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Risk factors associated with ACL registry compliance: can we predict who will follow-up?

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Abstract

Purpose The purpose of this study was to determine patient factors that influence patient compliance to fill out anterior cruciate ligament reconstruction (ACLR) registry forms.

Methods Patients prospectively enrolled in the ACLR registry at a single institution were retrospectively reviewed. Patients who were followed up for at least 6 months were included. Patients who did not fill out initial registry forms were excluded. Patients were asked to fill out forms preoperatively and at 6, 12 and 24 months postoperatively. The impacts of age, race, employment status, medical insurance, smoking status, driving distance to the hospital and importance to return to the same level of sporting activity were analyzed against patient compliance (yes/no) to complete registry forms at the respective follow-ups. Multivariate analysis was performed to analyze variables at 6 and 12 months postoperatively. The numbers of patients who were followed up for more than 24 months were too low to run a multivariate analysis, so only univariate analysis was performed on this cohort.

Results A total of 221 patients filled out the initial preoperative forms at least 6 months before data gathering was commenced and were included. At 6 months postoperatively, none of the variables significantly influenced patient compliance. At 12 months, younger age and longer driving distance to the hospital had a significant negative impact on compliance [OR per year: 0.92 (0.85–0.99), $p = 0.0237$; OR per mile: 1.01 (1, 1.01), $p = 0.0297$]. Patients who filled out registry forms at 6 months were significantly more compliant at 12 months postoperatively ($p < 0.0001$). At 24 months, the influence of age remained significant ($p = 0.0262$) and, additionally, patients who initially noted that it was important for them to return to the same level of sports were significantly less compliant ($p = 0.0367$).

Conclusion Younger age and longer driving distance to the hospital were significantly associated with less compliance to fill out ACLR registry forms at 12 months postoperatively. Patient perspectives on the importance to return to the same level of sports were inversely related to compliance at 24 months postoperatively. This information can be utilized to improve compliance in future studies as we have potentially identified patients that can be viewed as "at-risk" for registry noncompliance.

Keywords Hospital registry · Anterior cruciate ligament · Patient compliance

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Introduction

Injuries to the anterior cruciate ligament (ACL) are very common, and ACL reconstruction (ACLR) is one of the most frequently performed orthopedic procedures [1, 2]. The annual incidence of ACL tears is about 70 ACL tears per 100,000 persons [3]. Anterior cruciate ligament injuries and their management have been extensively studied. The high incidence of these injuries, their serious impact on patients and the frequently changing trends and concepts in ACLR make it a continuous topic of interest in the orthopedic literature. Most studies, however, focus mainly on surgical techniques and outcomes, while very few pay particular attention to analyzing and improving the methods of research to enhance validity and minimize variability in reported outcomes.

Pathology-driven registries, in general, play a pivotal role in monitoring the quality of clinical practice and provide a wide database that is vital for medical research. Despite being a valuable tool that is crucial to improve the standard of health care, registries are subject to various forms of bias [4]. Patient noncompliance to complete registry forms is a constant threat to the internal validity and generalizability of a registry, especially in registries in which patient-reported outcomes (PRO) largely contribute to the dataset that is gathered. Predicting and preventing noncompliance to fill out forms are important to improve the value and efficacy of registry-based data.

The purpose of this study was to identify patient-specific factors that influence patient compliance to fill out ACLR registry forms at 6, 12 and 24 months postoperatively after ACLR. We hypothesized that no patient-specific factors would be associated with compliance at all time points investigated.

Methods

Institutional review board (IRB) approval was obtained to prospectively enroll all patients undergoing ACLR in a single-institution ACLR registry since March 2015. All ACLR procedures were performed by fellowship-trained orthopedic sports medicine surgeons. In addition to the initial registry forms that were completed preoperatively, patients were asked to fill out similar forms at 6, 12 and 24 months postoperatively. Participation was voluntary, and an informed consent was taken from patients preoperatively. Forms were filled out either in person during outpatient visits, electronically or sent by mail. Forms included, but were not limited to, a demographic data survey (age, race, address, highest level of education, health insurance,

employment status and smoking status), in addition to International Knee Documentation Committee (IKDC) questionnaire, Knee Injury and Osteoarthritis Outcome Score (KOOS), Marx Activity Rating Scale and return to sports after injury scale. The binary question "is it important for you to return to the same level of sports you used to do before injury?" was included in the preoperative forms. All data were stored using research electronic data capture (REDCap) software (Nashville, TN, USA). In December 2017, data of all enrolled patients were retrospectively reviewed. Only patients who were followed up for at least 6 months were included, whereas those who did not fill out initial registry forms were excluded. The impacts of age, race, employment status, medical insurance, smoking status, driving distance to the hospital and importance to return to the same level of sports on patient compliance to fill out forms were analyzed.

Statistical analysis for categorical variables was performed using either Chi-square or Fisher's exact tests, while Wilcoxon signed-rank test was used to analyze continuous variables. Multivariate analysis was performed to analyze variables at 6 and 12 months. The numbers of patients who were followed up for more than 24 months were too low to run a multivariate analysis, so only univariate analysis was performed on this group. Statistical analysis was performed using SAS software (SAS Institute, Cary NC, USA).

Results

A total of 221 patients were included. All patients were followed up for 6 months or more, while 157 patients were followed up for 12 months or more, and 62 were followed up for 24 months or more. Overall rates of compliance to fill out forms were 50.2%, 59.9% and 24.2% at 6-, 12- and 24-month follow-ups, respectively. Among the patients who completed a 24-month follow-up, 22.6% were compliant at all time points.

At 6 months postoperatively, none of the variables significantly influenced patient compliance (Table 1). However, at 12 months postoperatively, younger age and longer driving distance to the hospital had a significant negative impact on compliance [OR per year: 0.92 (0.85–0.99), $p = 0.0237$; OR per mile: 1.01 (1, 1.01), $p = 0.0297$]. Patients who filled out registry forms at the 6-month follow-up were significantly more compliant at the 12-month follow-up ($p < 0.0001$) (Table 2). At 24 months postoperatively, the influence of age remained significant ($p = 0.0262$) (Table 3) and, additionally, patients who initially noted that it was important for them to return to the same level of sports were significantly less compliant ($p = 0.0367$) (Table 4).

Table 1 Variables affecting patient compliance to fill out ACLR registry forms at 6 months postoperatively

	Compliance [compliant/total (%)]	Multivariate analysis[a]	
		OR (95% CI)	*P*
Total	111/221 (50.2%)		
Age, per unit (year)	221	0.97 (0.93, 1.01)	0.1611
Race			
African American	10/40 (25%)	2.25 (0.88, 5.79)	0.0918
Caucasian	98/177 (55.4%)	1.00 referent	
Others	**3/4**		
Education			
Less than high school	16/40 (40%)	0.38 (0.11, 1.32)	0.1283
High school/diploma	9/36 (25%)	1.00 referent	
Some college, trade school or Associate's degree	48/84 (54.7%)	0.39 (0.13, 1.15)	0.0879
Bachelor's degree	18/33 (54.5%)	0.88 (0.25, 3.13)	0.8462
Master's, professional or doctorate degree	20/28 (71.4%)	0.44 (0.11, 1.8)	0.2557
Insurance			
Employer-sponsored	83/154 (53.9%)	1.00 referent	
Military	5/7 (71.4%)	0.46 (0.04, 6.03)	0.5552
Medicare	3/4 (75%)	0.34 (0.02, 5.6)	0.4488
Direct purchase	5/7 (71.4%)	0.37 (0.06, 2.33)	0.288
Medicaid/CHIP	10/34 (29.4%)	2.12 (0.8, 5.6)	0.1312
Uninsured	**0/3**		
No response	**5/12**		
Employment			
Employed	62/104 (59.6%)	1.00 referent	
Student	38/91 (41.8%)	2.17 (0.75, 6.25)	0.1509
Unemployed	10/23 (43.5%)	2.18 (0.57, 8.4)	0.2555
No response	**1/3**		
Smoking			
Daily	7/23 (30.4%)	1.37 (0.41, 4.57)	0.6121
Less than daily	5/7 (71.4%)	0.41 (0.06, 3.05)	0.3863
Nonsmokers	99/191 (51.8%)	1.00 referent	
Important to return to the same level of sports			
Yes	98/192 (51%)	0.56 (0.2, 1.53)	0.2548
No	13/27 (48.2%)	1.00 referent	
No response	**0/2**		
Driving distance to hospital, per unit (mile)	221	0.997 (0.991, 1.002)	0.2383

Bolded variables are excluded from the analysis

[a]Outcome modeled is noncompliance

Discussion

This study demonstrates that older age was significantly correlated with better compliance to fill out forms at 6 and 12 months postoperatively. Patients who were compliant at the 6-month follow-up were significantly more compliant at 12 months. Longer driving distance to the hospital was associated with less compliance at 12 months postoperatively.

Compliance rates at 6 and 12 months postoperatively were 50.2% and 59.9%, respectively, and markedly decreased to 24.2% at 24 months postoperatively. Among the patients who completed a 24-month follow-up, 22.6% were compliant at all time points. Cotter et al. [5] recently reported compliance rates to fill out patient-reported outcome forms after ACLR of 44.1%, 29.7% and 18.4% at 6, 12 and 24 months, respectively. In their study, only 7.4% completed PRO forms at all time points, and similar to our study, compliance at 24 months postoperatively was the lowest. The generally higher compliance at all time points in our study is possibly secondary to the various methods used to fill out forms. Cotter et al. had all their patients to fill out forms only electronically, whereas in the current study, patients were given the choice to fill out forms either in person during outpatient visits, or at home, and send the forms

Table 2 Variables affecting patient compliance to fill out ACLR registry forms at 12 months postoperatively

	Compliance [compliant/total (%)]	Multivariate analysis[a]	
		OR (95% CI)	P
Total	94/157 (59.9%)		
Age, per unit (year)		0.92 (0.85, 0.99)	0.0237
Compliant at 6 months			
No	23/70 (32.9%)	1.00 referent	
Yes	71/87 (81.6%)	0.04 (0.01, 0.14)	< 0.0001
Race			
African American	9/22 (40.9%)	4.3 (0.71, 25.93)	0.1114
Caucasian	82/131 (62.6%)	1.00 referent	
Others	**3/4**		
Education			
Less than high school	11/25 (44%)	1.7 (0.3, 9.71)	0.5483
High school/diploma	14/30 (46.7%)	1.00 referent	
Some college, trade school or Associate's degree	35/55 (63.6%)	0.88 (0.2, 3.94)	0.8725
Bachelor's degree	16/24 (66.7%)	1.59 (0.24, 10.45)	0.6300
Master's, professional or doctorate degree	18/23 (78.3%)	0.31 (0.03, 2.93)	0.3076
Insurance			
Employer-sponsored	63/107 (58.9%)	1.00 referent	
Military	6/7 (85.7%)	0.26 (0, 31.34)	0.5805
Direct purchase	3/6 (50%)	4.11 (0.48, 35.15)	0.1967
Medicaid/CHIP	13/20 (65%)	0.14 (0.02, 1.18)	0.0712
Medicare	**3/3 (100%)**		
Uninsured	**1/3 (33%)**		
No response	**5/11**		
Employment			
Employed	51/74 (68.9%)	1.00 referent	
Student	30/64 (46.9%)	0.35 (0.06, 1.92)	0.2272
Unemployed	11/16 (68.8%)	0.24 (0.03, 1.96)	0.1817
No response	**2/3**		
Smoking			
Yes	12/22 (54.5%)	4.28 (0.88, 20.84)	0.0721
No	82/135 (60.7%)	1.00 referent	
Important to return to the same level of sports			
Yes	81/138 (58.7%)	0.31 (0.05, 2.06)	0.2263
No	11/17 (64.7%)	1.00 referent	
No response	**2/2**		
Driving distance to hospital, per unit (mile)		1.01 (1, 1.01)	0.0297

Bolded variables are excluded from the analysis

[a]Outcome modeled is noncompliance

Table 3 Continuous variables affecting patient compliance to fill out ACLR registry forms at 24 months postoperatively

	Compliant (N = 15) [median (interquartile range)]	Noncompliant (N = 47) [median (interquartile range)]	P
Age	28 (25–37)	21 (17–30)	0.0262
Driving distance to hospital	16.2 (9.6–26.7)	13.5 (6.9–21.2)	0.5268

Table 4 Categorical variables affecting patient compliance to fill out ACLR registry forms at 24 months postoperatively

	Compliance [compliant/total (%)]	*P*
Total		
Compliance at 24 months	15/62 (24.2%)	
Compliance at all time points	14/62 (22.6%)	
Race		
African American	2/11 (18.2%)	0.5154
Caucasian	11/47 (23.4%)	
Others	2/4	
Education		
Less than high school	1/14 (7.1%)	0.3320
High school/diploma	2/10 (20%)	
Some college, trade school or associate's degree	6/21 (28.6%)	
Bachelor's degree	2/8 (25%)	
Master's, professional or doctorate degree	4/9 (44.4%)	
Insurance		
Employer-sponsored	10/46 (21.7%)	0.1699
Military	0/2 (0%)	
Medicare	2/2 (100%)	
Direct purchase	0/2 (0%)	
Medicaid/CHIP	2/7 (28.6%)	
No response	**1/3**	
Employment		
Employed	9/25 (36%)	0.0986
Student	4/31 (12.9%)	
Unemployed	1/5 (20%)	
No response	**1/1**	
Smoking		
Yes	2/8	0.7907
No	13/54	
Important to return to the same level of sports		
Yes	8/46 (17.4%)	0.0367
No	7/15 (46.7%)	
No response	**0/1**	

Bolded variables are excluded from the analysis

electronically or by mail. In a study that investigated the effect of means of PRO form completion on response rates after hallux valgus surgery, electronic method resulted in the lowest completion rates compared to traditional mail and telephone [6]. Jenkins et al. [7] studied the preferred means for filling out PRO questionnaires among orthopedic patients, and only 40% preferred electronic completion. They also reported a correlation between older age and lack of internet access [7]. Therefore, despite the widespread internet access, increasing digital literacy and relatively young age group in ACLR patients, traditional methods are still indispensable in order to maximize patient compliance to fill out forms.

None of the patient variables correlated with compliance to fill out forms at 6 months postoperatively. This is probably because at this time point patients are in rehabilitation and

still relatively concerned about regaining their pre-injury form and function. Patients who were compliant at 6 months were significantly more compliant at 12 months. This indicates that certain patients are generally more compliant than others. However, what makes that group more compliant can be related to patient, surgery or postoperative factors, and no precise conclusions can be interpreted from this finding alone.

Older age was associated with higher compliance rates at 12 and 24 months postoperatively. The effect of age on patient compliance to fill out forms in orthopedic literature is inconsistent. Similar to the current study, Imam et al. [8] reported better compliance to complete PRO questionnaires after total hip arthroplasty in older age groups. On the other hand, older age was associated with lower completion rates

in two other total joint arthroplasty studies [9, 10]. Cotter et al. [5] failed to show a significant correlation between age and patient compliance to complete PRO questionnaires after ACLR.

This study has several strengths. Studies that evaluate patient compliance to fill out registry forms are very few in the orthopedic literature. Furthermore, we used various methods of gathering data from patients in order to maximize compliance and minimize the risk of selection bias. Preoperative forms were always filled out directly on paper forms either in the surgeon's office or in the preoperative care unit. Postoperative forms were completed either during follow-up visits or sent to patients by mail or electronically.

There are a couple of limitations to this study. First, several factors potentially influence patient compliance to fill out registry forms including patient factors, surgeon factors, hospital factors and survey factors. In this article, we focused only on patient factors. Further studies may be needed to evaluate the effect of other variables. Second, the ACLR registry in our hospital is relatively new. A higher number of patients could've been included and longer follow-up periods achieved if registry data had been approved and stored earlier.

Conclusion

Younger age and longer driving distance to the hospital were significantly associated with less compliance to fill out ACLR registry forms at 12 months postoperatively. Patient perspectives on the importance to return to the same level of sports were inversely related to compliance at 24 months postoperatively. This information can be utilized to improve compliance in future studies as we have potentially identified patients that can be viewed as "at-risk" for registry noncompliance.

Compliance with ethical standards

References

1. Lyman S, Koulouvaris P, Sherman S et al (2009) Epidemiology of anterior cruciate ligament reconstruction: trends, readmissions, and subsequent knee surgery. J Bone Joint Surg Am 91:8–2321. https://doi.org/10.2106/JBJS.H.00539
2. Mall NA, Chalmers PN, Moric M et al (2014) Incidence and trends of anterior cruciate ligament reconstruction in the United States. Am J Sports Med 42:2363–2370. https://doi.org/10.1177/0363546514542796
3. Sanders TL, Maradit Kremers H, Bryan AJ et al (2016) Incidence of anterior cruciate ligament tears and reconstruction. Am J Sports Med 44:1502–1507. https://doi.org/10.1177/0363546516629944
4. Gliklich R, Dreyer N, Leavy M (2014) Registries for evaluating patient outcomes: a user's guide [Internet], 3rd edn. Agency for Healthcare Research and Quality, Rockville
5. Cotter EJ, Hannon CP, Locker P et al (2018) Male sex, decreased activity level, and higher BMI associated with lower completion of patient-reported Outcome measures following ACL reconstruction. Orthop J Sport Med 6:2325967118758602. https://doi.org/10.1177/2325967118758602
6. Palmen LN, Schrier JCM, Scholten R et al (2016) Is it too early to move to full electronic PROM data collection? Foot Ankle Surg 22:46–49. https://doi.org/10.1016/j.fas.2015.05.001
7. Jenkins PJ, Sng S, Brooksbank K, Brooksbank AJ (2016) Socioeconomic deprivation and age are barriers to the online collection of patient reported outcome measures in orthopaedic patients. Ann R Coll Surg Engl 98:4–40. https://doi.org/10.1308/rcsann.2016.0007
8. Imam MA, Barke S, Stafford GH et al (2014) Loss to follow-up after total hip replacement: a source of bias in patient reported outcome measures and registry datasets? HIP Int 24:465–472. https://doi.org/10.5301/hipint.5000141
9. Schamber EM, Takemoto SK, Chenok KE, Bozic KJ (2013) Barriers to completion of patient reported outcome measures. J Arthroplast 28:1449–1453. https://doi.org/10.1016/j.arth.2013.06.025
10. Patel J, Lee JH, Li Z et al (2015) Predictors of low patient-reported outcomes response rates in the California joint replacement registry. J Arthroplast 30:2071–2075. https://doi.org/10.1016/j.arth.2015.06.029