

Assessment of EVAR Complications using CIRSE Complication Classification System in the UK Tertiary Referral Centre: A ~6-Year Retrospective Analysis (2014–2019)

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Abstract

Purpose To retrospectively analyse complications in endovascular aortic repair (EVAR) interventions and evaluate if the CIRSE (Cardiovascular and Interventional Radiological Society of Europe) complication classification system is appropriate as a standardized classification tool for EVAR patients.

Materials and Methods Demographic, procedural and complication data in 719 consecutive patients undergoing EVAR at one institution from January 2014 to October

2019 were retrospectively reviewed. Data (imaging reports, procedural reports, nurse notes, discharge summary reports) were collected consulting the electronic patient record system (EPR) of the hospital and cleaned and stored in a Microsoft Excel database. All the procedures were analysed in consensus by two interventional radiology consultants and a resident radiologist and if an intra-, peri- or post-procedural complication occurred, a grade (1–6) was assigned using the CIRSE grading complication classification system.

Results Twenty-five patients were excluded from the analysis because of invalid or incomplete data. The final population was made up of 694 patients (mean age 75,4 y.o., 616 male/78 female, min age 23 y.o., max age 97 y.o.). Complications emerged in 211 patients (30,4% of cases, 22 female/189 male). The number of patients with CIRSE grade I, II, III, IV, V and VI complications was 36 (17%), 17 (8%), 121 (57,3%), 15 (7,1%), 3 (1,4%), 19 (9%). Nineteen (2,6%) patients succumbed after EVAR. Thirty-four complications (16,1%) were related to vascular access.

Conclusion The CIRSE complication classification system represents a broadly applicable and feasible approach to evaluate the severity of complications in patients following EVAR. However, some deficit may be considered relevant and as starting standing-point for future improvements.

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Keywords Endovascular aortic repair (EVAR) · CIRSE complication classification system · Complications · Endoleak · Complications management · Complications rate · Sequelae · Additional treatment · Reintervention · Access-site complications · Octogenarians · Standardization · Complication grading scale · Reporting system

Introduction

The limited literature exists on standardised reporting systems to evaluate EVAR complications. Moreover, a lack of agreement on the definition of complications and their severity hampers the comparison of different outcomes. As for many other kinds of surgery or intervention, most reports use term such as “minor”, “moderate” and “severe”, but they are subjective, unreliable and often inconsistently used among different authors and centres [1]. Some authors use a simple distinction in minor and major events whilst others employ the Complex Severity Index (CSI) in order to stratify the complications [2, 3]. This lack of uniform reporting throughout different practitioners results in a series of disadvantages to compare results over different time periods within the same institution, within different institutions and even for different treatments. Outcome data for the therapeutic techniques such as for the EVAR are strategically evaluated, and an accurate complication reporting system is necessary [4].

In order to standardize the complication reporting, some classifications have been developed, introduced and validated [5–8]. In the field of interventional radiology, the CIRSE Standards of Practice committee introduced in 2017 the CIRSE complication classification system. The classification system allows the evaluation of the safety of the procedures, comparison of different approaches and internal quality control to improve management and prevention of complications [9].

To our knowledge, the CIRSE complication classification system has not been reported in the literature in the assessment of EVAR complications. In our opinion, it may represent an appropriate choice in the analysis of the outcome in the EVAR scenario. The main aim of this study is to retrospectively analyse complications in EVAR interventions and evaluate if the CIRSE complication classification system is appropriate as a standardized classification tool for EVAR patients.

Materials and Methods

A retrospective analysis was conducted on all patients who underwent EVAR at our institution between January 2014 and October 2019, providing almost 6 years of consecutive data. All patient data (demographic data, sex, age, imaging reports, procedural reports, nurse notes, discharge summary reports, follow-up notes) were retrospectively extracted and reviewed consulting the electronic patient record system (EPR) of the hospital (Epic eHospital platform, Verona, WI, the USA). Data were cleaned and stored in a Microsoft Excel database. All the EVAR procedures

were analysed and reviewed by two interventional radiologists and a resident radiologist and if an intra-, peri- or post-procedural complication occurred, a grade (1–6) was assigned in consensus using the CIRSE complication classification system.

The data of the present study were collected in the course of common clinical practice, and accordingly, the signed informed consent obtained from each patient authorized also for research study purposes. The study protocol conforms to the ethical guidelines of the “World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects” adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, as revised in Tokyo 2004.

Complication’s Assessment and Grading

The CIRSE complication classification system takes into account intra-, peri- and post-procedure complications and uses a grading scale 1 to 6 where grade “1” is assigned to a complication that may be solved within the procedure operative session without additional therapy, sequelae or deviation from the normal post-therapeutic course, and “6” is assigned in case of death (Fig. 1). The grading was assigned by a radiologist in training and two trained interventional radiologists. In case of ambiguity of assignment, a consensus between the examiners was requested. Special attention was paid to the analysis of endoleak type II because it represents a common event in EVAR interventions. In our analysis, we decided to consider the endoleak type II a complication only in case it was the cause of aneurysm sac enlargement requiring reinterventions. The presence of hematoma at the access site was carefully evaluated, and it was considered a

Grade	Description
1	Complication during the procedure which could be solved within the same session; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course
2	Prolonged observation including overnight stay (as a deviation from the normal post-therapeutic course <48 h); no additional postprocedure therapy, no postprocedure sequelae
3	Additional postprocedure therapy or prolonged hospital stay (>48 h) required; no postprocedure sequelae
4	Complication causing a permanent mild sequelae (resuming work and independent living)
5	Complication causing a permanent severe sequelae (requiring ongoing assistance in daily life)
6	Death

Fig. 1 CIRSE complication classification system grading [9]

complication if caused a delay in discharge or reintervention.

Procedure and Follow-Up Details

Elective and emergency procedures were performed and included in the retrospective analysis. All elective cases were discussed in a multidisciplinary team (MDT) meeting with the interventional vascular radiologists, vascular surgeons, anaesthesiologists and clinicians. The procedures were performed by interventional radiologists with experience ranging from 5 to 20 years. The procedures were performed in a Hybrid EVAR theatre, equipped with a fully motorized C arm (Artis Zeego, Siemens Healthcare GmbH, Erlangen, Germany) or in angio-theatre with a fixed imaging system (Artis Zee, Siemens Healthcare GmbH, Erlangen, Germany). Percutaneous access was performed whenever possible in all patients with suitable iliofemoral anatomy (defined by normal location of the CFA bifurcation at least 2 cm below the inguinal ligament with no evidence of calcification in the anterior arterial wall or the presence of minimal calcification affecting 50% of the posterior arterial wall). The choice of technique for femoral access was at the discretion of the treating physician. Surgical access via femoral cut-down was deemed necessary and performed in case of hostile iliofemoral anatomy. In case of percutaneous access, the “preclosure technique” with Perclose Proglide (Abbott Laboratories, Abbott Park, Illinois, the USA) was used [10].

Post-operatively, patients were monitored with clinical and laboratory examinations. Post-operative surveillance followed an institution’s standard EVAR surveillance protocol in line with recommendations by the European Society for Vascular Surgery [11]. We included patients with a minimum follow-up of 3 months and at least 1 imaging follow-up exam. In particular, the availability of data of 1 CT/MR follow-up study was considered an essential inclusion criterion. Due the complexity of the procedure, we decided to consider both early (< 30 days) and late complications. Patients were followed up until the end of the study period, death, emigration, or if controls were ended either by the patient or medical team.

Statistical Analysis

Data were collected and analysed using a combination of Excel (Version 2010, Microsoft, Redmond) and SPSS (Version 23, IBM Corp, Armonk, NY). Descriptive statistics were reported as number (percentage) or mean (standard deviation), as appropriate. Continuous variables were compared using the Chi-square test and Mann–Whitney *U* test. *P* values less than 0.05 were considered statistically

significant and *p* values less than 0.01 highly statistically significant.

Results

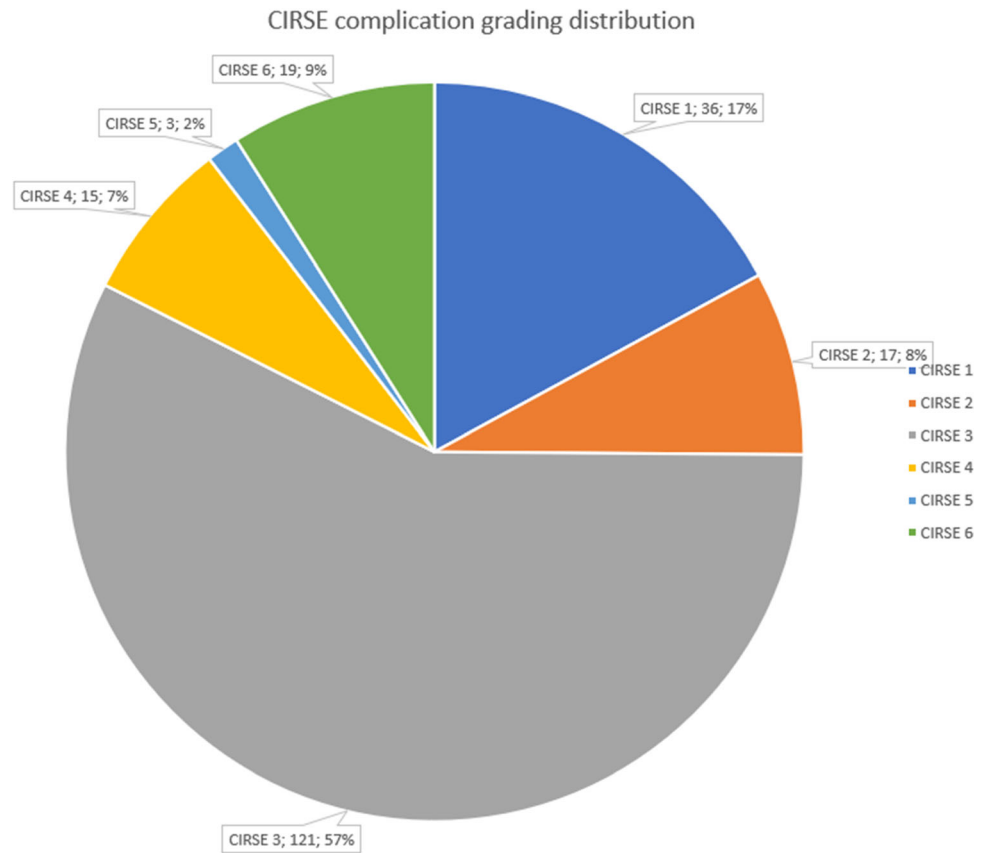
In the period between January 2014 and October 2019, 719 consecutive EVAR and emergency TEVAR cases were performed in our institution (included Fenestrated -EVAR and Branched-EVAR). Based on the EPR consultation, 25 procedures were excluded from the analysis because of incomplete data (21 patients were excluded because data were corrupted or not complete, this fact is mainly due to fallacious digitalisation of documents, and in order to easy the revision and uniform the criteria of analysis, we decided to include only patients without problem of data recording; four patients excluded because did not fulfil follow-up data inclusion criteria). Descriptive data of the final population are summarized in Table 1.

Uncertainty of grade assignment was rare, just in 13/694 cases (1,87%), the researchers were doubtful about the interpretation of the complication and its grading according to CIRSE complication classification system. In four cases, the revision of the data excluded the event may be considered a complication; in 1 case, the grade was confirmed; in 1 case, the grading was lowered (3 to 1 CIRSE grade); in 7 cases, the grade of the complication was increased. The final grade assignment according to CIRSE classification is reported in Fig. 2.

Table 1 Table showing descriptive data of the patients’ cohort and complication and death rate in subgroups (< 80y.o. vs ≥ 80 y.o.)

Final population	694
Male	616
Female	78
Patients ≥ 80 y.o	242/694 (34,9%)
Follow-up time	Min 3 months
Mean age	75,4 y.o
Max age	97 y.o
Min age	23 y.o
Complications	211/694 (30,4%)
Male	189
Female	22
Complications in ≥ 80 y.o.patients	72/242 (29,7%)
Complications in < 80 y.o. patients	139/452 (30,7%)
Death rate	19/694 (2,7%)
In ≥ 80 y.o.patients	7/242 (2,9%)
In < 80 y.o. patients	12/452 (2,6%)

Fig. 2 Pie-chart complications grading according to CIRSE classification system in 694 EVAR procedures, total numbers and percentage



Overall Mortality Causes

The main cause of death was perioperative bleeding from a ruptured aneurysm (6 cases). In one case, it was a late complication due to endoleak type 2. Two procedures were converted to open repair due to the intraoperative bleeding but without success. kindly post-operative respiratory failure and pneumonia were encountered in four patients as the leading causes of death. From the revision of the perioperative and surgical notes, Nellix (Endologix Inc., Irvine, CA, the USA) device failure (pressurisation of the sac and caudal migration) was the cause of death in 3 cases. Other causes are reported in Table 2.

Emergency and Elective Repair

In the period of analysis, 18 emergent procedures were performed. We encountered 16 complications in this cohort study (16/18, 88,8%), with an overall mortality rate of 38,8% (7/18). Data of complication grade assignment in elective and emergent EVAR procedures are represented in Fig. 3.

Complications Details

CIRSE grade 3, 4 and 5 grade complications occurred in 139/211 patients (66%). The most common CIRSE grade complication encountered was grade 3 and the analysis of the complications made year by year demonstrates this trend (Fig. 4). The group of complications graded as CIRSE 3 is widely heterogeneous. Looking to the causes of complications, we observed serious risky situations just like acute emergent limb ischemia but also recovery-related errors (example—wrong diet in a patient with celiac disease that caused gastro-intestinal discomfort and delayed discharge). Based on the analysis of the complication rate made year by year, we noticed the trend-rate goes from 44.18% in 2018 to the minimum of 17.74% in 2017. The trend of the complication rate year by year shows a not-constant incidence. This fluctuation appears to be time-wise related to some changes in our interventional radiology unit (staff member discontinuity, angio-theatre renovations transition, new protocol flowchart introduction), but it also could be part of a cyclic incidence fluctuation we are not able to demonstrate (Fig. 5). Thanks to the standardized method of evaluation of complications, we were able to stratify complications causes on the bases of CIRSE grade assignment (Table 2).

Table 2 Table showing different complications causes categorized by CIRSE complication grade

CIRSE 1	N
Access complication (difficult access, hematoma, seroma)	11
Renal–EIA–IIA inadvertent coverage (not planned stenting)	6
Additional moulding or cuff insertion (Type I endoleak)	6
Inadvertent artery dissection	4
Blood pressure drop/intraoperative trifascicular block	3
Conversion to open repair	2
Drop in PO2 saturation	1
Proglide failure	1
Embolectomy	1
Clot removal	1
CIRSE 2	
Post-EVAR urinary retention	4
Additional surveillance/delayed stay	4
Fever	3
Access-site complications	2
Hypotension/hypertension post-EVAR	2
Limb thrombus–delayed stay	1
Stent dislocation	1
CIRSE 3	
Reintervention	50
Causes	
Occlusion/embolectomy	13
Endoleak type 1	12
Access-site complications	8
Angioplasty	6
Endoleak type 2	3
Limb extension	3
others	5
Delayed discharge/adjunctive therapy	71
Pneumonia/respiratory tract infections	12
Access-site complications	11
Renal function impairment	11
Post-implantation syndrome	7
Cardiac event/requiring therapy	7
Various infections	6
Blood transfusion	4
Emergency repair/delayed stay	4
Adjunctive therapy various causes	4
Small bowel ileus/obstruction/ischemia	3
Others	2
CIRSE 4	
Claudication	5
Renal/splenic infarct	3
Acute coronary syndrome	2
Lifelong therapy	2
Perdurant weakness	2
Stroke	1

Table 2 continued

CIRSE 5	
Acute kidney injury (AKI)	2
Amputation	1
CIRSE 6	
Bleeding/ruptured aneurysm	6
Respiratory failure	4
MOF	2
Perioperative cardiac arrest	2
Bowel and leg ischemia	2
Nellix failure	3

Access-site-related complications were the commonest complication encountered in the different categories. A total of 34 complications were access-site related (16.1% of complications, 4.9% of procedures). The CIRSE complication grade assigned in these cases ranged from 1 to 4 (Fig. 6).

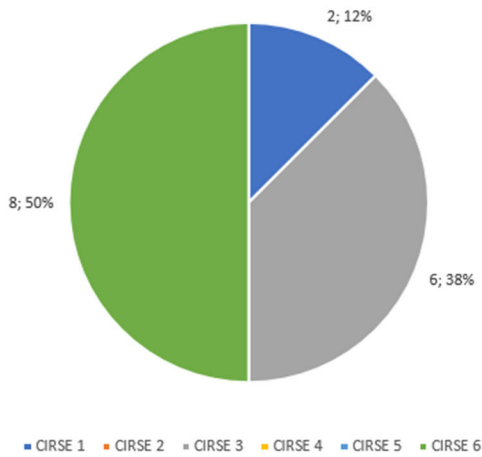
The review of the EPRs about access-site-related complications showed the presence of a seroma as the most common complication encountered (10 cases). The presence of a seroma leads to simple adjunctive surveillance in most of the cases, but in 3 cases, the excessive discomfort and extension caused new treatment/procedure or readmission. Other causes of access-site-related complication are reported in Table 3. Based on the analysis of the complications in the subgroups of patients ≥ 80 y.o. and patients < 80 y.o., the use of the Mann–Whitney U test testified no statistical difference in complications grade assignment ($p = 0,85$) (Fig. 7).

Discussion

A uniform, simple and reproducible system, like the CIRSE complication classification system, would permit comparison of outcomes between surgical procedures and between different institutions and allow for knowledge transfer for improvement in one's institution. The implications are wide-ranging as all disciplines would be empowered to work toward the same goal of improving surgical in-patient outcomes [12]. In our analysis, the use of CIRSE classification system filled the gap of the lack of an objective grading system able to detect all kind of complications with a special focus on their outcome and the consequent sequelae in the EVAR scenario.

In our study, the evaluation of complications in EVAR procedures by using the CIRSE complication classification system resulted in an easy applicable method to detect, stratify and categorize intraoperative and post-operative complications. Its wide applicability is testified by the fact

Emergent EVAR procedures complication grade according to CIRSE classification system Jan 2014 to Oct 2019



Elective EVAR procedures complication grade according to CIRSE classification system Jan 2014 to Oct 2019

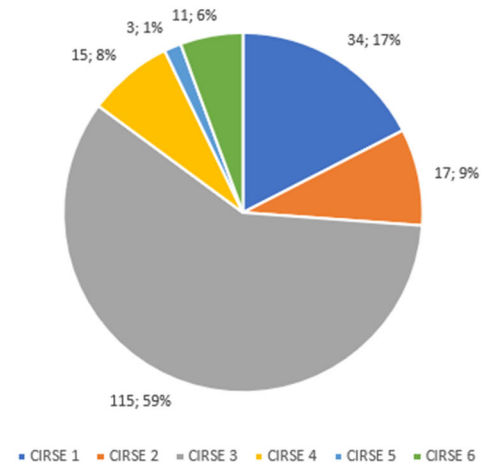
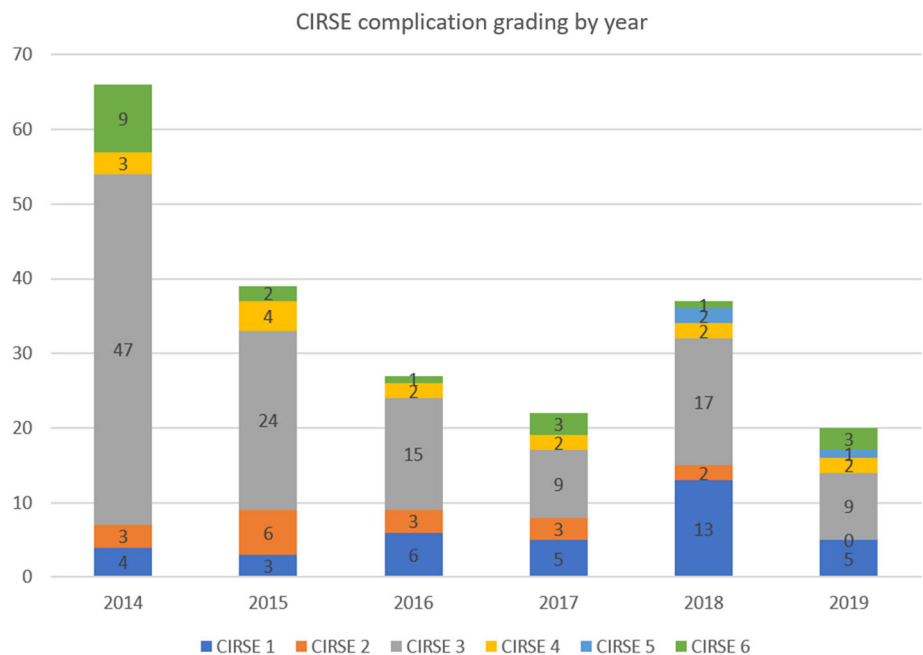


Fig. 3 Pie-chart complications grading according to CIRSE classification system in emergent and elective procedures, total numbers and percentage

Fig. 4 Bar-chart presents CIRSE complication grading by year



that no complications emerged as orphan of grade assignment and by the low rate of uncertainty grade assignment. The complication and the death rates encountered are in line with the results of the literature reports and testify the reliability of the study cohort [13–16]. As resulted by the rate of CIRSE grade 3 assigned, the need for reintervention and adjunctive therapy represents a common event after

EVAR and it has a relevant impact on the outcome and costs of the procedure [17].

The use of the CIRSE classification system allowed to discriminate permanent sequelae following treatment, differentiating mild from severe ones. The use of the CIRSE classification system permitted an immediate detection of the rate of these cases and creation of a useful amount of data to be used by hospital managers, insurance companies

Fig. 5 Line graph showing complication rate year by year

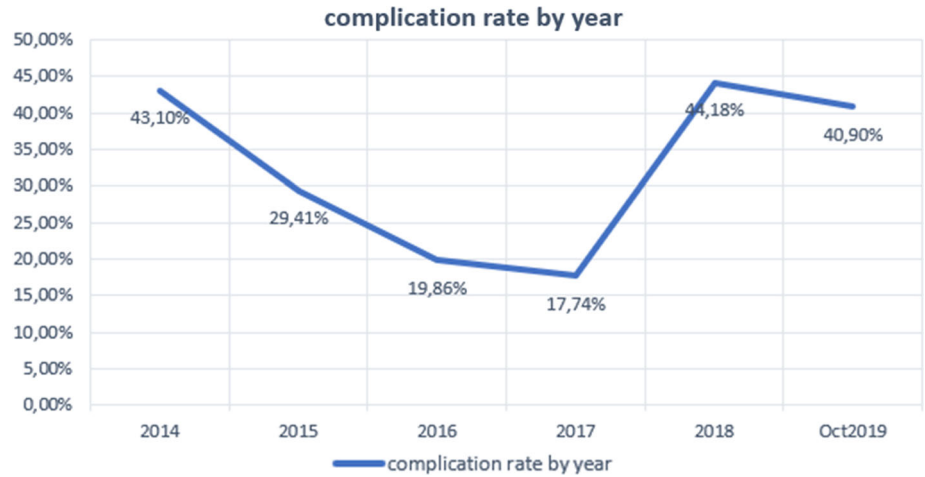


Fig. 6 Pie-chart access rate-related complication according to the CIRSE complication classification system

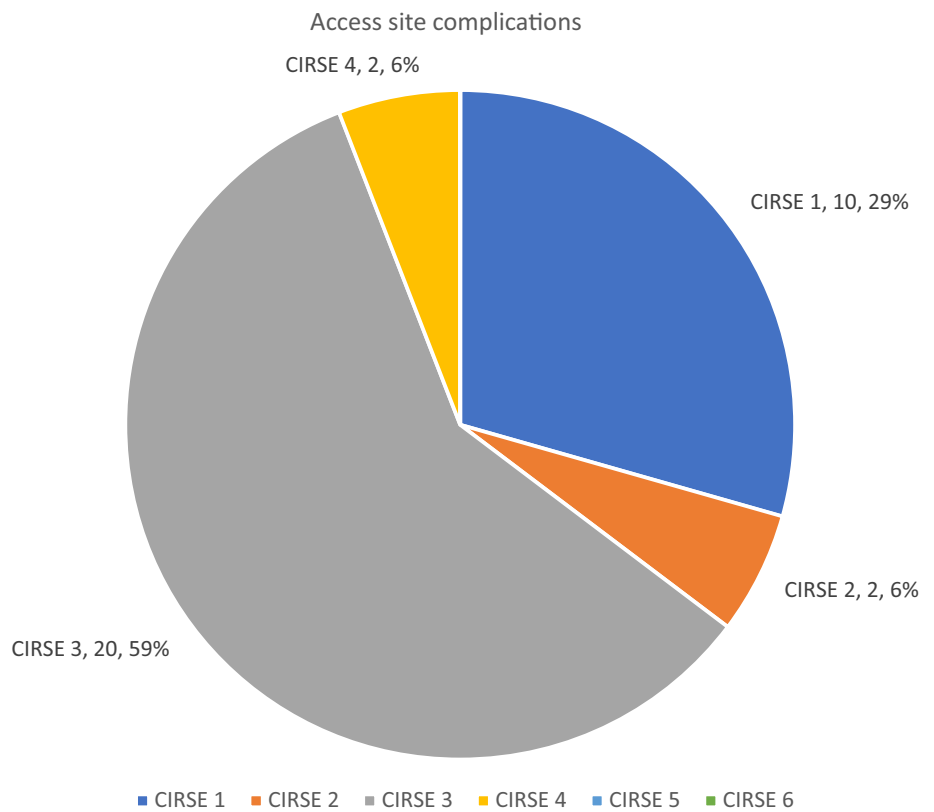
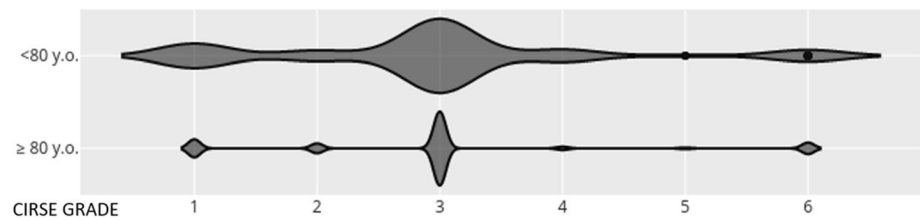


Table 3 Table showing access-site complication causes

Access-site complications causes	N
Seroma	10
Hematoma	8
Excessive bleeding and consequent conversion to open repair	6
Pseudoaneurysm and consequent thrombin injection treatment	6
Artery damage needing reintervention (embolectomy, stenting, etc.)	3
Infection	2
Nerve damage/plexopathy	1
Device failure	1

Fig. 7 Violin plot graph showing no difference in CIRSE grading complication attribution in < 80 y.o. vs ≥ 80 y.o. patients, based on Whitney U test result



and governments, in order to strategically plan their way to assess these events [4].

Our results support the findings of different papers that testify the efficacy and safety of EVAR in the octogenarian subgroup of patients as the evaluation of the mortality rate and grading assignment of complications demonstrated no differences in respect of a younger population [Fig. 7] [18, 19].

Our series highlighted the importance of vascular access care and management. In the literature, injury to access vessels has been reported to occur in up to 5%–17% of cases. These data are in keeping with our results [20–22]. In our institution, the policy of “percutaneous-first” (i.e. always percutaneous access if anatomically feasible in patients without hostile iliofemoral anatomy) was adopted during the study period. Several factors may be associated with access-site complications, including operator experience, vessel calcifications, obesity and large sheath size. The percutaneous access in EVAR procedures requires an adequate level of expertise in the evaluation and choice of puncture site and high-level technical skills. These aforementioned factors may be relevant also considering the learning curve and the scenario (University Hospital and training centre) and might have an impact on our results. However, no death or permanent severe sequelae (patients requiring ongoing assistance in daily life) due to access-site complications were detected in our series, but a relevant number of reinterventions or adjunctive therapy were encountered [Table 3, Fig. 6].

Moreover, the CIRSE complication classification system appears to be a useful and exhaustive tool to detect any kind of complications, including those that may happen during the interventions but that do not need any further management after the end of the treatment/procedure (CIRSE grade 1). In fact, if it is true that the impact of this kind of complications could be marginal with regards to patient outcome, their impact might not be negligible taking into account analysis of possible comparison of different approaches, analysis of learning curves, procedural time and costs. In our series, they represent a consistent part of the overall complications (17%), and the possibility to detect and analyse their occurrence with the CIRSE complication classification system represents a strong favourable point to its routine use since other classification systems do not take into account them [5–7].

As EVAR treatment represents a major procedure, many variables should be considered. In the application of the classification, we were driven to some interpretative efforts, for example, in the grade assignment in case of open conversion. In these cases, we decided to consider the conversion to open repair as a grade 1 because deemed as a complication inherent the percutaneous approach resolved by the alternative surgical approach in the same operative session. Obviously, this fact conditions also the hospital stay, and we believed it would be linear to consider the prolonged hospital stays after the conversion as a grade 2 or 3 only if an open repair-related complication was noted. The recovery time may be strictly related to the initial performance status of the patient and conditions of repair and may impair the definitions of the prolonged stay so that we decided to consider normal a < 48 h of stay if after elective repair. > 48 h but less than 72 h of hospital stay has been considered grade 2 and grade 3 if > 72 h of stay.

In addition, as the complexity of the EVAR requires long follow-up and some complications may arise also years after (endoleak II in primis may be cause of reintervention), we decided could be reasonable to include early and late complication in the same group of analysis. Even if it is true that the definition of temporally associated complication has not to be diluted in time, it is also linear that the cause-effect relationship has not to be considered negligible. About this point, in the CIRSE complication classification system, there is no clear definition regarding the time-course and this may represent a confounding factor in the evaluation of results.

Another important point is represented by the fact that the CIRSE complication classification system does not distinguish between emergent and elective procedure and this may represent an evaluation confounding factor. In our study, we were able to analyse the elective and emergent cohort study, and as expected, in the emergent repair group, the complication rate and the death rate were dramatically higher than in the elective one. This differentiation could be relevant in the evaluation of outcome and its inclusion may represent a suggestion to improve the classification and categorization method in future.

We believe that the CIRSE complication classification system allows an unbiased evaluation of procedure care quality. In our context, the EPR system represented a precious tool because it permitted easy and detailed

retrospective evaluation of patient data (imaging reports, procedural reports, laboratory tests, nurse notes, therapy diary, discharge summary reports, follow-up data).

The main limitation of this study is that even using the EPR system, some data may be missing or corrupted. We did not investigate interobserver reliability in the current study rather we attempted to eliminate any doubtful grade assignment by a consensus agreement between the researchers.

However, our dataset represents one of the biggest in the literature regarding EVAR and we believe that will provide a benchmark reference for future studies.

In conclusion, the CIRSE system of classifying complications provides a comprehensive and uniform platform for grading complications within complex contexts such as EVAR with the benefit of evaluating patients and hospital outcomes. The application of this grading system provides the opportunity to learn from and improve the treatment of complications and their management. However, some deficits have been encountered in our tool-applicability experience. In particular, the absence of clear distinction between early and late complication or between the emergency and elective procedure in the CIRSE classification complication system may confound the essence of the obtained results. These aspects may be considered as starting standing-point toward future improvements.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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