Complications Within 6 Months After Arthroscopic Rotator Cuff Repair: Registry-Based Evaluation According to a Core Event Set and Severity Grading

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Purpose: To report complications after arthroscopic rotator cuff repairs (ARCRs) in a large patient cohort based on clinical application of a newly defined core event set (CES) and severity grading. **Methods:** Consecutive primary ARCRs documented in a local clinical registry between February 2010 and September 2016 were included. Clinicians documented adverse events (AEs) reported until the final, 6-month postoperative follow-up according to the CES. The CES is an organized list of relevant AEs sorted into 3 intraoperative event groups (device, osteochondral, and soft tissue) and 9 postoperative event groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue). Severity was determined using an adaptation of the Clavien-Dindo classification. Cumulative complication risks were calculated per event group and stratified by severity and rotator cuff tear extent. **Results:** A total of 1,661 repairs were documented in 1,594 patients (mean age, 57 years [standard deviation, 9 years]; 38% women); 21% involved partial tears. All events were recorded according to the CES. Intraoperative events occurred in 2.2% of repairs. We identified 329 postoperative events in 307 repairs (305 patients); 93% had 1 AE. The cumulative AE risk at 6 months was 18.5%; AE risks were 21.8% for partial tears, 15.8% for full-thickness single-tendon tears, 18.0% for tears with 2 ruptured tendons, and 25.6% for tears with 3 ruptured tendons. AE risks per event group were as follows: 9.4% for deep soft tissue, with shoulder stiffness (7.6%) being the most common event; 3.4% for persistent or worsening pain; 3.1% for rotator cuff defects; 1.7% for neurologic lesions; 0.8% for surgical-site infection; 0.7% for device; 0.4% for osteochondral; 0.2% for superficial soft tissue, and 0.1% for vascular. Most AEs had severity grades I (160 [49%]) and II (117 [36%]). **Conclusions:** Comprehensive local AE documentation according to the CES and severity grading was possible and showed that about one-fifth of ARCRs were affected, mostly by one AE of low severity. Shoulder stiffness was the most frequent event. **Level of Evidence:** Level IV, case series.

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The treatment of rotator cuff injuries has evolved significantly in the past 20 years, with a steep rise in volume and complexity of procedures.[1] With the expansion of treatment possibilities, patients and health insurance providers rightfully demand an evidence-based intervention selection process based on relevant

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outcome information such as the rate and severity of adverse events (AEs).[2,3] Observational data from local outcome registries play an increasingly important role in providing necessary data for this process.[4]

Outcome parameters should be well defined and validated for the target population, along with the adoption of core outcome sets,[5] to achieve a high degree of standardization. A core outcome set represents an agreed minimum set of parameters to be assessed within the context of clinical studies and registries of health-related interventions. Such core outcome sets are increasingly being developed, particularly in orthopaedics with a special focus on AEs.[6]

To address the need for standardized AE reporting in arthroscopic rotator cuff repair (ARCR),[7] an international panel of experienced shoulder surgeons (H.D., M.F., and others) developed a core set of AEs (core event set [CES]) by means of a Delphi consensus process.[8] The assessment of AEs is, however, incomplete without a standardized and objective severity classification.[9] Because the Clavien-Dindo classification is well established for this purpose in general surgery,[10] an adaptation for ARCR and orthopaedics in general would be very useful.

The purpose of this study was to report complications after ARCRs in a large patient cohort based on clinical application of a newly defined CES and severity grading. We hypothesized that complete documentation and severity grading of AEs according to the CES and an adaptation of the Clavien-Dindo severity classification would be possible and that relevant safety data after ARCR could be produced on the basis of a large patient registry cohort.

Methods

This registry-based analysis involving the reuse of routine clinical data for research purposes (including the assessment of complications) was initiated after ethics committee approval (Cantonal Ethics Committee of Zurich, No. 2014-0253).

ARCR Registry

For prospective systematic documentation of ARCR patients in a clinical registry, we included patients in whom a rotator cuff tear was diagnosed in the absence of degenerative changes of the glenohumeral joint and in whom ARCR was planned. Baseline parameters included patient demographic characteristics, general health status, anamnesis, and shoulder condition. Rotator cuff tear severity (partial- or full-thickness tear and involved tendons) was assessed using magnetic resonance imaging and confirmed intraoperatively, along with concomitant shoulder injuries.

Shoulder arthroscopies were performed according to standardized clinic-specific and international guidelines.[11] Repair procedures were carried out or directly supervised by an experienced shoulder surgeon who performs more than 50 ARCRs annually (H.D., M.F., and others). Any additional procedures were documented.

Patients followed a standard 3-phase postoperative physiotherapy protocol involving (1) immobilization on an abduction pillow and passive mobilization for 6 weeks, (2) active mobilization and coordination training for a further 4 weeks, and (3) specific progressive resistance exercises thereafter. As part of routine practice, patients were clinically examined at baseline and 6 weeks, 12 weeks, and 6 months after surgery. The status of tendon healing was routinely determined by ultrasound examination at 6 months, unless performed earlier for a minority of patients at the surgeon's request; examinations were performed by highly trained and experienced medical professionals specializing in musculoskeletal ultrasound assessments.

A postoperative AE were defined as any AE that occurred during the postoperative observation period up to 6 months and was documented according to the CES. Attending clinicians were required to report every AE that occurred after surgery up to the final, 6-month clinical examination. The lack of AEs was also actively reported. For each AE, a specific form was used to document the period of occurrence (intraoperatively or postoperatively within 24 hours, at >24 hours up to 30 days, or at >30 days up to 6 months), the event description, the health-related intervention applied to treat the event, and the resulting outcome including any persistent disabilities, as well as specific assessment regarding causality, severity, and seriousness. ARCR registry data were entered electronically into a secure database using the REDCap electronic data capture system.[12]

Inclusion and Exclusion Criteria

For this retrospective analysis, all primary ARCRs performed and documented between February 2010 and September 2016 in our local registry were included. Patients were operated on at least 6 months before this selection was performed. Patients with irreparable tears, those with revision operations (i.e., if the rotator cuff tear had already been surgically repaired), and those who did not consent to the reuse of their clinical data for research purposes were excluded.

CES and Quality Control

On the basis of a previously proposed concept[8] and according to the CES, the AE form (Appendix Fig 1, available at www.arthroscopyjournal.org) was introduced for routine prospective documentation in January 2016. AE data used for this study were recorded retrospectively. A thorough clinical chart review of all included patients was performed by 1 of 4 independent clinicians (H.D., M.F., and others), and AE data were cross-checked by the primary author (Q.F.). Consistency checks were performed between events documented on the AE form and events mentioned by clinicians (H.D., M.F., and others) at the 6-

Table 1. Adapted Severity Classification of Postoperative Complications With Rotator Cuff Repair Examples

Grade	Definition	Examples
I	Any deviation from the normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic, and radiologic intervention; no deviation from routine postoperative follow-up; allowed therapeutic regimens comprise antiemetics, antipyretics, analgesics, diuretics, electrolytes, physiotherapy, and wound infections opened at the bedside	Postoperative fever, nausea, or minor urinary tract infection; wound problem not requiring any change in postoperative care; shoulder stiffness or persistent pain treated with analgesics (but no corticoid infiltration); or re-rupture of long head of biceps tendon
II	Any deviation from the normal postoperative course that requires treatment with drugs other than those allowed for grade I complications, blood transfusions, total parenteral nutrition, or close monitoring as an outpatient	Superficial wound infection (additional clinic visits and/or antibiotics); transient neurapraxia from positioning or surgical retraction that resolves under close observation; nerve palsy requiring bracing and close observation (complete resolution); asymptomatic rotator cuff rupture; frozen shoulder treated in outpatient clinic; bursitis; or symptomatic acromioclavicular arthritis
III	Any deviation from the normal postoperative course that is treatable but requires surgical, endoscopic, or radiologic intervention or an unplanned hospital admission	Symptomatic rotator cuff rupture; fracture; deep infection; surgical hematoma; implant failure or irritation that requires surgical excision; deep vein thrombosis (admission and anticoagulation); persisting pain requiring biceps tenodesis; or subacromial or subcoracoid impingement Excluded are osteonecrosis, arthroplasty, and arthrodesis
IV	Any deviation from the normal postoperative course that is life-threatening, requires intensive care unit admission, requires organ resection (e.g., joint replacement), or leads to permanent disability	Arthroplasty or arthrodesis; severe nerve plexus injury causing paralysis; major vascular injury; pulmonary embolism; central nervous system complications (brain hemorrhage, ischemic stroke, or subarachnoid bleeding but excluding transient ischemic attacks); or organ dysfunction
V	Death of patient	

month follow-up. In addition, repairs with a diagnosis of a recurrent tear by ultrasound were considered AEs within the rotator cuff event group, even if not associated with clinical symptoms and/or additional treatment.

The CES was developed by an international panel of experienced shoulder surgeons by means of a Delphi consensus process.[8] Panel members were selected worldwide among shoulder specialists with recognized experience in ARCR, after being nominated by their peers through multiple professional societies. The CES is an organized list of clinically relevant AEs sorted into 3 intraoperative event groups (device, osteochondral, and soft tissue) and 9 postoperative event groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue). Experts agreed on a documentation period for each event or group of events in the CES ranging from 3 to 24 months after ARCR. Because shoulder stiffness was not clearly defined in the CES, this event was identified based on the diagnosis and treatment of capsulitis, frozen shoulder, or shoulder stiffness with pain and/or limitation in range of motion persisting for a minimum duration of 12 weeks as documented by the involved shoulder surgeon at follow-up.

Severity Classification of AEs

A complication classification scheme was adapted from Dindo et al.[10] and Sink et al.[13] and comprised 5 grades of increasing AE severity (Table 1). All AEs were classified independently by 2 clinicians (Q.F. and V.M.) on the basis of completed forms including information about respective treatment modalities that were applied to resolve the events and their outcome; disagreement was resolved by consensus.

Statistical Analyses

Data analyses were implemented using Stata (version 14; StataCorp, College Station, TX). Patients were categorized into 4 groups based on tear severity and involved rotator cuff tendons: partial tear of 1 or more tendons, full-thickness tear of a single tendon, full-thickness tear of at least 1 of 2 involved tendons, and full-thickness tear of at least 1 of 3 involved tendons. Baseline patient demographic characteristics, health status, rotator cuff integrity, and operative parameters were tabulated separately per group using standard descriptive statistics.

AEs occurring intraoperatively and up to 6 months postoperatively were described by CES group and specification type for the whole patient collective, as well as separately according to tear severity group and AE severity level. For each patient group, event risks were calculated as the number of ARCRs with at least 1 of the considered events (e.g., specific group or type and severity level) divided by the number of documented ARCRs. Exact binomial 95% confidence intervals (CIs) were estimated and presented for event groups. For events with at least 30 documented occurrences, risks were compared between tear severity

Table 2. Baseline Patient and Operative Characteristics

Characteristic	All	Partial Tear	Full-Thickness Tears*		
			1 Tendon	2 Tendons	3 Tendons
No. of tears (%)	1,661	350 (21)	688 (41)	499 (30)	124 (8)
Age, mean (SD), yr	57 (9)	53 (10)	57 (9)	59 (8)	60 (7)
Sex, n (%)					
Female	626 (38)	146 (42)	297 (43)	149 (30)	34 (27)
Male	1,035 (62)	204 (58)	391 (57)	350 (70)	90 (73)
Smoker, n (%)					
No	1,239 (82)	254 (78)	514 (83)	377 (83)	94 (84)
Yes	272 (18)	71 (22)	108 (17)	75 (17)	18 (16)
ASA classification, n (%)					
I	412 (25)	106 (31)	174 (26)	101 (21)	31 (25)
II	1,015 (63)	208 (62)	423 (63)	307 (63)	77 (63)
III	191 (12)	24 (7)	74 (11)	79 (16)	14 (11)
History of trauma, n (%)					
Yes	988 (59)	202 (58)	380 (55)	321 (64)	85 (68)
No	673 (41)	147 (42)	308 (45)	178 (36)	40 (32)
Involved tendons, n (%)					
SSC	118 (7)	39 (11)	79 (11)		
SSP	841 (51)	232 (66)	609 (89)		
SSP and ISP	249 (15)	28 (8)		221 (44)	
SSP and SSC	328 (20)	50 (14)		278 (56)	
SSP, ISP, and SSC	125 (8)				125 (100)
Acromioplasty, n (%)					
No	129 (8)	43 (12)	57 (8)	23 (5)	6 (5)
Yes	1,530 (92)	307 (88)	631 (92)	474 (95)	118 (95)
AC joint resection, n (%)					
No	1,289 (78)	282 (81)	532 (77)	381 (77)	94 (76)
Yes	365 (22)	65 (19)	155 (23)	116 (23)	29 (24)
Biceps treatment, n (%)					
Already ruptured or treated	101 (6)	19 (5)	23 (3)	46 (9)	13 (10)
Tenotomy	411 (25)	47 (13)	154 (22)	161 (32)	49 (40)
Tenodesis	872 (52)	177 (51)	374 (54)	265 (53)	56 (45)
No treatment	277 (17)	107 (31)	137 (20)	27 (5)	6 (5)
Operation duration, mean (SD), min	83 (29)	76 (29)	75 (24)	93 (29)	108 (32)

SD, standard deviation; ASA, American Society of Anesthesiologists Physical Status classification system; SSC, subscapularis; SSP, supraspinatus; ISP, infraspinatus; AC, acromioclavicular

*At least 1 of the mentioned involved tendons had a full-thickness tear.

groups using logistic regression analyses while adjusting for the baseline patient factors of age and sex.

Results

Study Population and Demographic Characteristics

Within the defined inclusion period, our registry included 1,891 ARCRs in 1,793 patients. Excluded were 60 ARCRs (58 patients) with irreparable tears, 139 revisions (138 patients), and 31 ARCRs (31 patients) without consent for clinical data to be reused for research purposes. The selected study database included 1,661 primary ARCRs documented in 1,594 patients. A detailed description of the study population is given in Table 2.

Application of CES

The involved clinicians had no notable difficulty in allocating documented AEs to 1 of the 3 intraoperative and 9 postoperative event groups. AE data were cross-checked by the primary author, and consistency checks were performed between events documented on the AE form and events mentioned by clinicians at the 6-month follow-up. No relevant disagreements or mistakes were detected.

Documented AEs According to CES

The systematic and routine final follow-up ultrasound examination was performed in 90% of patients. A further 3% underwent magnetic resonance imaging (n = 33) or computed tomography (n = 8), whereas for the remainder (7%, n = 123), no images were available.

We documented 37 intraoperative device events in 37 ARCRs and patients (2.2%). These events included anchor pullout (n = 18), breakage (n = 10), and malpositioning (n = 3), as well as suture breakage (n = 3) and pullout (n = 1). Two additional events involving technical instrumentation issues occurred.

We identified 329 postoperative local AEs in 307 ARCRs; of these ARCRs, 93% experienced only 1 AE. The cumulative AE risk at 6 months' follow-up was

Table 3. Risks of Core Set Adverse Events According to Tear Severity

			Tear Severity Group							
	All Tears (N = 1,661)		Partial* (N = 349)		Full 1: 1 Tendon (N = 688)		Full 2: 2 Tendons (N = 499)		Full 3: 3 Tendons (N = 125)	
Event Groups and Specifications[†]	n	%	n	%	n	%	n	%	n	%
≥1 local event (95% CI)	307	18.5 (16.6-20.4)	76	21.8 (17.6-26.5)	109	15.8 (13.2-18.8)	90	18.0 (14.8-21.7)	32	25.6 (18.2-34.2)
Device	12	0.7	4	1.1	3	0.4	4	0.8	1	0.8
Anchor displacement	12		4		3		4		1	
Osteochondral	7	0.4	3	0.9	2	0.3	2	0.4	—	
Symptomatic acromioclavicular arthritis	5		2		1		2		—	
Fracture	2		1		1		—		—	
Persisting or worsening pain	56	3.4	15	4.3	19	2.8	18	3.6	4	3.2
Persisting	40		11		16		12		1	
Worsening	16		4		3		6		3	
Rotator cuff[‡]	51	3.1	3	0.9	16	2.3	24	4.8	8	6.4
New tear (nonrepaired tendon)	2		1		1		—		—	
Recurrent defect	49	3.2	2	0.6	15	2.4	24	5.1	8	7.1
Peripheral neurologic	29	1.7	5	1.4	10	1.5	9	1.8	5	4.0
Nerve injury	20		3		4		9		4	
Complex regional pain syndrome	9		2		6		—		1	
Vascular	1	0.1	—		1	0.1	—		—	
Hematoma	1		—		1		—		—	
SSI	13	0.8	1	0.3	4	0.6	5	1.0	3	2.4
Superficial incisional	8		1		2		3		2	
Deep	5		—		2		2		1	
Superficial soft tissue	3	0.2	1	0.3	1	0.1	1	0.2	—	
Delayed wound healing	2		—		1		1		—	
Hypertrophic scar and keloid	1		1		—		—		—	
Deep soft tissue[§]	156	9.4	48	13.8	59	8.6	37	7.4	12	9.6
Subacromial space	10		5		3		2		—	
Biceps	17		3		9		5		—	
Capsule (stiffness)	127	7.6	39	11.2	46	6.7	30	6.0	12	9.6
Deltoid	3		1		2		—		—	

N, total number of arthroscopic rotator cuff repairs; Full 1, full-thickness tear of single tendon; Full 2, full-thickness tear of least 1 of 2 involved tendons; Full 3, full-thickness tear of at least 1 of 3 involved tendons; n, number of arthroscopic rotator cuff repairs with at least 1 event for respective event groups and specifications; %, risk of experiencing event (n divided by N); CI, confidence interval; SSI, surgical-site infection.

*Partial tear of 1 or more tendons.

[†]According to consensus core event set.[8]

[‡]Rotator cuff events were documented by follow-up imaging in 1,538 arthroscopic rotator cuff repairs (93%), including 1,497 ultrasound examinations, 33 magnetic resonance imaging examinations, and 8 computed tomography examinations. No images were available for the remaining arthroscopic rotator cuff repairs (7%, n = 123). Risks were calculated for this event group on the basis of total numbers of arthroscopic rotator cuff repairs of 312, 638, 475, and 113 in the partial, full 1, full 2, and full 3 groups, respectively.

[§]Unfavorable events involving subacromial space (e.g., bursitis or impingement), biceps (e.g., persistent pain or tenodesis rupture), capsule (stiffness), or deltoid (e.g., subdeltoid bursitis).

Table 4. Risks of Core Set Adverse Events According to Level of Severity

Event Groups and Specifications[†]	All Events (N = 1,661)		Event Severity Grade[*]							
			Grade I		Grade II		Grade III		Grade IV	
	n	%	n	%	n	%	n	%	n	%
≥1 local event (95% CI)	307	18.5 (16.6-20.4)	158	9.5 (8.1-11.0)	111	6.7 (5.5-8.0)	45	2.7 (2.0-3.6)	5	0.3 (0.1-0.7)
Device	12	0.7	—		2	0.1	9	0.5	1	0.1
Displacement	12		—		2		9		1	
Osteochondral	7	0.4	2	0.1	4	0.2	1	0.1	—	
Symptomatic acromioclavicular arthritis	5		2		2		1		—	
Fracture	2		—		2		—		—	
Persisting or worsening pain	56	3.4	30	1.8	20	1.2	5	0.3	1	0.1
Persisting	40		20		16		4		—	
Worsening	16		10		4		1		1	
Rotator cuff[‡]	51	3.1	31	1.9	6	0.4	11	0.7	3	0.2
New tear (nonrepaired tendon)	2		2		—		—		—	
Recurrent defect	49	3.2	29	1.9	6	0.4	11	0.7	3	0.2
Peripheral neurologic	29	1.7	11	0.7	16	1.0	—		2	0.1
Nerve injury	20		11		7		—		2	
Complex regional pain syndrome	9		—		9		—		—	
Vascular	1	0.1	—		1	0.1	—		—	
Hematoma	1		—		1		—		—	
SSI	13	0.8	3	0.2	7	0.4	3	0.2	—	
Superficial incisional	8		3		5		—		—	
Deep	5		—		2		3		—	
Superficial soft tissue	3	0.2	2	0.1	1	0.1	—		—	
Delayed wound healing	2		2		—		—		—	
Hypertrophic scar and keloid	1		—		1		—		—	
Deep soft tissue	156	9.4	81	4.9	60	3.6	16	1.0	—	
Subacromial space	10		1		7		2		—	
Biceps	17		12		1		4		—	
Capsule (stiffness)	127	7.6	65	3.9	52	3.1	10	0.6	—	
Deltoid	3		3		—		—		—	

N, total number of included arthroscopic rotator cuff repairs; n, number of arthroscopic rotator cuff repairs with at least 1 event for respective event groups and specifications; %, risk of experiencing event (n divided by N); CI, confidence interval; SSI, surgical-site infection.

*According to adapted Clavien-Dindo complication classification, ranging from grade I (low severity) to V (dead). No event led to death in this study.

[†]According to consensus core event set.[8]

[‡]Rotator cuff events were documented by follow-up imaging in 1,538 arthroscopic rotator cuff repairs (93%), including 1,497 ultrasound examinations, 33 magnetic resonance imaging examinations, and 8 computed tomography examinations. No images were available for the remaining arthroscopic rotator cuff repairs (7%, n = 123). Risks were calculated for this event group on the basis of a total number of arthroscopic rotator cuff repairs of 1,538.

18.5%, with the lowest and highest risks in ARCRs with full-thickness tears of a single tendon (15.8%) and ARCRs with full-thickness tears of at least 1 of 3 involved tendons (25.6%), respectively ($P = .012$) (Table 3).

The most frequent AE was shoulder stiffness, with a risk of 7.6%. Patients with partial tears were 1.5 times more likely (95% CI, 1.0-2.1; $P = .050$) to experience stiffness than patients with full-thickness tears. There was a 3.2% risk of recurrent rotator cuff defects (failure of repair); this risk increased significantly with tear severity ($P < .001$). Most were treated nonoperatively, whereas 11 were re-reconstructed and 3 underwent arthroplasty.

Complication Severity

Severity classification of AEs was performed independently by 2 clinicians for all events with a κ coefficient (i.e., reliability) of 0.84. Of 329 AEs, 48.6% were severity grade I, 35.6% were grade II, 13.7% were grade III, and 2.1% were grade IV; there were no grade V events (Table 4). Patients with partial tears had a 1.8 times higher risk of experiencing a grade II AE (95% CI, 1.2-2.6; $P = .003$) and a 1.9 times higher risk of a grade III AE (95% CI, 1.0-3.5; $P = .040$) than patients with full-thickness tears (Appendix Table 1, available at www.arthroscopyjournal.org).

Discussion

The most important finding of this study was that comprehensive and valid AE safety data could be documented from a large cohort of 1,661 rotator cuff tears. The CES and adapted Clavien-Dindo severity classification proved to be suitable tools for the standardized documentation and evaluation of AEs after ARCR. With 329 postoperative events identified in 307 repairs, the cumulative AE risk of postoperative events at 6 months was 18.5% overall and was higher for tears with 2 or 3 ruptured tendons. The risk of a deep soft-tissue event was 9.4%, with capsular stiffness being the most common event in this group. Most AEs were classified as severity grades I and II.

The overall risk of experiencing a local postoperative AE in this study was higher than that generally referenced by the working groups of Brislin et al.,[14] Strauss et al.,[15] and Kelly et al.[16] (2.5%-16.2%). An explanation could be the specific focus of our study on AEs, as well as the standardized and comprehensive AE documentation process according to the CES. The previous reports potentially underestimated the risk of local events because of small cohorts[15,17] or a short postoperative observation period.[14] In addition, we noted rare events (e.g., hematoma) or events with a low severity grade (e.g., transient great auricular neurapraxia) owing to the CES. These may not have been recorded in studies with fewer ARCRs or studies without a standardized and comprehensive AE documentation protocol.

Shoulder stiffness, as reported by the treating surgeons (H.D., M.F., and 4 other attending, consultant, or head surgeons working at the department during the selected study period) at follow-up, was the most frequent AE in this study, with an overall risk of 7.6%. Postoperative stiffness is a commonly reported morbidity after ARCR, with a wide range of incidence risks between 3% and 25%.[7,14,17-19] This variation is generally explained by the lack of a defined set of diagnostic criteria and the great variety of patient risk profiles.[7,18] The documented risk of shoulder stiffness is similarly limited by the lack of systematic use of a consensus definition; this rate of risk, however, is comparable to previously published rates in studies that also specifically focused on postoperative AEs or stiffness after ARCR.[14,20] In addition, diagnosis and documentation were performed by the 6 aforementioned experienced shoulder surgeons during follow-up. In concordance with other reports, we found that postoperative shoulder stiffness is more likely to develop in patients with smaller cuff tears.[14,17,20] Some studies purport a greater risk with full-thickness tears.[21,22]

Recent literature has reported a 6-month postoperative risk of 13% for recurrent defects after ARCR,[23,24] with considerable variation between 4.5% and 94%.[18] In comparison, our risk of 3.2% is very low. In concordance with previous data,[23,25,26] the rate of repair failure increased with tear severity. Because adequate imaging diagnostics were performed in the vast majority of patients, the results report a realistic recurrent defect rate after ARCR in the study population and within the defined 6-month postoperative follow-up period. For the detection of recurrent cuff defects, an ideal postoperative imaging period of 10 to 15 months has been stipulated.[25] Because of the registry setting of our study, the final ultrasound follow-up was routinely conducted 6 months after surgery, potentially resulting in a lower retear rate. However, multiple studies have defined a "critical period," between 3 and 6 months after surgery, during which 82% to 95% of recurrent defects occur,[23,25] which mitigates the possible effect of the shorter follow-up period on our retear rate. Inclusion of partial tears in the calculation of recurrent defects is also associated with a higher risk,[27] as observed by Diebold et al.[24] In accordance with the CES, we included only complete Sugaya type IV and V tears, which could be another reason for the lower retear rate. As suggested in the recent literature,[28] surgeon experience as well as the learning curve of the surgical team could be another factor for the lower retear rate in our cohort in comparison to previously reported data. All ARCRs in this study were performed by experienced specialized shoulder surgeons.

Our results regarding iatrogenic nerve injury were broadly in line with earlier reports in 2 systematic reviews,[19,29] with rates ranging from 0.4% to 3.4%. For the 3-tendon repair group, the risk was considerably higher, possibly because of a longer operating time and more extensive procedure.

Surgical-site infection is a rare AE after ARCR. Overall, our results are consistent with previously published infection risks.[14,18,30-32] In our study, the risk increased depending on tear severity, from 0.3% for partial tears to 2.4% for 3-tendon tears. In a retrospective analysis of 3,294 ARCRs, Pauzenberger et al.[30] identified operating time as an independent risk factor for infection after rotator cuff repair. Arthroscopic repair of massive rotator cuff tears takes substantially longer and is more extensive in its technique,[18,30] which could explain the higher infection risk in our group with 3-tendon tears.

On the basis of the CES, all identified AEs could be documented within 1 of the defined event groups without relevant disagreements. General adoption of the CES would increase scientific comparability and reporting of complications and thus improve the quality and safety of ARCR, as shown in other fields of surgery.[33] Only 1 event, shoulder stiffness, was insufficiently detailed in the CES. Currently, there is no internationally accepted consensus regarding shoulder stiffness, and much debate arises, especially when considering pain and the minimal duration of postoperative stiffness as diagnostic criteria.[7] To improve future documentation, further work is necessary to develop a consensus definition of shoulder stiffness.

Systematic and standardized documentation of AEs is not complete without a reproducible and reliable severity grading system. The Clavien-Dindo classification[9] is an established severity grading system for postoperative complications. This classification was adapted to be applicable for all orthopaedic AEs and was used with high reliability between 2 clinicians.

Limitations

The strength of this study is the successful application of a CES of AEs in a large registry-based patient cohort with extensive baseline information, precise intraoperative details, and secondary interventions, as well as a standardized clinical 6-month follow-up examination. Nevertheless, we acknowledge several limitations. First, most AE data were documented retrospectively. This type of data collection can miss or misinterpret information that is not recorded properly in medical charts. Furthermore, data collection was performed by 4 separate investigators, which could lead to differences in documentation despite initial training, thorough coordination, and rigorous cross-checking. Moreover, because the registry setup included a short clinical and sonographic follow-up period of 6 months, this aspect does not cover the recommended follow-up period of 24 months to document all AEs according to the CES.

Conclusions

Comprehensive local AE documentation according to the CES and severity grading was possible and showed that about one-fifth of ARCRs were affected, mostly by 1 AE of low severity. Shoulder stiffness was the most frequent event.

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