

Should We Question the External Validity of Database Studies? A Comparative Analysis of Demographics



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Purpose: To define the external validity of national and institutional databases for common sports medicine procedures. **Methods:** Patient demographic data including age, sex, body mass index (BMI), and 4 racial categories were aggregated between 2007 and 2016 across 2 databases for 4 common sports medicine procedures: anterior cruciate ligament reconstruction, arthroscopic rotator cuff repair (RCR), partial meniscectomy (PMx), and both arthroscopic and open shoulder stabilization. The first database of interest was a prospectively collected institutional database. The second was the National Surgical Quality Improvement Program (NSQIP) database. Two-sample *t* tests were performed to examine mean differences (MDs) in age and BMI, and χ^2 testing was used to test differences in sex and race. **Results:** A total of 7,019 institutional and 108,881 NSQIP patients were examined. The NSQIP cohort was significantly older (MD, 1.40 years), included more female patients (42.60% female patients vs 35.67% female patients), and showed a different racial distribution compared with the institutional data (all $P < .0001$). The NSQIP PMx cohort (MD, 7.38 years) was significantly older and the NSQIP RCR cohort (MD, 1.97 years) was significantly younger than their institutional counterparts (all $P < .0001$). The NSQIP anterior cruciate ligament reconstruction cohort (MD, 2.53) showed a greater average BMI ($P < .0001$). The NSQIP RCR cohort (41.8% female patients vs 33.3% female patients) and PMx cohort (46.0% female patients vs 37.9% female patients) also included more female patients. Race was distributed variably between databases for each procedure code (all $P < .0001$). **Conclusions:** Significant differences in age, BMI, sex, and race distributions were observed between an institutional database and the NSQIP database. This study underlines the importance of defining the generalizability of database research, particularly when significant demographic differences between databases may underlie differences in postoperative outcomes. **Level of Evidence:** Level III, cross-sectional study.

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From 2000 to 2010, publications in the field of orthopaedics increased greater than twofold (384.6 articles per year; from 2,889 to 6,909) due in large part to retrospective studies using clinical registry and insurance claims data.¹⁻⁵ Database studies are of particular interest in our current health care environment because policy makers, administrators, and physicians may use national and private-payer databases to evaluate trends in surgical management, optimize patient outcomes, and risk stratify surgical candidates, respectively.⁶⁻⁸ With continued growth of database utilization in orthopaedic research, it is becoming increasingly important for researchers and clinicians alike to recognize and understand the strengths, weaknesses, and limitations of database studies.^{2,3,6}

Despite offering large sample sizes, database studies have important considerations including (1) highly significant *P* values that may lack clinical significance, (2) the potential for residual confounding by uncoded variables, (3) the risk of user input errors, (4) recording bias due to financial and other incentives, and (5) inconsistent handling of missing variables across studies.^{6,8-10} Of equal concern is the concept of external validity, or the idea that a study's generalizability is dependent on the patient population and other factors potentially impacting data collection.^{11,12} Although the external validity of national data sets relative to multiple randomized controlled trials has previously been compared for sports medicine procedures, as well as across databases in total hip arthroplasty, the external validity of national data sets relative to high-volume institutional data sets for sports medicine procedures has not been established.^{12,13} This is particularly important in determining whether differences in specific demographic factors, such as age, sex, and body mass index (BMI), may prohibit the generalization of results from a given study to particular practice scenarios.

For the aforementioned reasons, the purpose of this study was to define the external validity of national and institutional databases for common sports medicine procedures. We hypothesized that (1) significant mean differences (MDs) with respect to age, sex, BMI, and race would exist between databases; (2) significant differences in BMI and race would persist when stratifying by Current Procedural Terminology (CPT) code; and (3) significant differences in age and sex would become insignificant after CPT stratification.

Methods

Cohort Establishment

This study was approved by our institutional review board based on the analysis of retrospective, deidentified data. Two databases were used in this study. The first is the database of the American College of Surgeons (ACS)—National Surgical Quality Improvement Program

(NSQIP), a national clinical registry used across a variety of disciplines that aggregates data across multiple participating hospitals nationwide.¹⁴⁻¹⁶ The second database is an institutional database used for a variety of case series and cohort studies.¹⁷⁻²² Cohorts from both databases were established using CPT codes to cover a broad range of common sports medicine procedures, inclusive of anterior cruciate ligament reconstruction (ACLR) (code 29888), partial meniscectomy (PMx) (code 29880 or 29881), arthroscopic rotator cuff repair (RCR) (code 29827), and both arthroscopic soft-tissue and open bony shoulder stabilization (SS) procedures (code 29806). The ACS-NSQIP cohort was constructed using data from July 2007 to June 2016. This database includes prospectively collected, deidentified data gathered by trained operators at participating hospitals using a systematic sampling process.²³ The NSQIP database contains over 5.5 million patient cases, with the 2016 report compiling 150 coded variables inclusive of demographic, intraoperative, and postoperative variables.²⁴ The institutional database was similarly queried for the aforementioned procedures between July 2007 and June 2017 using an electronic data collection service (Outcome Based Electronic Research Database; Universal Research Solutions, Columbia, MO). This database is a prospectively collected, single-institution clinical registry from an orthopaedic group based in Chicago, Illinois.

Variables Examined and Statistical Analysis

All statistical analyses were conducted with RStudio software (version 1.0.143; R Foundation for Statistical Computing, Vienna, Austria). Demographic variables of interest were deidentified for comparison of 4 variables across the prospective databases: sex, age, BMI, and race. All BMI measurements were coded for in the NSQIP database. In the institutional database, BMI was either gathered from a form or directly calculated from measurements of height (in square meters) and weight (in kilograms). Race was categorized into 4 distinct categories: American Indian, Asian, African American, and white. "American Indian" was the sum of "American Indian or Alaska" and "American Indian or Alaskan Native" responses; "Asian" included both those who responded "Asian" and those who responded "Native Hawaiian or Pacific Islander." Other variables of interest including smoking status, medical comorbidities, orthopaedic-specific variables (i.e., duration of symptoms and injury mechanism), and other racial categories (i.e., Hispanic) were unavailable in 1 or both compared databases and thus were excluded from the analysis. Power analysis revealed minimum cohort sizes of 2,976 to provide 90% power in detecting a year difference in age with a type I error rate of 1%. Continuous variables including age and BMI were compared across prospective studies using the Student *t* test. Categorical variables including sex and race were

Table 1. Overall Trends in Age, Sex, BMI and Race Between Institutional and NSQIP Databases Without Stratification

Variable	Institutional (n = 7,019)	NSQIP (n = 108,881)	P Value
Age, mean (SD), yr	48.45 (17.10)	49.85 (15.51)	5.02×10^{-5} (Student <i>t</i> test)
BMI, mean (SD)	31.16 (7.11)	31.33 (7.00)	.0486 (Student <i>t</i> test)
Female sex, n (%)	2,504 (35.67)	46,383 (42.60)	2.21×10^{-26} (χ^2 test)
Race, n (%) ^a			4.29×10^{-59} (χ^2 test)
AI	10 (0.15)	1,046 (1.22)	
Asian	177 (2.69)	4,171 (4.83)	
AA	932 (14.14)	8,009 (9.27)	
White	5,471 (83.02)	73,210 (84.68)	

AA, African American; AI, American Indian; BMI, body mass index; NSQIP, National Surgical Quality Improvement Program; SD, standard deviation.

^aThe race variable includes a total of 6,590 institutional and 86,469 NSQIP patients, excluding racial groups that were not coded for similarly across the 2 databases.

examined between databases using the Pearson χ^2 test. After initial analysis, the data were stratified by CPT code and the aforementioned analysis was repeated. All statistical tests were 2-tailed, with the level of significance set at $\alpha = .01$. We used a greater threshold for significance in the context of comparing 2 highly powered, large databases that could allow for the detection of small differences without clinical significance.^{11,13,25,26} Thus, when comparing *P* values, we examined magnitudes of differences with thresholds greater than twofold being suggestive of important clinical differences.¹³

Results

Overall Cohort

We identified a total of 108,881 patients (63,545 with PMx, 24,354 with RCR, 16,222 with ACLR, and 4,760 with SS) in the NSQIP database and a total of 7,019 patients (3,478 with PMx, 2,469 with RCR, 625 with ACLR, and 447 with SS) in the institutional database.

Overall cohort comparisons showed a significant difference in age (48.45 ± 17.10 years vs 49.85 ± 15.51 years, $P < .0001$) between the single-institution and NSQIP patients, without a significant difference in BMI ($P = .048$). The results of χ^2 testing revealed significantly different distributions of female and male patients between databases (42.60% female patients vs 35.67% female patients, $P < .0001$), as well as significant differences in racial distributions between the 2 cohorts ($P < .0001$) (Table 1). The high-volume institutional database showed a greater proportion of African American patients (14.14% vs 9.27%), whereas the NSQIP data set had greater percentages of American Indian (1.22% vs 0.15%), Asian (4.83% vs 2.69%), and white (84.68% vs 83.02%) patients (Fig 1).

Age and BMI Stratified by CPT Code

Table 2 displays mean and standard deviation values for age and BMI after the 2 cohorts were stratified by CPT code. With respect to age, PMx patients showed the most significant difference when mean values were

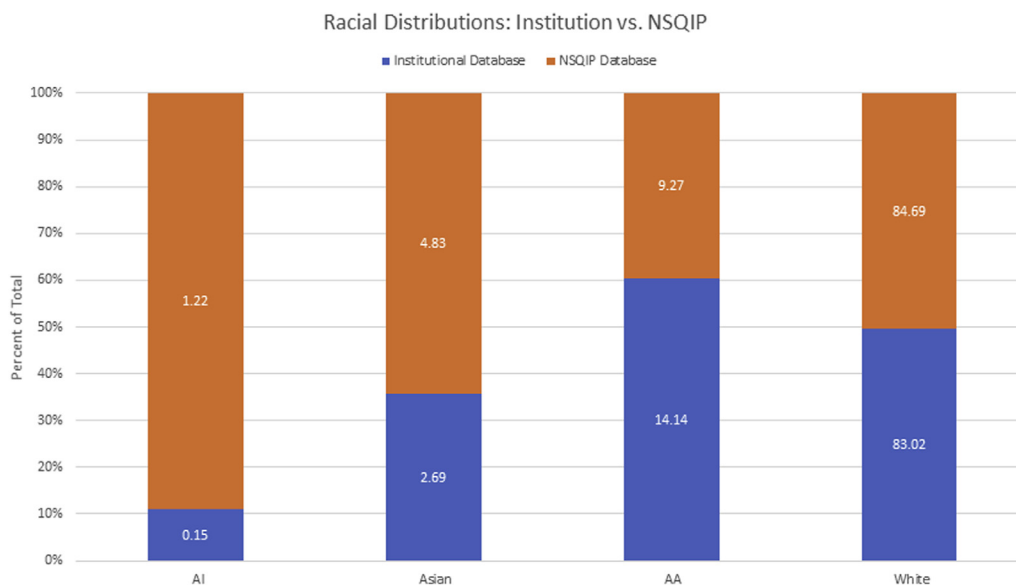


Fig 1. Racial distributions for institutional versus National Surgical Quality Improvement Program (NSQIP) databases. Significant differences ($P < .0001$) were observed during χ^2 testing across the 4 listed categorical variables. AA, African American; AI, American Indian.

Table 2. Weighted *t* Tests for Age and BMI Stratified by Procedure Between Institutional and NSQIP Databases

Procedure	Institutional	NSQIP	<i>P</i> Value (Weighted <i>t</i> Test)
Age, yr			
ACLR	30.46 (12.22)	32.16 (10.71)	$6.97 \times 10^{-4*}$
RCR	60.38 (10.00)	58.41 (10.92)	$1.06 \times 10^{-26*}$
PMx	45.07 (14.87)	52.45 (12.15)	$1.48 \times 10^{-123*}$
SS	31.55 (15.05)	32.27 (12.03)	.03
BMI			
ACLR	26.27 (5.56)	28.80 (6.01)	$6.84 \times 10^{-26*}$
RCR	31.35 (6.19)	31.30 (6.60)	.71
PMx	31.46 (7.76)	32.20 (7.34)	.28
SS	27.51 (5.40)	28.19 (5.70)	.01

NOTE. Data are presented as mean (standard deviation).

ACLR, anterior cruciate ligament reconstruction; BMI, body mass index; NSQIP, National Surgical Quality Improvement Program; PMx, partial meniscectomy; RCR, rotator cuff repair; SS, shoulder stabilization.

* $P < 10^{-10}$.

compared between the institutional patients and their NSQIP counterparts (45.07 ± 14.87 years vs 52.45 ± 12.15 years, $P < .0001$). The RCR cohort (60.38 ± 10.00 years vs 58.41 ± 10.92 years, $P < .0001$) and ACLR cohort (30.46 ± 12.22 years vs 32.16 ± 10.71 years, $P < .0001$) also displayed significant MDs, with only the SS cohort showing an insignificant difference in age ($P = .03$).

With respect to BMI, ACLR patients exhibited a significant difference between the institutional and NSQIP cohorts (26.27 ± 5.56 vs 28.80 ± 6.01 , $P < .0001$). However, neither RCR patients ($P = .71$), PMx patients ($P = .28$), nor SS patients ($P = .01$) showed significant MDs with respect to BMI (Table 2).

Sex and Race Stratified by CPT Code

Significant differences in the distribution of sex existed across the institutional and NSQIP databases for RCR patients (33.3% female patients vs 41.8% female patients, $P < .0001$) and PMx patients (37.9% female patients vs 46.0% female patients, $P < .0001$) (Table 3). However, we observed no significant differences when examining the ACLR cohort (39.2% female patients vs 35.8% female patients) and SS cohort (27.1% female patients vs 24.6% female patients) (Fig 2).

With respect to the stratification of race by CPT code, racial distributions differed for each CPT code of interest, although the distribution of *P* values was highly variable (ranging from $P = 5.73 \times 10^{-50}$ to $P = .0071$) (Table 4). The results of χ^2 testing for the RCR cohort ($P < .0001$) showed the greatest magnitude of significant differences in categorical distributions, followed by the PMx cohort ($P < .0001$). Both the ACLR cohort ($P = .0007$) and SS cohort ($P = .007$) showed significant differences although less in magnitude than either the RCR or PMx cohort. The greatest differences by racial category between the institutional and NSQIP cohorts observed included the following: 6% (80.1% vs 86.1%) and 5.9% (90.9% vs 85.0%) differences in the percentage of white patients in the RCR and SS cohorts, respectively; a 9.1% difference (18.5% vs 9.4%) in the percentage of African American patients treated in the RCR cohort; a 2.3% difference (1.3% vs 3.6%) in the percentage of Asian patients treated in the RCR cohort; and a 2.5% difference (0.2% vs 2.7%) in the percentage of American Indian patients treated in the ACLR cohort (Table 4, Fig 3).

Discussion

The main findings of this study were that significant differences with respect to age, BMI, sex, and race exist between a prospectively collected institutional database and the ACS-NSQIP national database, both of which represent highly used databases well represented in the literature. Overall, the NSQIP cohort was older, included a greater percentage of female patients, and had a different racial distribution without significant differences in the average BMI overall. When data were stratified by CPT code, the greatest MDs in age were observed for the PMx cohort (45.07 years vs 52.45 years), and the ACLR cohort was the only procedural cohort to show significant MDs with respect to BMI. Large differences ($>5\%$) in the distribution of sex were particularly apparent for the PMx and RCR cohorts. Each of the 4 procedural cohorts (PMx, RCR, ACLR, and SS) exhibited significant differences in racial distributions. The greatest differences in cohort percentages by racial category were observed for the RCR (6%) and SS (5.9%) cohorts for white patients, the

Table 3. Results of χ^2 Testing for Sex Stratified by Procedure (CPT Code) Between Institutional and NSQIP Databases

Procedure	Institutional		NSQIP		χ^2 Statistic	<i>P</i> Value
	Male	Female	Male	Female		
ACLR	380 (60.8)	245 (39.2)	10,429 (64.3)	5,793 (35.7)	2.97	.085
RCR	1,648 (66.7)	821 (33.3)	14,174 (58.2)	10,180 (41.8)	67.1	2.54×10^{-16}
PMx	2,161 (62.1)	1,317 (37.9)	34,309 (54.0)	29,236 (46.0)	38.8	4.76×10^{-10}
SS	326 (72.9)	121 (27.1)	3,591 (75.4)	1,169 (24.6)	2.67	.102

NOTE. Data are presented as number (percentage).

ACLR, anterior cruciate ligament reconstruction; CPT, Current Procedural Terminology; NSQIP, National Surgical Quality Improvement Program; RCR, rotator cuff repair; PMx, partial meniscectomy; SS, shoulder stabilization.

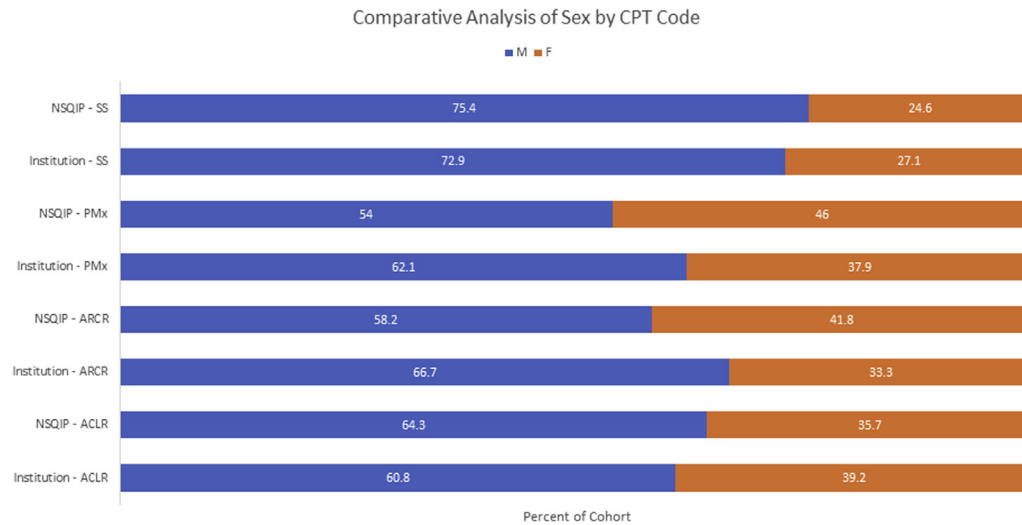


Fig 2. Distribution of sex by Current Procedural Terminology (CPT) code for institutional versus National Surgical Quality Improvement Program (NSQIP) databases. ACLR, anterior cruciate ligament reconstruction; ARCR, arthroscopic rotator cuff repair; F, female; M, male; PMx, partial meniscectomy; SS, shoulder stabilization.

RCR cohort (9.1%) for African American patients, the RCR cohort (2.3%) for Asian patients, and the ACLR cohort (2.5%) for American Indian patients. Taken together, the important demographic differences our study identifies serve to better define the important factors one must consider prior to translating the results of database research into practice.

The most important corollary of the aforementioned data is the translation of the results of our highly powered database comparison into clinical significance. Numerous previous studies have reported that even minor differences in patient demographic characteristics may exert significant effects on patient outcomes, including small differences in age and BMI impacting mean patient-reported outcome (PRO) scores, patient satisfaction, or complications such as SS revision, redislocation, and anterior cruciate ligament retear.^{12,27-29} Although we did not find any significant differences with respect to BMI between databases for the overall cohort, we did find significant MDs in age ($P < .0001$), with the PMx cohort showing the greatest MD and

P value (MD, 7.38 years; $P = 1.48 \times 10^{-123}$) followed by the RCR cohort (MD, 1.97 years; $P = 1.06 \times 10^{-26}$) and ACLR cohort (MD, 1.7 years; $P = 6.97 \times 10^{-4}$). These differences in age may be explained in part by regional population variations but also may be a result of practice differences between the academic hospitals comprising the NSQIP database and the single center included in our study. Age has previously been shown to influence preoperative and postoperative changes in mean PRO scores, as well as complications, in arthroscopic PMx patients.³⁰⁻³² In addition, age has been shown to be predictive of unanticipated hospital admission in RCR patients³³⁻³⁵ and of minimal clinically important difference achievement and ligament retear in ACLR patients.^{36,37} Although the MDs in age for the RCR and ACLR cohorts were both less than 2 years, the MD in age between databases for the PMx cohort was 7.38 years. This finding suggests that the older NSQIP PMx cohort may be uniquely susceptible to both poor outcomes (i.e., meniscal retear and decreased PRO improvements) compared with the younger institutional PMx cohort.

Table 4. Results of χ^2 Testing for Race Stratified by Procedure (CPT Code) Between Institutional and NSQIP Databases

Procedure	Institutional				NSQIP				χ^2 Statistic	P Value
	AI	Asian	AA	White	AI	Asian	AA	White		
ACLR	1 (0.2)	32 (6.0)	70 (13.2)	427 (80.6)	308 (2.7)	944 (8.0)	1,295 (11.0)	9,215 (78.3)	16.96	.00072
RCR	2 (<0.1)	31 (1.3)	433 (18.5)	1,870 (80.1)	184 (0.9)	757 (3.6)	1,945 (9.4)	17,944 (86.1)	231.77	5.73×10^{-50}
PMx	2 (<0.1)	103 (3.2)	416 (12.6)	2,786 (84.2)	520 (1.1)	2,326 (4.6)	4,423 (8.8)	43,031 (85.5)	95.69	1.31×10^{-20}
SS	5 (1.1)	11 (2.6)	23 (5.4)	388 (90.9)	34 (1.0)	144 (4.2)	337 (9.8)	2,920 (85.0)	12.09	.0071

NOTE. Data are presented as number (percentage). The race variable includes a total of 6,590 institutional and 86,469 NSQIP patients, excluding racial groups that were not coded for similarly across the 2 databases.

ACLR, anterior cruciate ligament reconstruction; CPT, Current Procedural Terminology; NSQIP, National Surgical Quality Improvement Program; PMx, partial meniscectomy; RCR, rotator cuff repair; SS, shoulder stabilization.

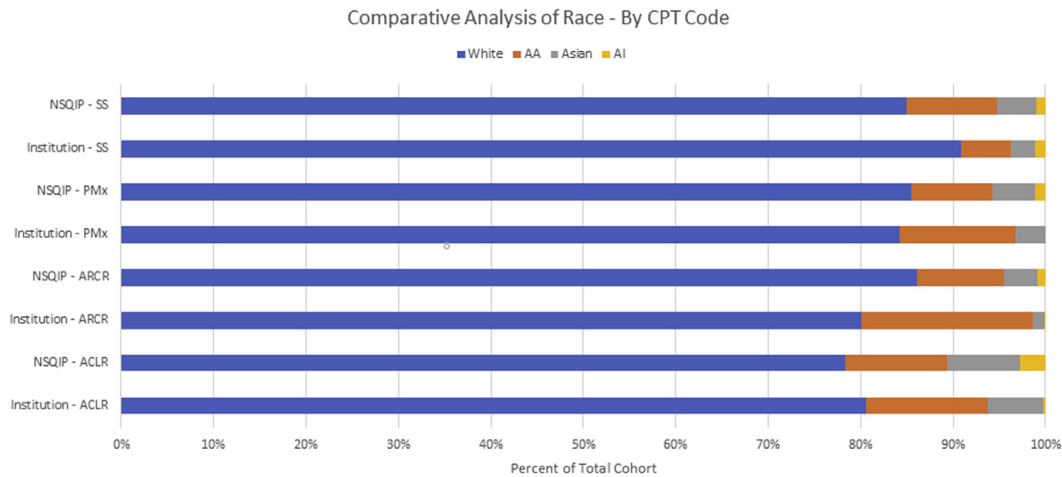


Fig 3. Racial distributions by Current Procedural Terminology (CPT) code for institutional versus National Surgical Quality Improvement Program (NSQIP) databases. AA, African American; ACLR, anterior cruciate ligament reconstruction; ARCR, arthroscopic rotator cuff repair; AI, American Indian; PMx, partial meniscectomy; SS, shoulder stabilization.

With respect to the RCR cohort, unanticipated readmission was specifically studied in an NSQIP population found to be significantly younger, with variable sex and race distributions, compared with the institutional cohort used in our study. Examination of readmission rates at our single institution is warranted to understand whether age is similarly predictive of readmission despite the demographic differences observed between databases. This example underlines the importance of careful demographic examination between study cohorts prior to the application of a study's findings to a specific clinical practice.

With respect to BMI, we did find a significant MD in the ACLR cohort (MD, 2.53; $P < .0001$), a finding that has particular significance given that greater BMI has been linked to worse outcomes after ACLR.^{38,39} Studies have yet to comparatively examine outcomes of ACLR between national and single-institution data sets.⁴⁰ An important limitation of such study designs is inconsistent coding of variables across databases, making the analysis of outcomes more challenging. Future studies examining ACLR outcomes, particularly when comparing multiple data sets, should consider BMI an important variable that can affect both outcomes and generalizability. In addition, important differences with respect to the distribution of sex existed for both the RCR (MD, 8.5%; $P < .0001$) and PMx (MD, 8.1%; $P < .0001$) cohorts. Female sex has been identified as a risk factor for decreased functional outcomes after arthroscopic partial RCR in irreparable rotator cuff tears, as well as for unexpected hospital readmission^{33,35}; however, other studies have reported insignificant relations between female sex and outcomes after RCR.^{41,42} It is interesting to note that the association with unanticipated readmission was examined in an NSQIP cohort, which our study shows contains disproportionately more female patients who may be more susceptible to

worse outcomes. Further examination of the role of female sex regarding outcomes after RCR is warranted given inconsistent relation reporting in the literature. With respect to PMx, decreased postoperative knee function and a longer time to maximal medical improvement after PMx have been reported for female patients.^{43,44} It is important to note that differences in the distribution of sex may underlie any differences in outcomes after PMx between high-volume institutions and national data sets. Further studies comparing outcomes across databases should consider using matched-cohort designs that control for the important demographic factors that may influence outcome attainment.

The observed differences in racial distributions are likely due to geographic variations in patient populations between the single-institution and national databases used in this study. Stratifying by procedure identified the RCR cohort as the main driver of significant differences in overall cohort racial distributions ($P = 5.73 \times 10^{-50}$). The PMx ($P = 1.31 \times 10^{-20}$), ACLR ($P = .0007$), and SS ($P = .007$) cohorts also showed significantly different racial distributions; however, differences in the magnitude of association suggest the RCR cohort to have the greatest clinical significance, followed by the PMx cohort. Within the RCR cohort, the NSQIP cohort contained 6.1% more white patients and 2.3% more Asian patients whereas the institutional cohort contained 3.8% more African American patients. The impact of race on outcomes after RCR, PMx, and SS is not well described in the literature and represents an important area of future study to better ascertain the role of observed demographic differences between databases. An interesting finding was that the ACLR cohort showed 2.3 more white patients per 100 in the institutional database than in the NSQIP database. Recent literature has suggested that white patients

are less likely to achieve the minimal clinically important difference in the International Knee Documentation Committee score after ACLR, although the highly powered 10-year MOON (Multicenter Orthopaedic Outcomes Network) ACLR cohort did not show any specific race as a risk factor for poor outcomes after ACLR.^{36,45} Longitudinal follow-up data from the MOON shoulder instability cohort may help better ascertain the role of race regarding outcomes after SS procedures.⁴⁶ Similarly designed highly powered cohort studies that follow up patients longitudinally are indicated for both RCR and PMx populations to better ascertain the role of race regarding outcomes after common sports medicine procedures.

Previous studies have compared NSQIP and randomized controlled trial data for common sports medicine procedures, identifying important demographic differences between trial and national data.¹² In addition, other studies have reported differences in total knee arthroplasty rates based on sex, race, and geographic region within the United States and found important differences in patient demographic characteristics when comparing international ACLR cohorts with United States–based cohorts.^{47,48} Our study adds to the growing body of necessary literature that better defines the scope of generalizability of database studies. We additionally identify important potential areas for future research into the role of demographic factors regarding outcomes after orthopaedic sports medicine procedures and encourage future research to use study designs that control for the possible impact of variable demographic characteristics on study findings.

Limitations

This study does have limitations to consider. First, our comparison relies on 2 specific databases—1 institutional, the other a clinical registry. Health claims–based databases are gaining increased attention in the health literature, in part from insurance companies but also from national discharge databases and Medicare. Our study does not assess sports medicine research using health claims data and instead uses national data from participating hospitals via the NSQIP database. Second, both databases are highly powered (institution, $n = 7,019$; NSQIP, $n = 108,881$). As a result, we report large P values, making it difficult to conceptualize and compare magnitudes of significance. We attempted to address this important limitation through (1) a smaller threshold of significance ($\alpha = .01$) and (2) a comparative analysis focusing on the magnitude of difference between P values. Methodologies connecting statistical significance to clinical significance, such as an anchor- or distribution-based calculation of the minimal clinically important difference, were unable to be used given a lack of PRO data.⁴⁹ Nonetheless, our results must be interpreted within the scope of clinical relevance to

avoid generating unnecessary conclusions. Third, our analysis of race was limited by differences in the coding of variable categories between databases, limiting our analysis to races with concurrent coding between the NSQIP data set and our institutional data set. Similarly, we were unable to include data on operative side because of variable limitations associated with our institutional electronic registry. Finally, all database studies may be subject to the effect of residual confounding if uncoded variables exert important effects on observed relations. This effect is more concerning in studies using regression models, however, and less concerning in studies such as ours that define variable distributions to test for significant differences between groups.¹⁰

Conclusions

Significant differences in age, BMI, sex, and race distributions were observed between an institutional database and the NSQIP database. This study underlines the importance of defining the generalizability of database research, particularly when significant demographic differences between databases may underlie differences in postoperative outcomes.

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