, smoking has been reported to be a predictor of poorer patient-reported outcomes in ACL reconstruction.9,10 In line with this, smokers in the present study had significantly lower scores than nonsmokers in terms of all the KOOS subscales both preoperatively and at 2 years. One possible confounding factor is that the scores for the smokers were lower both preoperatively and at follow-up, and the improvement over time for all KOOS subscales seems to be similar for smokers and nonsmokers.

The strengths of the present study are the large number of patients that were included and that the evaluation of the results was performed by the patients. The major limitations are that no clinical or radiological follow-up was performed and that several patients were lost to follow-up. In terms of KOOS, the rate of nonresponders ranged from 36% (preoperatively) to 60% (5-year follow-up), which is a major limitation. However, no selection bias in terms of sex or age when comparing responders to nonresponders has been found in the register (unpublished data from the register).

Taken as a whole, the Swedish National ACL Register offers an opportunity for numerous future research projects. We hope that, by using the register, we shall be able to identify both superior and inferior techniques, implants, and grafts. Moreover, inferior features will be detected at an
earlier stage than would be the case if the surgeons had to experience good or inferior outcomes with a more limited number of patients. Every year, a written report is distributed to all participating clinics, hospital administrators, and representatives of the health care system in Sweden.

CONCLUSION

Primary ACL reconstruction significantly improves all the subscales of the KOOS for patients. Moreover, young female soccer players run a major risk of reinjuring their ACL or injuring the contralateral ACL, and revision ACL reconstructions do less well than primary reconstructions. Furthermore, smokers do less well than nonsmokers.

REFERENCES


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