

Safety of arthroscopic rotator cuff repair: using a core event set for clinician and patient assessment of risks in a multicenter cohort study

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ABSTRACT

Objectives Reporting standards for adverse events (AEs) in arthroscopic rotator cuff repair (ARCR) vary. A standardized “core event set” (CES) was developed to enhance AE documentation. This study describes AE risks in a large Swiss-German ARCR cohort, evaluates concordance between patient-reported and clinician-reported events, and investigates AE variability according to tear severity.

Design Prospective multicenter cohort study.

Setting Between June 2020 and November 2021, 973 patients were enrolled across 19 orthopedic centers and followed for 24 months.

Participants Adult patients with a rotator cuff tear.

Interventions Primary ARCR.

Main outcome measures AEs were documented using a structured CES and classified into five severity grades. AE reporting was compared between patients and clinical staff. AE cumulative risks (CR) were calculated by occurrence period, severity grade, and tear severity.

Results A total of 342 AEs were documented in 314 patients within 2 years. Of these, 41% were reported only by clinical staff, 40% only by patients, and 19% by both. The 2-year CR of AEs was 29.1%, with persistent pain (12.2%) and deep soft tissue complications (10.6%) being most common. Severity classification revealed 61.7% grade I, 24.3% grade II, 13.2% grade III, and 0.9% grade IV. Tear severity was inversely associated with overall AE risk, ranging from 41.5% in partial tears to 28% in massive tears.

Conclusions Standardized AE documentation using CES identified pain, deep soft tissue complications, and rotator cuff issues as the most frequent local AEs. Both clinicians and patients should be involved in AE reporting. Most AEs were mild, and tear severity predicted AE risk, highlighting the need for tailored postoperative strategies and further research on preventive measures.

INTRODUCTION

Rotator cuff tears (RCTs) are a common disorder affecting the shoulder joint, frequently leading to pain and functional limitations that can significantly impact daily activities.¹

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Prior to this study, while arthroscopic rotator cuff repair (ARCR) was known to improve shoulder function and quality of life, complications such as pain, stiffness, and persistent defects were common, with reporting standards varying across studies. This study was needed to provide comprehensive, standardized safety data using a core event set (CES) to better understand and predict adverse events (AEs) in ARCR.

WHAT THIS STUDY ADDS

⇒ This study revealed that the CES enables standardized and comprehensive documentation of AEs following ARCR. It highlights the importance of involving both clinical staff and patients in AE reporting to capture the full spectrum of complications. Furthermore, it identified that most AEs were mild, occurred within the first 12 months postsurgery, and varied according to tear severity.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study emphasizes the need for comprehensive and standardized AE documentation using a CES to improve postoperative care and patient outcomes. It provides a reliable framework for future research to assess and compare AE risks in ARCR, supporting the development of evidence-based guidelines and improving patient safety.

Studies have demonstrated clinically relevant improvements in shoulder function and quality of life after arthroscopic rotator cuff tear repair (ARCR).^{2–6} However, several complications such as pain, shoulder stiffness, and prolonged rehabilitation can arise. About 20% of patients may show a persistent rotator cuff defect⁷ typically diagnosed within 12 months following ARCR; however, reported risks depend on diagnostic imaging and the definitions used. Similarly,

postoperative shoulder stiffness was reported to occur in 1.5%–11.1% of ARCRs⁸; incident data are impaired by the heterogeneity in definition and reporting.⁹ While these complications can often be managed effectively, resulting in full recovery, some patients may suffer from permanent disabilities.¹⁰

Comprehensive, valid, and reliable safety data related to ARCR are sparse.^{9,11} Reporting standards are a prerequisite for outcome and safety data. A core outcome set (COS)¹² for shoulder disorders was defined previously, which includes inner core domains of pain, physical function and activities, global perceived effect (a person's assessment of their recovery or degree of improvement), and adverse events (AEs).^{13,14} A minimum set of AEs to be documented in ARCR was defined by international consensus and presented as a core event set (CES).¹⁵ This CES was found to be relevant and practical in a retrospective chart review as part of a local clinical register,¹⁶ reporting a cumulative AE risk at 6 months of 18.5% from 1,661 ARCRs.

A prospective multicenter study (ARCR_Pred) was implemented to document and predict the safety and effectiveness of ARCR in a representative Swiss-German patient cohort.¹⁷ The purpose of this analysis was (1) to assess all types of AEs and severity for 24 months by patients and professionals using the CES (ie, ARCR CES 1.0),¹⁵ (2) to compare reports made by patients and professionals, and (3) to quantify the incidence of AEs within 24 months following surgery overall, as well as corresponding to tear severity.

METHODS

ARCR_Pred study setting

Between June 2020 and November 2021, a cohort of 973 adult patients with partial or full-thickness RCTs and treated with primary arthroscopic surgical repair was prospectively enrolled at 18 Swiss and one German orthopedic center.¹⁷ Patients undergoing specific surgical procedures for irreparable tears (ie, tendon transfer, subacromial spacer, or superior capsular reconstruction), revision surgeries, open or mini-open reconstructions were excluded. Additional exclusions included those unable to give written informed consent, attend follow-up visits, communicate in German, French, Italian, or English, and pregnant women. Patients undergoing bilateral ARCR were only included for their first intervention.

Baseline demographics, psychological, socioeconomic, and clinical factors, as well as rotator cuff integrity, concomitant local findings, surgical details, and postoperative management factors, were documented. Tear location (supraspinatus, infraspinatus, subscapularis tendon) and severity (partial, full-thickness) were initially determined via MRI and confirmed intraoperatively. Objective clinical outcomes were documented at 6-week, 6-month, and 12-month follow-up, respectively, while subjective patient-reported outcome measures were documented at 6, 12, and 24-month follow-up.

AE documentation

AEs could occur at any time during the study's 24-month postsurgery observational period. Surgeons were required to document intraoperative AEs. At follow-ups, patients and clinical staff (surgeons, other clinicians, or study nurse performing the clinical examinations) were systematically surveyed individually regarding the occurrence of postoperative AEs. These were classified as either "local" to the operated shoulder using the consensus CES,¹⁵ or "non-local, affecting the rest of the body", as proposed by Audigé *et al.*¹⁸

The CES categorizes AEs into three intraoperative event groups (device, osteochondral, and soft tissue) and nine postoperative event groups (device, osteochondral, pain, rotator cuff, surgical-site infection, peripheral neurologic, vascular, superficial soft tissue, and deep soft tissue). Each group includes specific event categorizations; for instance, neurological events are divided into nerve injuries and complex regional pain syndrome (CRPS), with nerve injuries further described according to the affected nerves and lesion type.¹⁹

Local events were fully documented throughout the study, whereas non-local events were recorded only when occurring within the first 6 months post-ARCR and categorized per organ system. A structured AE form captured details, such as occurrence date/period, affected location (local at the operated shoulder/non-local), event group and specification, applied health-related intervention(s) (operative/nonoperative procedure(s)), outcome at the time of reporting (or end of the study) (ongoing recovery/resolved without symptom or impairment/persistent impairment(s)/death), and assessment of the event (causal factor(s)/severity grade/seriousness).

The severity of local events was graded by clinicians using a five-graded classification scheme of increasing AE severity from grade I (any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiologic intervention; no deviation from routine postoperative follow-up) to grade V (AE causing the patient's death).¹⁶ Non-local events were graded according to Dindo *et al.*²⁰

An AE Review Committee (LA, AM, HD, DS, and TS) was established to oversee AE documentation, recommend corrections and changes to the CES regarding event categorization issues, and, when necessary, provide final adjudication for documentation and analysis. Three additional CES-trained clinicians (KG, CB, and SAM) supported the committee by performing detailed AE reviews to ensure unambiguous and consistent documentation (eg, a fall was considered a potential cause of AEs and not an AE itself).¹⁸ Data queries were directed to the respective operating surgeons or site principal investigators as needed and resolved through on-site or remote monitoring activities (TS and LA), or with the support from the AE Review Committee.

During the project, disagreements arose regarding AE classification in the extremity distal to the operated shoulder, with some labelled "local" (eg, peripheral

neurological events) and others “non-local” (eg, arm swelling). To enhance clarity, the AE Review Committee recommended fine-tuning the CES definition of “local” events to include those affecting both the operated shoulder and the ipsilateral distal extremity, ensuring more precise categorization.

Data management and statistical analyses

A target sample size of 970 ARCRs was predetermined for prognostic model development on shoulder stiffness, and patient-reported shoulder function score,¹⁷ rather than secondary AE reporting. Nevertheless, this sample allowed AE risk estimation with 95% CI around 5% and 10% within 1.4% and 1.9% margin of error, respectively.²¹ Study data were managed using the REDCap Electronic Data Capture system²² and exported for variable transformation and statistical analysis using Intercooled Stata software, V.17 (StataCorp).

Patients were categorized into four groups based on tear severity and involved rotator cuff tendons: (1) one or more partial tears, (2) single full-thickness tears, (3) two or three tendons involved with only one full-thickness tear, and (4) two or three full-thickness tears (massive tear). Baseline demographics, health status, rotator cuff integrity, and operative parameters were summarized per group using standard descriptive statistics.

AEs were categorized by CES group and specification type and reviewed by the AE Review Committee. Post-operative events affecting the ipsilateral distal extremity were grouped separately, with peripheral neurological events reassigned. AEs analysis covered the entire cohort, incorporating reports from patients, clinical staff, or both over the 24-month postoperative period. Agreement on local AEs between patients and staff was assessed using the kappa coefficient. AEs were stratified by tear severity and AE severity, with event risks calculated based on ARCR cases and exact binomial 95% CIs estimated for each group.

RESULTS

Study population

The ARCR_Pred cohort enrolled 973 patients undergoing primary rotator cuff repair, representing 51.5% of 1890 consecutive eligible patients during the enrollment period on respective study sites. Our study cohort included 15% of partial tears and 44% of massive tears, as opposed to 20% and 32% in the target population, respectively. Clinical follow-up rates were 99%, 95%, and 89% at 6 weeks, 6 months, and 12 months, respectively. Patient questionnaires were completed in 94%, 90%, and 88% of the cases at 6, 12 and 24 months, respectively.²³

Reported events

There were 19 intraoperative AEs documented by operating surgeons in 19 ARCRs including 3 implant breakages, 12 anchor pullouts, 2 suture breakages, 1 suture pullout, and 1 bleeding.

Over a 2-year period, a total of 300 local events were recorded in 283 patients, with 94.3% of these patients experiencing only one local event. Among the events affecting the ipsilateral extremity, 19% were reported by both clinical staff and patients, 41% were reported by clinical staff only, and 40% by patients only (table 1; figure 1). The kappa level of agreement for identifying ARCRs as being affected by an AE between clinical staff and patients was 0.199. When assessed separately for AE types, it ranged from 0.165 (local pain events) to 0.496 (local osteochondral events). The most common reported local events included persistent/worsening pain (41%), deep soft tissue complications (35%), and rotator cuff issues (16%), with pain predominantly reported by patients (70%), deep soft tissue complications by clinicians (50%), and rotator cuff issues by clinicians (65%).

Additionally, 42 events affecting the ipsilateral extremity distal to the operated shoulder were reported, including mostly peripheral neurological events (23/42) and deep soft tissue events (13/42). Neurological events involved 12 cases of CRPS and 11 nerve injuries. Neurapraxia (temporary paralysis) was noted in nine patients affecting the median (n=7), radial (n=1), ulnar (n=2), and plexus brachialis (n=1) nerves. Axonotmesis (severe nerve fiber damage resulting in complete peripheral degeneration) occurred in two patients, involving the axillary and plexus brachialis nerves, respectively.

Within 6 months postoperatively, 126 non-local AEs were recorded in 114 patients (11.7%) (online supplemental file 1; figure 1).

Period of occurrence

By 3 months postsurgery, 38% of local and other ipsilateral events had occurred. The majority (69%; 235/342) occurred within 6 months, and 89% within 12 months (table 2). While pain and rotator cuff events were primarily observed within 12 months, 17% (21/122) of pain events and 8% (4/48) of rotator cuff events occurred later. Similarly, 7% (7/104) of local deep soft tissue events arose beyond the predefined 12-month minimum observation period. Among other ipsilateral events, 22% (5/23) of peripheral neurological events, which were defined within the original CES, occurred after the initial 3-month period. By 24 months, 66% of ipsilateral events had fully resolved. However, 10% remained in recovery, 21% had stabilized yet with persistent damage or symptoms, and 3% had an unknown recovery status.

Event risks

The risk of experiencing at least one local event within 2 years post-ARCR was 29.1% (95% CI 26.2% to 32.1%; table 3). The most common were persisting or worsening pain (12.2%) and deep soft tissue complications (10.6%). Rotator cuff-related issues, such as symptomatic recurrent defects, had a risk of 4.9%, while symptomatic capsule stiffness occurred in 8% of cases.

Additionally, patients had a 4.3% risk of experiencing another ipsilateral event, including peripheral

Table 1 Documented adverse events affecting the ipsilateral arm per type group and reporting source

Event group	Reporting by			All	Kappa Coefficient*
	Clinic	Patient	Clinic and patient		
Event of the ipsilateral extremity†	141 (41%)	136 (40%)	65 (19%)	342	0.199
Local events ipsilateral					
Device	5	–	1	6	
Osteochondral	6 (50%)	2 (17%)	4 (33%)	12	0.496
Persisting or worsening pain	24 (20%)	85 (70%)	13 (11%)	122	0.165
Rotator cuff	31 (65%)	5 (10%)	12 (25%)	48	0.385
Vascular	1	–	–	1	
Surgical site infection	2	1	–	3	
Superficial soft tissue	0	1	–	1	
Deep soft tissue	52 (50%)	28 (27%)	24 (23%)	104	0.336
Other events	1	1	1	3	
All	122 (41%)	123 (41%)	55 (18%)	300	0.200
Other events ipsilateral	0	0	0	0	
Osteochondral	–	1	–	1	
Persisting or worsening pain	–	1	–	1	
Peripheral neurological	13 (57%)	4 (17%)	6 (26%)	23	0.406
Superficial soft tissue	1	1	1	3	
Deep soft tissue	5 (38%)	6 (46%)	2 (15%)	13	0.347
Other events	–	–	1	1	
All	19 (45%)	13 (31%)	10 (24%)	42	0.368

*For each event group with at least 10 reported events, the level of agreement between clinicians and patients in identifying adverse events affecting ARCRs was assessed.

†Event groups were defined by an international consensus core event set,¹⁵ which focused on local events only, including peripheral neurological events. The project AE review committee considered expanding the core set to include other events affecting the ipsilateral arm distal to the operated shoulder.

AE, adverse event; ARCR, arthroscopic rotator cuff repair.

neurological complications such as nerve injury (2.4%) and CRPS (1.2%). Risks for other complications, such as surgical site infections (0.3%) and hematomas (0.1%), were lower. Overall, the risk of experiencing at least one local or ipsilateral event within 3, 6, 12, and 24 months post-ARCR was 12.8%, 23.0%, 29.1% and 32.3%, respectively.

Event severity grading

Local and ipsilateral events were classified as severity level I (61.7%), II (24.3%), III (13.2%), and IV (0.9%) (online supplemental file 2). No patient experienced severity grade V (death) from a local or ipsilateral event. The risk of experiencing at least one grade II–IV AE was 12.6%, whereas the risk for grade III–IV was 4.7%. Surgical intervention was required for 13% of local and ipsilateral events, affecting 4.2% of patients. All pain events were grade less than I or II, with a 2.0% risk of pain event grade II (online supplemental file 3). Rotator cuff events were typically grade III or IV when treated surgically (revision repair or shoulder arthroplasty, respectively). Peripheral neurological events were all grade I or II, except for one nerve injury. The three surgical infections were grade III

or IV. Deep soft tissue events (primarily shoulder stiffness) were mostly grade I or II, except for four grade III events.

Tear severity

The ARCR_Pred cohort included 147 partial tears (15%), 255 single full-thickness tears (26%), 143 tears involving at least two tendons with only one full-thickness tear (15%), and 428 massive tears (44%) with at least 2 full-thickness tears. There was a negative association between tear severity and ipsilateral extremity event risk, with an

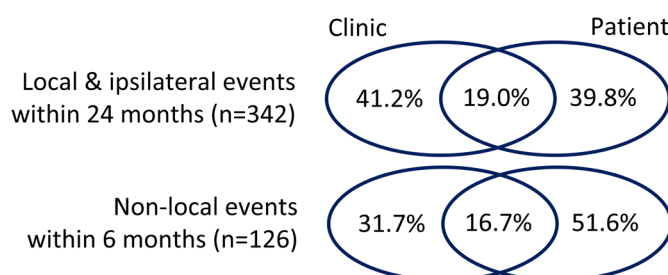


Figure 1 Discrepancy in reporting local and other ipsilateral adverse events and non-local events between clinics and patients.

Table 2 Postoperative adverse events affecting the ipsilateral arm by event group and time period of occurrence

Event group	CES Period	Period of occurrence						All
		≤24h	>24h–30d	>30d–3m	>3m–6m	>6m–12m	>12m–2yrs	
Ipsilateral arm*		2	43	84	106	70	37	342
Local events ipsilateral								
Device	24m	–	1	1	1	2	1	6
Osteochondral	24m	–	1	1	3	5	2	12
Persisting or worsening pain	12m	–	15	12	38	36	21	122
Rotator cuff	12m	–	3	12	13	16	4	48
Vascular	30d	–	1	–	–	–	–	1
Surgical site infection	30d to 12m	–	2	–	–	–	1	3
Superficial soft tissue	30d to 6m	–	–	–	1	–	–	1
Deep soft tissue	12m	–	8	41	40	8	7	104
Other events		–	–	1	2	–	–	3
All		–	31	68	98	67	36	300
Other events ipsilateral								
Osteochondral		–	–	–	–	–	1	1
Persisting or worsening pain		–	–	–	1	–	–	1
Peripheral neurological	3m	2	4	12	3	2	–	23
Superficial soft tissue		–	2	1	–	–	–	3
Deep soft tissue		–	6	3	4	–	–	13
Other events		–	–	–	–	1	–	1
All		2	12	16	8	3	1	42

*Event groups were defined based on an international consensus CES,¹⁵ which focuses on local events only, including peripheral neurological events. The project AE review committee considered expanding the core set to include additional events affecting the ipsilateral arm distal to the operated shoulder.

AE, adverse event; CES, core event set; d, days; h, hours; m, months; yrs, years.

overall 24-month AE risk of 41.5%, 34.9%, 30.8% and 28% for these subgroups, respectively (table 4). The risk of persistent or worsening pain events decreased from 15.6% in partial tears to 10.0% in massive tears, while deep soft tissue events, particularly shoulder stiffness, declined from 13.6% in partial tears to 5.8% in massive tears. The risk of symptomatic rotator cuff events, however, increased from 2.0% in partial tears to 6.5% in massive tears.

DISCUSSION

Our study's key finding is that the CES is an appropriate tool for the standardized documentation and evaluation of AEs following ARCR. The CES facilitated gaining important insights into the incidence of local postoperative events. Notably, the role of clinical staff and patients in documenting AEs comprehensively was emphasized, with only about one-quarter of events documented by both. Among the 973 patients included in our study, the majority completed their initial follow-up at 6 weeks, with slightly lower but still substantial follow-up rates around 90% and above at 6, 12 and 24 months. Within 2 years post-ARCR, 32% of patients experienced at least one local

AE, though 62% thereof were classified as low severity (grade I). Surgical intervention was required for 13% of local and ipsilateral events, affecting 4.2% of patients. Most patients experienced a single local event, predominantly worsening pain, deep soft tissue complications (eg, shoulder stiffness), or rotator cuff integrity issues.

Intraoperative AEs were recorded in only 19 cases, suggesting they are relatively uncommon. Although this report does not expand in detail on their specific nature, the findings reinforce the importance of intraoperative protocols and surgeon experience in mitigating risks.²⁴ The risk of intra-operative AEs aligns with Felsch *et al*'s retrospective chart review,¹⁶ yet it is likely underestimated when documented solely by surgeons. Expanding AE documentation to other staff during surgery (eg, anesthesiologists, surgical assistants, nurses) could improve the comprehensiveness of documentation, particularly for non-local events.²⁵

Of all AEs registered during follow-up, 69% occurred and took place within the first 6 months, with the remaining cases emerging between 6 months and 2 years. This emphasizes the importance of specifying the follow-up duration when reporting AEs risks.¹⁸ The

Table 3 Risks of postoperative adverse events affecting the ipsilateral arm within 2 years of primary arthroscopic rotator cuff repairs

Event group*	Local events			Other events		
	N	Risk (%)	95% CI	N	Risk (%)	95% CI
At least one event	283	29.1	(26.2 to 32.1)	42	4.3	(3.1 to 5.8)
Device	6	0.6	(0.23 to 1.3)			
Displacement	6					
Osteochondral	12	1.2	(0.64 to 2.1)	1	0.1	
Acromioclavicular arthropathy	7			–		
Fracture	4			1	0.1	
Other osteochondral event†	1			–		
Persisting or worsening pain	119	12.2	(10.2 to 14.5)	1	0.1	
Persisting pain	61			–		
Worsening pain	60			1		
Rotator cuff	48	4.9	(3.7 to 6.5)			
Recurrent defect‡	43					
Medial cuff failure	5					
Peripheral neurological				23	2.4	(1.5 to 3.5)
Nerve injury§				11		
CRPS				12		
Vascular	1	0.1	(0 to 0.6)	0	–	
Hematoma	1					
Surgical site infection	3	0.3	(0.06 to 0.9)			
Deep SSI	3					
Superficial soft tissue	1	0.1	(0 to 0.6)	3	0.3	(0.06 to 0.9)
Hypertrophic scar and keloid	1			–		
Oedema	–			3		
Deep soft tissue	103	10.6	(8.7 to 12.7)	13	1.3	(0.71 to 2.3)
Subacromial space	13			–		
Biceps	8			–		
Capsule (stiffness)	78	8	(6.4 to 9.9)	–		
Deltoid	2			–		
Bursitis¶	–			7		
Tendinitis**	–			3		
Other deep soft tissue event††	3			4		
Other post-operative local‡‡	3	0.3	(0.06 to 0.9)	0		

N, number of arthroscopic rotator cuff repairs.

*Event groups were defined by an international consensus CES,¹⁵ which focused on local events, including peripheral neurological events. The project AE review committee considered expanding the core set to include additional events affecting the ipsilateral arm distal to the operated shoulder. Peripheral neurological events were therefore defined as distal events.

†Unclear ossification scarring lateral to the coracoid.

‡13 of the recurrent defects were considered retears occurring after initial healing was achieved.

§Neurapraxia (temporary paralysis) was observed in 9 patients affecting the median (n=7), radial (n=1), ulnar (n=2), and plexus brachialis (n=1) nerves. Axonotmesis (severe nerve fiber damage leading to peripheral degeneration) occurred in 2 cases, affecting the axillary and plexus brachialis nerves, respectively.

¶All cases were inflammation of the elbow bursa (bursitis olecrani).

**Cases included one tennis elbow, one De Quervain's tenosynovitis, and one unspecified tendinitis within the wrist/hand.

††Local events: one case of unspecified "Shoulder locked, hard back muscles", one pseudoparalysis during flexion associated with atrophy of the rotator cuffs, and one muscular overload. Distal events: trigger thumb, developing ganglion associated with scaphotrapeziotrapezoidal joint arthrosis, and trigger fingers.

‡‡These events include sensations of tendon jumping/cracking in the operated shoulder during movement, which could not be categorized under predefined CES event groups.

AE, adverse event; CES, core event set; CRPS, complex regional pain syndrome; SSI, surgical site infection.

Table 4 Risks of postoperative adverse events within 2 years of primary arthroscopic rotator cuff repairs stratified by tear severity subgroup

Event group*	Partial tear (N=147)		Single full tear (N=255)		2–3 tendons (only 1 full) (N=143)		Massive tear (≥2 full tears) (N=428)	
	n	%	n	%	n	%	n	%
Ipsilateral arm*	61	41.5	89	34.9	44	30.8	120	28.0
Local event	53	36.1	81	31.8	38	26.6	111	25.9
Other event	11	7.5	14	5.5	8	5.6	9	2.1
Device	0	0.0	2	0.8	0	0.0	4	0.9
Displacement	0		2		0		4	
Osteochondral	5	3.4	3	1.2	2	1.4	3	0.7
Acromioclavicular arthropathy	4		1		1		1	
Fracture	1		1		1		2	
Other osteochondral event	0		1		0		0	
Persisting or worsening pain	23	15.6	35	13.7	19	13.3	43	10.0
Persisting pain	11		21		8		21	
Worsening pain	12		15		11		23	
Rotator cuff	3	2.0	10	3.9	7	4.9	28	6.5
Recurrent defect	2		10		6		25	
Retear	1		4		2		6	
Medial cuff failure	1		0		1		3	
Peripheral neurological	6	4.1	6	2.4	6	4.2	5	1.2
Nerve injury	3		2		3		3	
CRPS	3		4		3		2	
Vascular	0	0.0	1	0.4	0	0.0	0	0.0
Hematoma	0		1		0		0	
Surgical site infection	1	0.7	0	0.0	0	0.0	2	0.5
Deep SSI	1		0		0		2	
Superficial soft tissue	0	0.0	2	0.8	0	0.0	2	0.5
Oedema	0		2		0		1	
Hypertrophic scar and keloid	0		0		0		1	
Deep soft tissue	26	17.7	36	14.1	16	11.2	35	8.2
Subacromial space	2		4		3		4	
Biceps	0		4		2		2	
Capsule (stiffness)	20	13.6	23	9.0	10	7.0	25	5.8
Deltoid	1		0		0		1	
Bursitis	2		3		1		1	
Tendinitis	1		2		0		0	
Other deep soft tissue event	1		2		1		3	
Other postoperative local events	0	0.0	1	0.4	0	0.0	2	0.5

n or N = Number of arthroscopic rotator cuff repairs; risk (%) = n/N.

*Event groups were defined by an international consensus core event set,¹⁵ which focused on local events, including peripheral neurological events. The project AE review committee considered expanding the core set to include additional events affecting the ipsilateral arm distal to the operated shoulder.

AE, adverse event; CRPS, complex regional pain syndrome; SSI, surgical site infection.

consensus CES was defined along with prespecified minimum periods.¹⁵ While most pain, rotator cuff events, and local deep soft tissue events were observed within 12

months, a notable fraction of them (17%, 8%, and 7%, respectively) emerged beyond this period. The proposed “critical period” of 6 months for recurrent defect rate may

lead to an underestimation of the actual re-tear rate.^{26 27} Furthermore, while pain levels generally were low and acceptable by 12 months, several patients continued to experience persistent pain beyond this period, which does not seem to be related to immediate postoperative pain.²⁸ Peripheral neurological events were originally defined as occurring within the first 3 months following surgery, yet 5 out of 23 events occurred between 6 and 12 months. The original consensus for the CES initially proposed varying observation periods for different AE types. For consistency and comprehensiveness of documentation, we recommend adopting a unified observation period for all AE types and groups.

Our study found a 32.3% cumulative risk of experiencing at least one AE affecting the ipsilateral extremity within 2 years following ARCR. This is higher than the 18.5% reported by Felsch *et al*¹⁶ within 6 months, primarily due to the differing follow-up periods. Our study extended the follow-up to 2 years, allowing the capturing of additional long-term events. It also exceeds previously reported risks, ranging from 2.5% to 16.2%,^{29–31} likely due to our standardized and comprehensive AE documentation process.

The most frequently observed local events were persisting or worsening pain (12.2% risk) and deep soft tissue complications (10.6%), including shoulder stiffness (8%). However, comparing these findings to existing literature is challenging due to a lack of an international consensus on the definition for “frozen shoulder” or “postoperative shoulder stiffness”.⁹ Our project investigators defined stiffness based on restricted range of motion in at least two planes, yet stiffness events in the CES were defined as requiring additional treatment.

Shoulder stiffness is among the most frequently reported AEs following ARCR, with incidence rates ranging from 2.6% to 23.3%^{8 9 29 32 33} in previous studies. The risk observed in our cohort aligns closely with that reported by another retrospective study using a similar definition.¹⁶ Pain events were documented when they lacked a clear association with a specific diagnosis such as stiffness, recurrent defect, infection, or others. Some pain events reported by patients at 24 months may have been associated with other problems, though these could not be confirmed by clinical examination unless the patient actively sought medical evaluation. Additionally, our study found a 4.9% risk of recurrent rotator cuff defect, a figure comparable to the 3.2% reported by Felsch *et al*¹⁶ from a single-center cohort. Notably, our data set includes only symptomatic recurrent defects. Other studies reported a higher risk of recurrent defects ranging in variation between 4.5% and 94%,^{27 33} which reflects the variability of follow-up periods, inclusion of asymptomatic patients, and imaging (ultrasound or MRI examination) used for screening.

We observed that the cumulative risk of experiencing at least one AE increased over time from 12.8% at 3 months to 32.3% at 24 months. These results reinforce the consensus agreement that a 2-year follow-up period

is necessary for comprehensive AE documentation, with at least 12 months considered essential for adequate AE monitoring following ARCR.

The severity of local AEs following ARCR was generally mild to moderate, with 61.7% graded as severity level I. This aligns with previous retrospective observations¹⁶ suggesting that most AEs were clinically manageable and did not require major intervention. However, the risk of experiencing more severe events (grades II–IV) in 12.6% of cases is noteworthy, including a 4.7% risk of experiencing a severe event requiring significant medical intervention, particularly patients with rotator cuff events. Persistent or worsening pain, while common, was mostly mild, with only a small portion (2.0%) reaching grade II severity. This finding aligns with existing literature, which highlights pain as a frequent but less severe postoperative issue following ARCR.²⁸ Peripheral neurological events were generally mild, classified as grade I or II, except for one case involving nerve injury—consistent with previous reports.^{8 34} Surgical site infections, though rare, had more serious implications, with three cases graded as III or IV. Deep soft tissue events, mainly shoulder stiffness, were largely low-severity (grades I–II), though four grade III events underscored the functional challenges such complications can pose. Overall, these findings suggest that while ARCR has a favorable safety profile, certain subgroups require more intensive management. Severity grading plays a key role in informing surgical decision-making and transparent patient counseling.

In our cohort, the AE risk over 24 months varied significantly depending on tear severity. Our analysis revealed a decreasing trend in AE risk from 41.5% in partial tears to 28% in massive tears. This trend appears linked to lower rates of persistent or worsening pain (from 15.6% in partial tears to 10.0% in massive tears) and fewer deep soft tissue events, particularly shoulder stiffness (13.6% in partial tears compared with 5.8% in massive tears). Notably, such a decreasing trend in AE risk from partial to massive tears was not reported by Felsch *et al*.¹⁶ This discrepancy suggests that prospective AE documentation using all relevant data sources (medical staff and patients) in a multicenter setting may be a more valid approach to documenting trends and subgroup differences in AE occurrence due to higher-qualitative and comprehensive safety data. Moreover, our data revealed that the risk of symptomatic rotator cuff events significantly increased from 2.0% in partial tears to 6.5% in massive tears. This suggests that although the overall AE risk may be lower in massive tears, their severity and nature are more serious, often requiring higher surgical revision rates.

The reporting of AEs demonstrated a balanced contribution from both patients and clinics for local AEs, with each group accounting for 41% of reports. However, the level of agreement between patients and clinicians in documenting AEs is low as reflected by the Kappa coefficients for various AE types, the lowest being for pain events. This finding highlights the under-reporting of several AEs without patient involvement. The substantial

participation of patients in AE reporting may be attributed to the increased feasibility of online reporting via self-completed questionnaires.³⁵

Clinics, however, were the primary reporters of distal events (45%), potentially due to their ability to assess AEs beyond patient-reported symptoms. In contrast, non-local events—those not directly related to the shoulder—were more frequently reported by patients (38.2%) than by clinical staff (23.5%). This suggests that non-local AEs may manifest in ways that patients experience more acutely, outside the usual focus of clinical examinations. Alternatively, surgeons may have placed less emphasis on events unrelated to the operated shoulder or the surgical intervention itself.

Pain was overwhelmingly reported by patients (70%), likely because patients are best positioned to perceive and quantify their pain more accurately, whereas surgeons may downplay the significance of pain as an AE, given that patients should expect to experience some level of pain following ARCR. The frequent reporting of pain by patients is an important finding, as pain is often under-reported or overlooked.^{36 37} While some argue that pain events have minimal impact on patient safety or key trial end points,³⁸ reporting them remains vital for the long-term patient follow-up.^{39 40} This highlights the importance of patient-reported outcomes in postsurgical monitoring, particularly for subjective symptoms like pain. Conversely, rotator cuff-related issues were predominantly identified and reported only by clinical staff (65%), reinforcing the necessity of clinical evaluation to detect structural or functional deficits.

A key strength of this study lies in the effective implementation of the CES for AEs within a large, registry-based patient cohort with standardized follow-up extending up to 2 years. However, several limitations must be acknowledged. First, data collection was conducted by many independent investigators, including 54 shoulder surgeons. Despite their medical background, meticulous coordination, and stringent cross-checking procedures, this likely introduced some variability in documentation. Second, although the study design adhered to the recommended 24-month follow-up period to capture all AEs according to the CES, some AEs may still have affected patients beyond this timeframe. Third, the final follow-up at 24 months relied on patient questionnaires, preventing clinicians from systematically examining patients for AE occurrence at that time point unless a clinical follow-up was requested. We cannot exclude that some patients may have sought consultation and care elsewhere in case of an AE. Fourth, since we enrolled a little more than half of all consecutive eligible patients with proportionally less partial tears and more massive tears, it illustrates that estimated overall complication risks after ARCR may be affected by various influencing factors including tear severity that require further thorough investigations.

Lastly, a tendency among some surgeons to minimize or overlook certain events, particularly intraoperative AEs, was observed during data collection. This aligns with previous

reports highlighting the tendency both to minimize the reporting of intraoperative⁴¹ and postoperative events.⁴² Therefore, involving patients in this process proves essential for the documentation of postoperative events.

CONCLUSIONS

Comprehensive documentation of AEs in accordance with the CES and its severity grading criteria was successfully achieved. Pain, deep soft tissue complications, and rotator cuff-related issues constituted the most common local AEs, while other events affecting the ipsilateral extremity were predominantly neurological. Most AEs occurred within the first 12 months following surgery, emphasizing a critical period for monitoring and intervention. Severity grading indicated that the majority of AEs were of mild to moderate intensity (grades I and II), with only 14.1% classified as grade III or IV.

Subgroup analysis identified tear severity as a significant predictor of AE risk, with massive tears showing higher risks for symptomatic rotator cuff recurrent defects but lower risks for pain and stiffness compared with partial tears. These findings underscore the importance of standardized postoperative surveillance of AEs involving clinician and patient reporting.

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Contributors LA and AM are the initiators and project leaders. LA, AM, HD and DS were members of the project adverse event (AE) review committee and involved in the study design regarding AE documentation and analysis. KG and TS checked responses from clinicians and patients at follow-up time points regarding the occurrence of AEs, and ensured related AE forms were documented, generated data clarification queries, as well as communicated with sites. All AE records were reviewed and validated by CB and SAM, and discussed at AE review committee meetings as required. Preparation of the manuscript was done by LA, KG and DS. AM, HD, CB, SAM and TS edited and critically revised the paper. All authors have read and approved the manuscript. LA is the guarantor of the manuscript.

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