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Development and assessment of the AE-RADS standardized grid for specifically evaluating adverse events in diagnostic radiology and teleradiology

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Abstract

Background A specific grid for analyzing and grading adverse events in diagnostic radiology is lacking. In France, the standard HAS grid, a generic 5-point scale adapted from the Common Terminology Criteria for Adverse Events (CTCAEs), is criticized for limited applicability in radiology. Our aim was to develop and evaluate a radiology-specific AE grid (AE-RADS) tailored to diagnostic and teleradiological practices and to compare its performance against the CTCAEs-based HAS grid regarding inter-observer reproducibility and agreement with expert consensus.

Methods AE-RADS, structured as a decision tree with 90 items, was developed by four senior radiologists with extensive AE experience. To assess it, 100 AE cases from early 2022 were reviewed by two radiologists and two non-physician support members, all blinded to the initial AE grading. Observers rated AEs using both the HAS and AE-RADS grids, comparing severity, AE frequency per patient, sources, and types for inter-observer reproducibility and expert agreement. Tests included intra-class correlation coefficient (ICC), Fleiss Kappa and Krippendorff alpha for reproducibility and McNemar test for comparing agreement with consensus.

Results Among 100 patients (49 women, median age 66.9 years), 104 AEs were identified. AE-RADS achieved higher inter-observer reproducibility for AE frequency (ICC = 0.690 vs. 0.642 with HAS) and for grading the most serious AE (Krippendorff alpha = 0.519 vs. 0.506 with HAS). Agreement with expert consensus was significantly greater with AE-RADS (63–81%) than with HAS (25–47%; P-value range: 0.0001–0.0051).

Conclusion AE-RADS shows improved, though still imperfect, agreement between evaluators and experts, supporting its potential for more precise AE assessment in diagnostic imaging.

Keywords Adverse events, Teleradiology, Radiology, Healthcare evaluation, Management by quality

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Background

Adverse events (AEs) related to medical care carry significant medical, legal, insurance, human, and financial implications [1]. Today, managing AEs is an essential aspect across all medical specialties [2]. In France, this management is integral to quality initiatives and is a key criterion for healthcare institution certification by the French 'Haute Autorité de Santé' (HAS, French National Authority for Health). The primary goals are to systematically record and analyze all AEs, implement corrective and preventive measures, reduce risks, and drive continuous improvement in clinical practices.

Medical imaging, especially in emergency departments, plays an increasingly crucial role in patient care globally [3]. Yet, the rise in imaging exams—particularly CT scans—outpaces the growth of emergency patient visits. Between 2012 and 2019, CT scans increased by over 50%, while emergency visits rose by just over 20%, with the number of radiologists remaining constant [4]. This disparity raises concerns about a potential increase in AEs, as both the number of exams per patient and per radiologist rise. Consequently, AE management is a growing concern in diagnostic imaging and better understanding and reporting them is crucial for patient safety and quality improvement in radiology [5, 6]. Previous studies have quantified the types and frequencies of AEs. For example, Hannaford et al. analyzed 3,976 AEs in the Australia and New Zealand RaER database found that the majority of incidents occurred during patient preparation (34%), imaging requests (27%), and diagnosis communication (23%) [7]. Specific issues included inadequate patient handovers (41%), unsafe or inappropriate patient transfers (35%), incorrect request form information (52%), and delayed or incorrect diagnosis communication (36%). Moreover, Mansouri et al., based on 4,234,208 examinations over six years, the overall incident reporting rate was 0.23%, with inpatients having the highest rate (0.30%) [8]. More specifically, emergency radiology departments had a reporting rate of 0.19%, with less than 1% of incidents causing major harm, in another study of 881,194 examinations [9].

Teleradiology further amplifies AE risks [10]. The physical separation between the referring physician, the radiologist, and the technician can lead to more technical and communication issues [11]. Since teleradiologists often interpret exams from multiple centers with differing practices, identifying AE sources and providing effective feedback can be more complex.

In France, any AE must be reported to the responsible team or designated personnel, with a comprehensive record of the incident, contributing factors, consequences, and corrective actions. Serious AEs are reported to the HAS [12], and reviewed in multidisciplinary conferences to develop preventive measures [12–14]. The HAS provides a generic 5-point ordinal AE analysis framework (called HAS grid) based on the international Common Terminology Criteria for Adverse Events (CTCAEs) [15]. Although intended for broad use, this framework often lacks the specificity and detail needed in radiology. Certain situations, such as inappropriate imaging protocols, issues with contrast medium injection, or radiation dosage concerns, are not covered by the HAS grid. While these events may initially lack a clear clinical impact, they still require documentation within a quality framework to prevent recurrence, manage potential risks, and address any long-term effects on patient safety. Hence, currently, no international standard offers a detailed, objective, reproducible, and radiology-specific AE framework suitable for both in-person and remote settings [16].

This study proposes and evaluates the AE-RADS (Adverse Events Radiological Scoring System), a robust, standardized AE rating grid tailored to radiological practices in diagnostic imaging. Secondary objectives include comparing the AE-RADS performance against the HAS-recommended framework.

Methods

Study design and gold standard

This observational study was approved by the Institutional Review Board of the French Society of Radiology (approval number: CRM-2306-350). This study did not involve human participants, but only anonymized data from health care. The need for specific written informed consent for this study was waived due to the retrospective nature of the data study, but specific consent for teleradiology and the re-use of anonymized health care data was indeed presented to patients. All patients were informed that their anonymized health care data could be reused for nonprofit research. This study was performed in accordance with relevant guidelines/regulations concerning studies on anonymized data derived from care and in compliance with the Helsinki Declaration.

We randomly included 100 solved cases out of 280 cases from the AE database of IMADIS-Groupe, a medical company dedicated to the remote interpretation of imaging for 105 emergency departments in French public and private hospitals, between January 1st, 2022 and April 30th, 2022 (i.e., study cohort). For comparison, during the same study period, 142,995 examinations were interpreted by radiologists working at IMADIS-Groupe. Inclusion criteria were (i) AE case entered and managed by the AE team from IMADIS-Groupe and (ii) considered as solve by all parts (i.e., IMADIS-Groupe, patient and partner center). AE cases without validated conclusion were excluded.

All these cases were entered in the AE registry on a routine basis, either by representative of the hospitals or

Table 1 Initial adverse event grid according to the French National authority for health (HAS grid for French 'haute autorité de Santé')

Grade	Explanations
G1	Minor consequences without prejudice for patients (for instance: simple minor delay)
G2	Incident with temporary injury (for instance: delay causing disruption in patient care)
G3	Incident with an impact (for instance: prolonged hospitalization, unplanned transfer, or temporary loss of function)
G4	Incident with serious consequences (for instance: re-intervention, impact on daily life or partial permanent disability)
G5	Incident with very serious consequences (for instance: death, major sequelae and permanent disability)

by members of IMADIS-Groupe, because of an inquiry on an AE.

In general, the AEs were prospectively and routinely analyzed by a dedicated team of experts, including 4 radiologists (JFB, FG, BP and PE) and one paramedical representative from IMADIS-Groupe, who were not involved in the events. Additionally, a legal expert could be solicited in difficult situations. The findings were then discussed with medical and administrative representatives from the hospital where the AE occurred. The clinical consequences of the AE were systematically collected and analyzed. After resolving the cases, a summary report was written and validated by all parties, detailing various educational, organizational, legal, and improvement actions. A follow-up schedule was also established to ensure these actions were implemented to prevent similar future adverse events.

Before this study, AE experts commonly used the standard HAS grid, which consists of five categories (Table 1) and served as the primary reference for AE evaluation.

This study aimed to develop a standardized grid specifically designed for reporting AEs in radiology and teleradiology departments-the AE-RADS grid-to enhance the identification of both the source and severity of these events.

A summary of the study workflow is provided in Fig. 1.

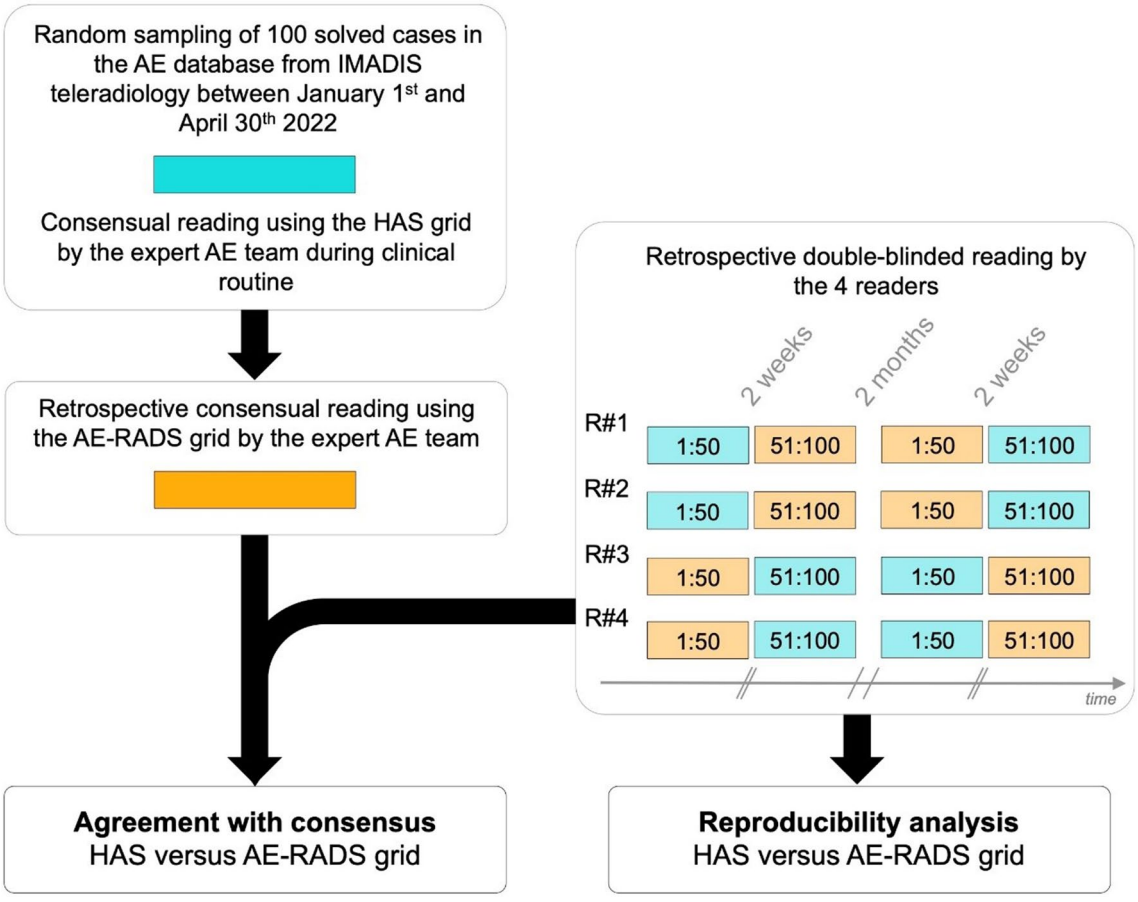

Fig. 1 Study workflow. Abbreviations: AE: adverse events, AE-RADS: adverse events radiological system, HAS: standard French '*Haute autorité de santé*', R#x: reader number 'x'. Readings according to the HAS grid are in light blue; readings according to the AE-RADS grid are in orange. The numbers inside the boxes in the panel corresponding to the 4 retrospective reading are the case numbers

Development and explanation of the AE-RADS analysis grid

Table 2 details the 90 items of the AE-RADS grid.

The Fig. 2 represents the organization of the items in a chronological way, including the involved professionals (i.e., requesting physician, radiographer, radiologist), the main step of the patient management (i.e., imaging request, protocol proposal, image acquisition, image interpretation, subsequent medical actions) and the technical features involved at each of those steps (i.e., phone, PACS, internet server, image acquisition system, radiology information system [RIS]).

To develop this grid, the AE team randomly extracted 100 different consecutive AEs from the IMADIS AE registry between September and November 2021 (i.e., development cohort, over a distinct study period), reviewed them in consensus and implemented the grid to account for all possible situations, based on their experience in AE reporting since the creation of IMADIS-Groupe (2009) and based on literature review. The grid is organized as a decision tree, starting from the source of the incident (categorized as radiologist, radiographer, prescribing physician, or related to the information, technology and communication tools), followed by the main category of issue, and a modulation factor to determine the grade of seriousness of the adverse events. The grid includes both radiological adverse events (those precursor with no immediate impact on patients but requiring reporting in a quality framework due to potential future patient safety implications) and combined radiological and clinical adverse events, labeled 'G+' when there is an associated clinical impact (G + being a temporary status). For these 'G+' cases, the HAS grading scale is applied with its G2, G3, G4, and G5 categories to evaluate the impact on patient health once all clinical consequences are established. Ultimately, the grading system for the clinical severity is similar to the CTCAE and HAS grades, ranging from G1 (minor consequence without impact on the patient) to G5 (worst possible with major consequences on the patient's health with the requirement to submit mandatory reports to the relevant authorities, for example, in the case of a significant radioprotection event).

After developing the AE-RADS grid using the development cohort, the expert team annotated the 100 AE cases from the study cohort through a consensus process. It is important to note that the study cohort had already been prospectively annotated using the HAS grid as part of the routine practice of the AE team.

Retrospective readings

Four additional readers retrospectively evaluated the entire study cohort of 100 patients using both the HAS and AE-RADS grids. The readers included two senior radiologists (NL and RM) and two radiographers (SLN and VF). All readers were prospective members of the AE team and were blinded to both each other's evaluations and the reference readings. Importantly, the four readers participated in a training session, where they reviewed 5 other randomly-sampled cases over 2 h with the AE team from the IMADIS group. During this session, they were encouraged to ask questions to standardize their approach to filling out the AE-RADS grid.

To limit memory bias, the real readings included in the study were scheduled as follows (Fig. 1): two readers (Reader-1 [NL] and Reader-2 [RP]) first analyzed the 50 cases using the HAS grid, followed by the next 50 cases using the AE-RADS grid. Two months later, they re-evaluated the first 50 cases using the AE-RADS grid and the subsequent 50 last cases using the HAS grid. Conversely, the other two readers (Reader-3 [VF] and Reader-4 [SLN]) began by analyzing the first 50 cases with the AE-RADS grid, then the next 50 cases with the HAS grid. After three months, they re-evaluated the first 50 cases using the HAS grid and the last 50 cases using the AE-RADS grid.

Ultimately, the study dataset comprised the reference readings and the four independent readings according to both the HAS grid and the AE-RADS grid.

Clinical and radiological data collection

For each of the 100 cases of the study cohort, the following data were collected: patient age, sex, imaging modality, body area involved, and use of contrast medium injection. Using both the HAS and AE-RADS grids, the four readers recorded the number and grade of each reported AE. Additionally, they noted the source and description of each adverse event as specified in the AE-RADS grid. The readers also tracked the total time spent reviewing the 100 cases with each grid.

Statistical analysis

Statistical analyses were performed using R (Vienna, Austria, v4.1.0). All tests were two-tailed, and a *P*-value less than 0.05 was considered significant. Figure 1 also summarizes the statistical workflow. Random sampling was ensured using the 'sample' R function in the AE database over the appropriate time period for both the development and study cohorts.

Descriptive statistics

Numeric variables were described as mean ± standard deviation (SD) or median and range, depending on the results of the Shapiro-Wilk normality test. Categorical variables were presented as numbers and percentages.

Table 2 Adverse event in radiology systems (AE-RADS) grid

Source of AE	Type of AE	Immediate type of impact on patient	Detailed type of immediate impact	Additional gravity criterion	Final score
Requesting physician	Patient identification vigilance (examination requested under the wrong name)	Patient not imaged	Error corrected by the radiographer	No radiological examination acquired	G1
		wrong patient imaged	Patient who should benefit from this type of imaging (same modality)	If the same protocole is achieved	G1
				If more acquisitions were performed on the CT (same area or additional area)	G3
				Injection not requested but performed without patient impact.	G2
				Injection not requested but performed with patient impact (acute renal failure or reaction to contrast agent)	G2-G5§
				If there is no risk of over-radiation and no contraindication to performing the examination.	G1
			Patient who should not benefit from this type of imaging.	Unrequested injection performed with no impact on the patient.	G3
				Unrequested injection performed with patient impact (acute kidney injury or reaction to contrast agent)	G2-G5§
				Without injection: depending on whether there is over-radiation or not.	G2-G5§
	Issue with the initial request wording	Inappropriate use of the RIS	Misuse of the RIS (bypassing alert systems/mandatory fields when applicable)	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Other	Incomplete request/incorrect information from the referring physician.	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
Radiologist	Mistake on protocolization process	Assignment of an inadequate protocol	Inappropriate protocol for the correct anatomical area	Depending on the impact of the contrast medium	G2-G5§
			Request for an additional scan on an anatomically unrequested area in CT	Over-radiation	G3
			Missing a requested anatomical area.	With clinical impact on patient	G2-G5§
			Oversight - Lateralization error in the protocol or related issue.	Acquisition of the incorrect laterality	G3
				Acquisition of the correct laterality	G1
			Non-compliance with radiological recommendations	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Inappropriate use of the RIS	Misuse of alerts regarding pregnancy	Over-radiation	G2-G5§
			Protocol modification noted in the RIS communication module but no change made to the protocol	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Misuse of other alerts: e.g., renal function, hyperthyroidism, allergy as applicable.	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
	Failure to adhere to good organizational and medical practices	Transmission of results to the requesting physician during the examination	Mandatory call for conditions affecting vital prognosis	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		RIS communication module not or insufficiently filled out	RIS communication module not or insufficiently filled out	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Unreported modification of the radiological report	Modification with medical impact but not traced in the radiological report	With clinical impact on patient	G2-G5§
			Modification with medical impact traced in the report but not communicated to physician.	With clinical impact on patient	G2-G5§

Table 2 (continued)

Source of AE	Type of AE	Immediate type of impact on patient	Detailed type of immediate impact	Additional gravity criterion	Final score
	Patient identification vigilance	Incorrect association of images, patient and exam date	Interpretation of the wrong patient or the wrong examination of a correct patient	-	G2-G5§
	Error in the radiological report	Diagnostic mistake	Identified by the requesting physician or the radiographer	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Identified during an internal quality process	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Error corrected by artificial intelligence	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Error in the writing of the radiology report	Partial interpretation (uninterpreted level or incomplete description of a anatomical level)	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Lack of or inadequate review or re-reading of the report by the radiologist	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Lateralization error	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
Radiographer	Patient identification vigilance	Correct patient imaged	Incorrect initial identification of the patient, subsequently corrected.	Without clinical impact on patient	G1
		Wrong patient imaged	Patient who should receive this type of imaging	if the same protocol is achieved	G1
				If more acquisitions were performed with CT scan.	G3
				Injection not requested but performed without patient impact	G2
				Injection not requested but performed with patient impact (acute renal failure or reaction to contrast agent).	G2-G5§
			Patient who should not receive this type of imaging	Injection not requested but performed without patient impact and the examination is radiating.	G3
				Injection not requested but performed without patient impact and the examination is non-radiating	G2
				Injection not requested but performed with patient impact (acute renal failure or reaction to contrast agent)	G2-G5§
				Without injection and non-irradiating examination	G1
				Without injection and irradiating examination	G3
	Non-compliance with the imaging protocol	Failure to check for contraindications	Failure to check for contraindications	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§

Table 2 (continued)

Source of AE	Type of AE	Immediate type of impact on patient	Detailed type of immediate impact	Additional gravity criterion	Final score
		Resulting in an additional series in CT (requested and/or non-requested anatomical area)	Without a request from the clinician or radiologist.	Not justified	G3
				Justified by the radiographer as he/she detected an anomaly and quickly initiated a complementary series.	G1
				Technical incident (patient movement, equipment failure)	G1
				Re-injection or 2 or more additional acquisitions in CT scan	G2-G5§
			At the request of the clinicians but without going through the radiologist	Adapted protocol	G1
				Inappropriate protocol	G2-G5§
		Issue related to contrast medium injection	Contrast medium injection not requested but performed	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Contrast medium injection requested but not performed	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Incomplete acquisition	Execution error: missing a series or partial acquisition of a good series	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Issue regarding imaging reconstruction	No transmission or partial transmission to the PACS due to the oversight of reconstructing by the radiographer	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		No phone call from the radiographer when required	No call from the radiographer when required	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
Multiple sources	Communication issue	Between requesting physicians and radiologists	Additional information affecting the protocol or interpretation received after the exam request but not communicated to the radiologist.	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			No communication regarding a report with radiological-clinical discordance	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Urgent information transmitted but not documented in the report	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Non-compliance with organizational guidelines for information transmission	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Between radiographers and radiologists	Misunderstanding regarding the written imaging protocol	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
			Misunderstanding during a phone call or using the communication module of the RIS	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Involving paramedical and administrative staff	Involving paramedical and administrative staff	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
Information, technology and communication tools	Technical accident	Image transfer failure (excluding network issues)	No image transfer or delay in image transfer	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§
		Internet/network outage	Issue with telephony system or RIS or PACS	Without clinical impact on patient	G1
				With clinical impact on patient	G2-G5§

Note- §: Corresponds to a radiological adverse events with a clinical impact on patient health, the final grade should refer to the HAS grid

Inter-reader Reproducibility of standard and AE-RADS grids

The inter-rater reproducibility for the number of AEs according to the standard HAS and AE-RADS grids was assessed using intra-class correlation coefficient (ICC, 'icc' function from the 'irr' package) with a two-way model, agreement type, and average unit. For the grade, source and type of AEs, the dataset was simplified by selecting the most serious AE for each patient (if multiple events were described). Indeed, the readers could have identified different AEs in a same patient precluding pairwise comparisons.

Afterwards, Krippendorf's alpha (α_K) was estimated to measure the inter-rater reproducibility of this grade (i.e., an ordered variable over more than two raters, herein 4 raters) using the 'kripp.alpha' function from the 'irr' package with the ordinal method (https://github.com/cran/irr/). For the sources and subtypes of AEs (nominal variables), Fleiss' Kappa (κ) was used ('kappam.fleiss' function from the 'irr' package). Indeed, as previously demonstrated, for studies involving three or more raters evaluating the same set of categorical data, Fleiss' kappa is the recommended choice over multiple pairwise Cohen's kappa calculations. In contrast, Krippendorff's alpha is particularly advantageous for ordinal data owing to its adaptability [17]. The ICC and α_K obtained with the standard and AE-RADS grids were then compared using the bootstrapping method, which involved 1000 random replicates of the study population ('boot' package).

Agreement between readers and expert consensus

For each grid and each reader, the percentage of exact agreement with the reference reading for the severity of the most serious AE per patient was estimated (and averaged over the four readers) and compared between the standard HAS and AE-RADS grids using the McNemar test. The same analysis was performed for the exact agreement between the four readers and the consensual reading. 95% confidence intervals (95%CIs) for binomial proportions were estimated using the 'BinomCI' function and the Clopper-Pearson method ('DescTools' package).

Given that this was a pilot study, no prior statistical data were available to estimate the required sample size to detect a significant difference in agreement between readers and consensus for HAS and AE-RADS. Instead, we estimated the statistical power of the comparison using the 'power.2p.test' function from the 'pwr' package, with an alpha level of 0.05, under the assumption that the agreement with AE-RADS would exceed that of HAS.

Figures were created using the 'ggplot2' and 'cowplot' packages.

Results

Study population and reference readings

Table 3; Fig. 3 outlines the patient characteristics and the AEs.

The AEs involved 49/100 (49%) women, with a median age of 66.9 years (IQR: 40.5–83.4, range: 7.7–97.6). The teams of experts reported a total of 104 AEs, related to the radiologists in 49/104 (47.1%) cases, to the radiographers in 49/104 (47.1%) cases, to the prescribing physicians in 2/104 (1.9%) cases and to multiple sources in 4/104 (3.8%) cases.

These AEs involved the analyses of 125 performed or cancelled imaging including 116/125 (92.8%) CT-scans.

Based on the HAS grid and the expert consensus reading, the most serious AEs per patient were categorized as follows: 24/100 (24%) G1, 41/100 (41%) G2, 30/100 (30%) G3, 3/100 (3%) G4, and 0/100 (0%) G5, with two patients (2%) considered not to have experienced any AE (Table 4). Utilizing the AE-RADS grid for the most serious AE per patient, there were 94/100 (94%) G1, 1/100 (1%) G2, 1/100 (1%) G3, 3/100 (3%) G4 and 1/100 (1%) G5 (Table 4). There was no significant association between the two grids ($P = 0.2571$, Chi-square test). An exact agreement between the two grids was reached in 27/100 (27%) cases. Notably, many events categorized as grade G2, G3, and G4 under the standard grid were downgraded to Grade G1 in the AE-RADS grid (40, 26, and 2 cases, respectively).

Inter-observer reproducibility

On average, the times (over the 4 readers) spent to analyze one case with the standard HAS and AE-RADS grids were 4.0 ± 0.3 min and 5.3 ± 0.6 min, respectively.

Table 4 also shows the results of the readings performed by the experts and the four readers according to the two grids. Table 5; Fig. 4.A summarize the reproducibility analysis.

Regarding the number of detected AEs, the readers described an average of 1.18 events (range: 1.1–1.34, with a maximum number of AE per patient of 5 for one reader) with the standard grid and 1.15 (range: 1.11–1.18, with a maximum number of AEs per patient of 3 for one reader) with the AE-RADS grid. Overall, with the HAS grid, the four readers identified 146 distinct AEs in 100 patients, whereas they identified 130 distinct AEs with the AE-RADS grid.

Regarding the number of AEs per patient, the ICC was 0.642 (95%CI: 0.510–0.745, $P < 0.0001$) with the reference grid and 0.690 (95%CI: 0.578–0.779, $P < 0.0001$) with the AE-RADS grid, which was not statistically different (P-value = 0.3888).

Regarding the grade of the most serious AEs per patient, α_K was 0.506 (95%CI: 0.413–0.614) with the HAS grid and 0.519 (95%CI: 0.412–0.654) with the

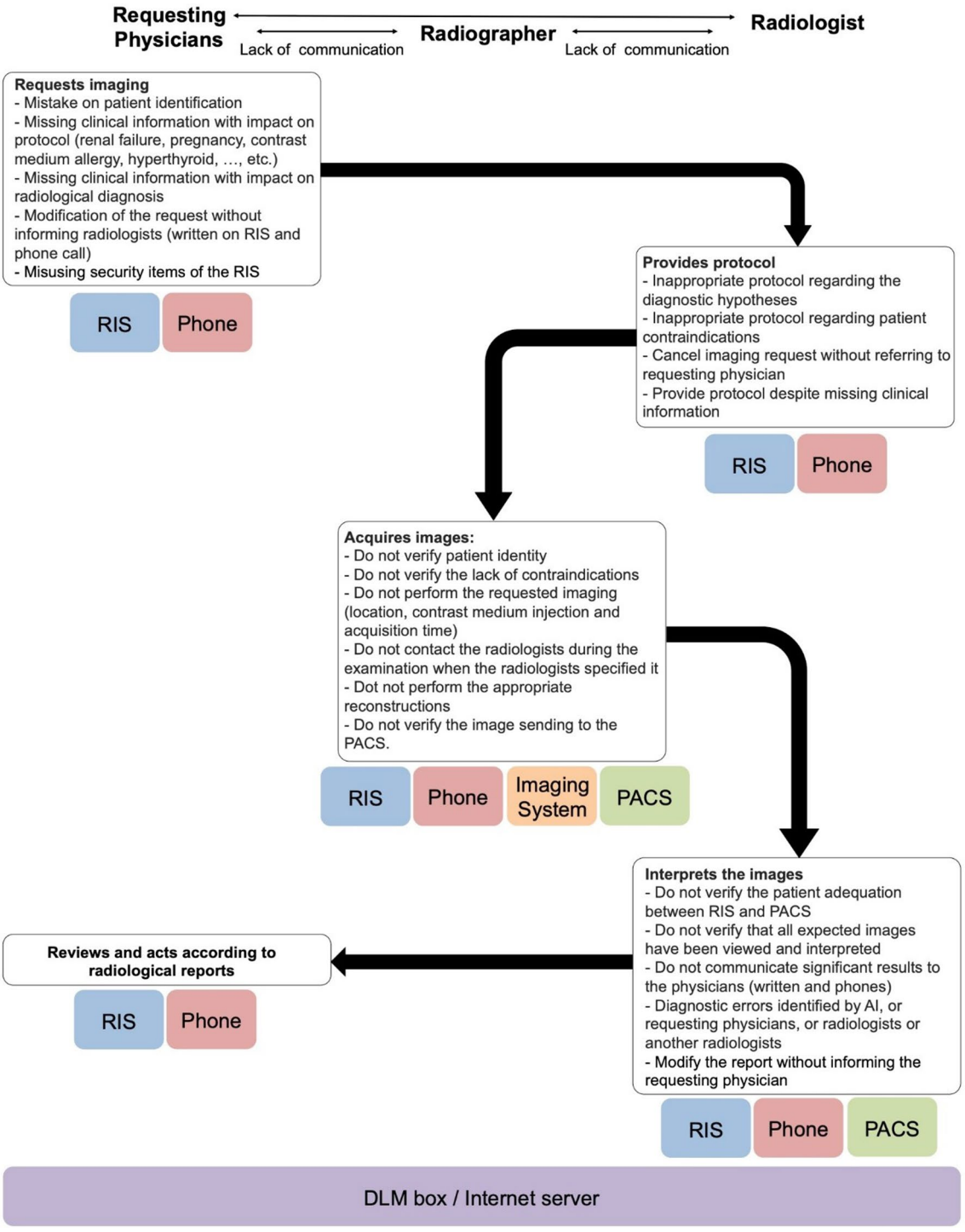

Fig. 2 Chronological representation of the AE-RADS grid items to identify adverse events (AEs). In addition to AEs related to requesting physicians, radiographer and radiologist, AEs can also come from information, technology and communication tools they use, as represented in colored boxes. Abbreviations: DLM: data lifecycle management (i.e., module that manages data from initial acquisition and storage to access, archiving, and eventual deletion if required), PACS: picture archiving and communication system, RIS: radiology information system

AE-RADS grid, which was not statistically different (P-value = 0.4013).

Using the AE-RADS grid, regarding the source of the adverse events, Kappa Fleiss was 0.827 (95%CI: 0.752–0.909, $P < 0.0001$). Regarding the type of adverse event, Kappa Fleiss was 0.857 (95%CI: 0.795–0.924, $P < 0.0001$). Of note, the HAS grid did not include the source and type of AE.

Table 3 Characteristics of the study population, adverse events and examinations

Characteristics		Patients / Adverse events / Examinations (%)
Patients (*N* = 100)		
Age (years)		66.9 [40.5–83.4] (7.7–97.6)
Sex (women)		49/100 (49)
Adverse events (*N* = 104)&		
Source of adverse event&		
	Radiographer	49/104 (47.1)
	Radiologist	49/104 (47.1)
	Prescribing physician	2/104 (1.9)
	Multiple sources	4/104 (3.8)
Type of adverse event&		
	Mistake in the radiological interpretation	39/104 (37.5)
	Wrong imaging protocol	9/104 (8.7)
	Imaging protocol not respected	30/104 (28.8)
	Patient identification issue by the radiographer	19/104 (18.3)
	Patient identification issue by the physician	2/104 (1.9)
	Lack of communication	4/104 (3.8)
	No respect of good clinical and radiological practices	1/104 (1)
Final grade of the serious events&		
	G1	97/104 (93.3)
	G2	1/104 (1)
	G3	1/104 (1)
	G4	4/104 (3.8)
	G5	1/104 (1)
Examination (*N* = 125)		
Imaging modality		
	CT-scan	116/125 (92.8)
	Cancelled examination	4/125 (3.2)
	MRI	1/125 (0.8)
	Second reading	4/125 (3.2)
Involved anatomical regions		
	arterial CT angiography of the aorta and lower limbs	2/125 (1.6)
	Cancelled examination	4/125 (3.2)
	Abdomen-pelvic	25/125 (20)
	Whole-body CT-scan	14/125 (11.2)
	Ankle	2/125 (1.6)
	Brain	26/125 (20.8)
	Brain and spine	1/125 (0.8)
	Brain and chest	1/125 (0.8)
	Shoulder	2/125 (1.6)
	Knee	3/125 (2.4)
	Neck and face	2/125 (1.6)
	Pelvic	2/125 (1.6)
	Spine	2/125 (1.6)
	Spine and pelvic	1/125 (0.8)
	Chest	23/125 (18.4)
	Thorax-abdomen-pelvic	15/125 (12)
Contrast medium injection		
	No	44/125 (35.2)
	Yes	81/125 (64.8)

Note: Data are number of patients with percentage in parentheses, except for age given as median, interquartile range (IQR, in bracket) and minimum-maximum range (in parentheses)

&: according to the new AE-RADS grid and the consensus reading by the expert team

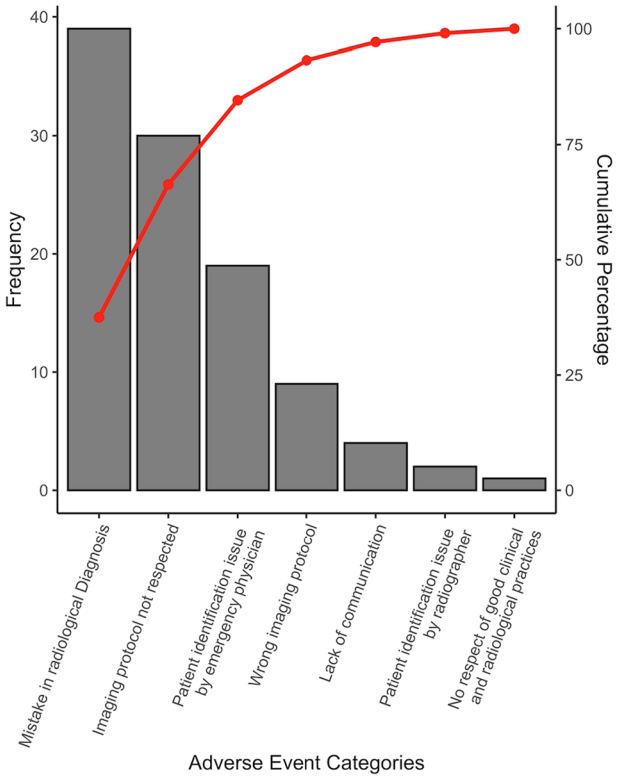

Fig. 3 Pareto chart showing the frequency of main adverse event categories (bars) and their cumulative contribution (line) to total adverse events

Agreements between readers and experts for the severity of the most serious adverse event

Table 6; Fig. 4.B summarize the agreement analysis.

At the reader level, the agreement between consensus and readers was always significantly higher using the AE-RADS grid compared to the HAS grid (P-value range: <0.0001 [Reader-2]-0.0051 [Reader-3]). The average agreement over the 4 readers was 40.1 ± 10.1% with HAS grid versus 71.8 ± 7.5% with AE-RADS grid. Similarly, the perfect agreement between all readers and the consensus reading was significantly higher with the AE-RADS grid (53%, 95%CI: 42.8–63.1) compared to the HAS grid (19%, 95%CI: 11.8–28.1, $P < 0.0001$).

Regarding the assessment of statistical power, with an average accuracy of 40.1% for HAS and 71.8% for AE-RADS, a sample size of $N = 125$ AEs and an alpha level of 5%, the statistical power was 0.999. This indicated a Type II error (beta) risk of less than 0.1%, meaning a very low likelihood of failing to detect a true difference.

Table 5 Inter-observer reproducibility over the four readers

Characteristics	Inter-observer reproducibility	Test
Number of adverse events per HAS grid	0.642 (0.510–0.745)	ICC
Number of adverse events per AE-RADS grid	0.690 (0.578–0.779)	ICC
Grade of adverse events per HAS grid	0.506 (0.413–0.614)	α_K
Grade of adverse events per AE-RADS grid	0.519 (0.412–0.654)	α_K
Source of adverse events[1]	0.827 (0.752–0.909)	Kappa Fleiss
Type of adverse events[1]	0.857 (0.795–0.924)	Kappa Fleiss

Note: Results are given with 95% confidence intervals

Abbreviations: ICC: intraclass correlation coefficient, α_K: Krippendorff's alpha

1: The source and type of adverse events were only evaluated with AE-RADS

Case exemple

A thoraco-abdominopelvic CT scan was requested by an emergency physician on February 26, 2021, at 2:20 a.m., for a patient who had suffered a fall with trauma to the left ribs and left hypochondrium. The patient was on anticoagulation therapy. Clinical notes indicated left rib pain, reduced respiratory movement on the affected side, and tenderness on palpation of the left hypochondrium. The initial radiologist's interpretation at 3:20 a.m. reported no traumatic lesions, and AI software did not detect any rib fractures. This interpretation was performed by a teleradiologists working from a remote teleradiological center. An addendum by a second on-site radiologist on March 1, 2022, at 3:41 a.m., noted: "*Fracture of the posterior arch of T10 on the right, bifocal, without lung parenchymal abnormality. Possible fracture of the posterior arch of K9 on the right. Hematoma within the right gluteus maximus muscle, with associated subcutaneous hematoma. Although there is only one phase of contrast, some vascular blushes are visible within the hematoma. As of today (03/01/2022), the patient shows no signs of blood loss. Adjacent bone lesions are not evident, but movement*

Table 4 Summary of the readings performed by the expert team and the four readers according to the HAS and AE-RADS grid

Grade	Consensus reading		Reader-1 (*N*)		Reader-2		Reader-3		Reader-4	
	HAS	AE-RADS	HAS	AE-RADS	HAS	AE-RADS	HAS	AE-RADS	HAS	AE-RADS
No AE (G0)	2/100 (2)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)	0/100 (0)
G1	24/100 (24)	94/100 (94)	63/100 (63)	66/100 (66)	89/100 (89)	82/100 (82)	54/100 (54)	64/100 (64)	69/100 (69)	71/100 (71)
G2	41/100 (41)	1/100 (1)	3/100 (3)	8/100 (8)	6/100 (6)	15/100 (15)	36/100 (36)	27/100 (27)	1/100 (1)	8/100 (8)
G3	30/100 (30)	1/100 (1)	31/100 (31)	23/100 (23)	4/100 (4)	1/100 (1)	7/100 (7)	9/100 (9)	24/100 (24)	18/100 (18)
G4	3/100 (3)	3/100 (3)	2/100 (2)	2/100 (2)	1/100 (1)	2/100 (2)	2/100 (2)	0/100 (0)	5/100 (5)	1/100 (1)
G5	0/100 (0)	1/100 (1)	1/100 (1)	1/100 (1)	0/100 (0)	0/100 (0)	1/100 (1)	0/100 (0)	1/100 (1)	2/100 (2)

Note: Data are number of patients with percentage in parentheses

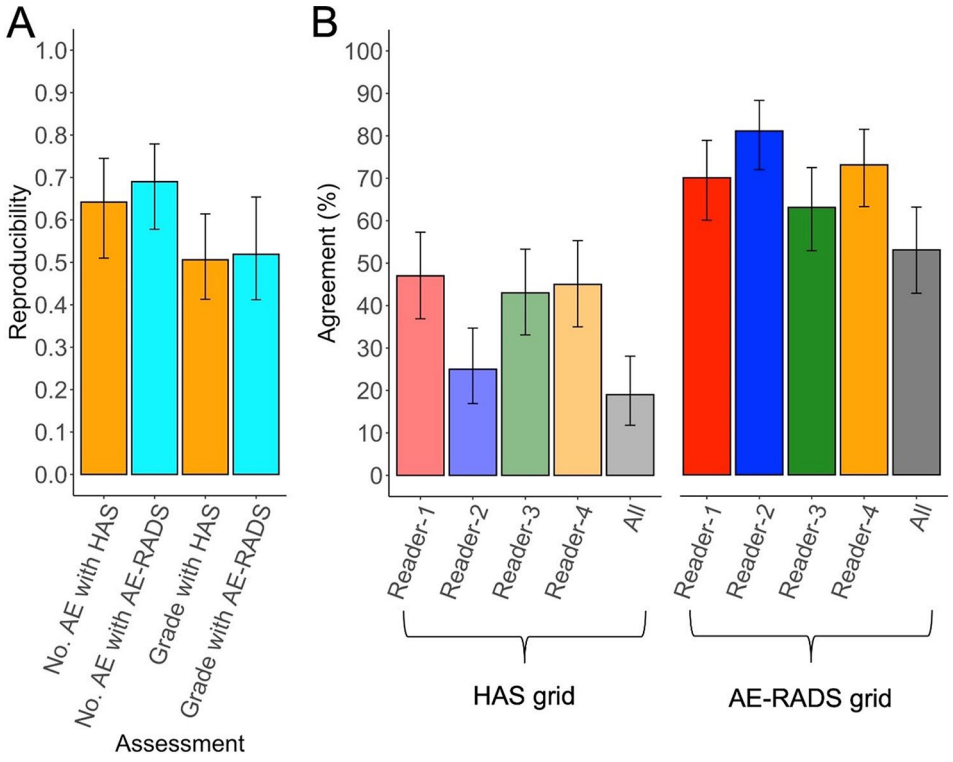

Fig. 4 Comparisons of the standard HAS grid and AE-RADS grid. (**A**) Comparisons of the inter-observer reproducibility for the number of reported adverse events and the grade/severity of adverse events. (**B**) Comparisons of the exact agreement between the consensus reading and each reading. 'All' corresponds to the exact agreement between the 4 readers and the expert reading. All comparisons between exact agreements were statistically significant ($P < 0.05$)

Table 6 Agreement between readers and expert consensus for the severity of adverse events

Characteristics	HAS grid	AE-RADS grid	*P*-value
Reader-1 vs. consensus	47/100 (47% [36.9–57.3])	70/100 (70%, [60.0-78.8])	0.0042**
Reader-2 vs. consensus	25/100 (25% [16.9–34.7])	81/100 (81% [71.9–88.2])	< 0.0001***
Reader-3 vs. consensus	43/100 (43% [33.1–53.3])	63/100 (63% [52.8–72.4])	0.0051*
Reader-4 vs. consensus	45/100 (45% [35.0-55.3])	73/100 (73% [63.2–81.4])	0.0006***
Average agreement over the 4 readers	40% +/- 10.1%	71.8% +/- 7.45%	-
Exact agreement between all readers and consensus	19/100 (19% [11.8–28.1])	53/100 (53% [42.8–63.1])	< 0.0001***

Note: Proportions of exact agreement are given with 95% confidence interval in bracket (except for the average agreement, as mean +/- standard deviation)

P-value of McNemar tests are: *: <0.05, **: <0.005, ***: <0.001

artifacts are present.". The emergency physician was notified by phone on March 1, 2022, at 3:41 a.m., and an email was sent to the radiology department on March 2, 2022, to report this updated finding.

Using the AE-RADS grid, all reviewers identified one AE and classified it correctly as G1 (source: 'radiologist', type: 'in the radiological report', immediate consequence: 'diagnostic mistake', gravity criterion: 'no clinical/therapeutic impact for the patient'). However, with the HAS grid, reviewers identified either one or two AEs, classified either as G1 or G2.

Discussion

AEs are an inevitable part of diagnostic imaging, as in any area of medical practice, and they carry significant human, financial, and legal implications [5]. Effective AE management depends on accurately classifying these incidents by type and severity, which is essential for implementing targeted corrective actions and preventive measures [18]. However, to date, no validated ordinal scoring grids specific to AEs in diagnostic radiology exist in the USA or the European Union. Our study aims to address this gap by proposing a unified, structured grid for AE reporting, which is essential for harmonizing AE assessment across radiology departments and teleradiological structures. Previous studies have used varying categorizations, leading to inconsistencies in AE reporting.

The AE-RADS grid consolidates these approaches into a clear, practical tool for standardized AE assessment, facilitating better comparison across studies. The newly developed AE-RADS grid addresses these needs by providing a structured decision-tree approach that aims to reduce subjectivity, improve classification consistency and account for both radiological adverse events alone and radiological + clinical adverse events. This study highlights the AE-RADS grid's advantages. It offers more detailed classification options but also shows improved inter-reader agreement compared to the HAS grid. By reducing ambiguity in AE categorization, the AE-RADS grid can support more accurate tracking and analysis of AEs, allowing radiology departments to better address the unique challenges they face. These improvements address specific limitations of the HAS grid, positioning AE-RADS as a more tailored and precise tool for assessing AEs in radiological practices.

The AE-RADS grid showed improved inter-reader reproducibility, evidenced by its higher intra- ICC and αK values compared to the HAS grid. Although the ICC and α_K values did not show statistically significant differences, the trends suggest that AE-RADS may offer slightly enhanced consistency in evaluating AE severity across different readers. Importantly, the AE-RADS grid also enabled high inter-reader agreement regarding AE sources and types, which the HAS grid did not assess. This finding reflects the added specificity of AE-RADS, which allows for more detailed categorization—a critical feature for targeted quality improvement efforts in radiology. Another observation was the substantial difference in the grading of AEs between the two grids. The average agreement increased from 40.1% with the HAS grid to 71.8% with AE-RADS. This substantial increase in agreement indicates that AE-RADS may provide a more intuitive and accurate method for grading adverse events in radiology. The AE-RADS grid also tended to categorize more cases as less severe (G1), which might reflect a more nuanced approach suited to radiology. This discrepancy between the grids is particularly significant when considering the higher number of AEs initially graded as G2, G3, or G4 in the HAS grid that were later downgraded to G1 under AE-RADS. This redistribution suggests that AE-RADS may be better calibrated to the specific context of diagnostic radiology, potentially avoiding overestimation of event severity. This is typically exemplified with the case study presented in the results. In this case, all reviewers using the AE-RADS grid consistently identified the diagnostic mistake as a single AE and correctly classified it as G1, indicating no clinical or therapeutic impact on the patient. This consistency in classification helps reduce subjectivity and variability, which can be a limitation in other systems, such as the HAS grid, where reviewers identified multiple AEs and used varying severity grades (G1 and G2). In fact, internal and on-site re-reading of the examinations (especially whole body CT-scans for multiple trauma patients) and secondary specialized opinions for challenging diagnoses have certainly limited the clinical impact of diagnostic errors [19]. Indeed, in the AE-RADS grid, the expert team based their grading on years of experience and feedback, incorporating the real impact on the patient. By providing detailed explanations for each AE in the comprehensive AE-RADS grid, they reduced subjectivity in the grading process. This approach avoids the potential overestimation of consequences from a single radiological act, acknowledging that patient management involves a series of radiological and non-radiological steps, including second readings, which help minimize errors and adverse events, much like a safety net.

It is also crucial that that all personnel using any AE reporting system undergo dedicated training to understand how to use the system and the broader significance of AE reporting for patient safety, quality improvement, and healthcare system accountability. Effective training helps standardize the identification, classification, and documentation of AEs, reducing variability between evaluators and ensuring consistency across practices. It also fosters a culture of transparency and continuous improvement by emphasizing the critical role AE reporting plays in preventing future incidents. Furthermore, training sessions provide an opportunity to clarify complex cases, discuss borderline situations, and align interpretations, ultimately leading to more reliable data collection and analysis.

The average time spent analyzing each case was slightly longer with AE-RADS compared to the HAS grid (5.3 *versus* 4.0 min). Although a longer analysis time might have been anticipated, this acceptable duration can be explained by two factors. First, the AE-RADS grid is organized as a decision tree, which allows readers to follow a clear, step-by-step process from left to right: starting with the identification of the AE source, then categorizing the type of AE, and finally detailing the consequences and applying a modifier factor for additional severity. Furthermore, the checklist items in the AE-RADS grid were presented in an evolving, dynamic dropdown menu. Additionally, the four readers participated in a training session, which have helped minimize significant deviations in AE-RADS grading and ensured the readings were completed within an acceptable timeframe. The improved accuracy and additional information provided by AE-RADS could justify this modest increase in analysis time. Indeed, the AE-RADS grid not only provides a more nuanced classification of AEs but also reduces subjectivity by guiding evaluators through a systematic process, from identifying the source and type of AE to assessing its consequences and severity. This

level of detail is crucial for developing targeted corrective actions and improving patient safety. Furthermore, this time could be improved through an application-based interface.

In the future, artificial intelligence (AI) tools are expected to enhance and automate the analysis of AEs. Ferrara et al. highlight in their recent review several studies that explore how AI can improve AE management by automating specific tasks, standardizing AEs based on type and severity, and analyzing contributing factors [20]. AI can improve AE management by automating tasks, standardizing AEs by type and severity, and analyzing contributing factors. Leveraging deep learning techniques, AI algorithms can analyze imaging data to identify subtle abnormalities that human observers may overlook, thereby detecting changes indicative of AEs. Typically, the implementation of AI algorithms follows this approach for identifying incidental pulmonary embolisms, spine fractures, rib fractures, and pneumoperitoneum [21–24]. Additionally, AI can provide consistent evaluations across numerous images, reducing inter-observer variability. By analyzing historical data, AI can predict which patients are at higher risk for AEs based on underlying conditions and the type of imaging performed. It can also optimize workflows by recognizing trends in AE occurrence, thereby minimizing situations that may lead to adverse events. Furthermore, real-time monitoring of imaging processes allows AI to detect deviations from established protocols, alerting radiologists to potential AEs. These systems can provide immediate feedback on radiologist performance, promoting continuous improvement. Through machine learning algorithms trained on extensive datasets, AI can identify patterns and inform preventive measures. As these systems evolve with new data, they will become increasingly effective at recognizing emerging types of AEs in radiology. However, it is important to emphasize that developing an effective AI-driven real-time monitoring system for AE reporting would require training on large, high-quality AE datasets, with expert-driven labeling to ensure accurate reporting and management. Regarding AE labeling, it would be valuable to add a label in RIS and PACS to identify sensitive patients with a history of AEs who may require special care. Additionally, creating a dedicated AE training database for radiologists could be beneficial, allowing them to learn more about potential AEs, their causes, and how to recognize them in practice.

Furthermore, as the AE-RADS grid has shown improved alignment with expert evaluations, its integration into real-world clinical workflows presents a logical next step. This would involve (i) developing user-friendly applications to seamlessly encode AE-RADS items into RIS, PACS, and AE databases, and (ii) validating its effectiveness through prospective multiple center studies. This exploration would help assess its scalability and effectiveness in reducing AE incidence. Future enhancements could also include involving health law experts to anticipate potential legal challenges and evaluating the AE-RADS grid across diverse radiological populations and performed by all possible stakeholders such as radiologists, electro-radiographers, technicians, referring physicians and hospital administrators. Moreover, in future research, Failure Mode and Effect Analysis (FMEA) could enhance the AE-RADS framework by identifying potential weaknesses in the grading process, such as inconsistencies or delays in reporting. FMEA could help optimize workflows, improve user experience, and ensure consistent application of AE-RADS across clinical settings. At this point, we believe that the AE-RADS can be used at this stage of tis development (in fact, we are already using it within our group). However, we recommend providing conclusions based on both AE grading systems for AE occurring in France (i.e., HAS and AE-RADS). It is important to note that the AE-RADS has not yet been independently validated on external cohorts outside our structure. Additionally, the impact on patients and radiological department organization has not been prospectively assessed.

Our study has limitations. First, the initial sample size was small, and the analysis was conducted at a single center. Second, while reflecting the reality of AEs in emergency imaging, a large proportion of the analyzed cases were of low severity. Third, we could not assess intra-observer agreement due to a significant memory bias, but this could be examined in a new cohort. Fourth, our grid was initially built in a teleradiology setting, which increased risk of errors and liability is currently being questioned [10, 25]. Importantly, the IMADIS-Groupe cohort consisted of patients from emergency departments where there was a very short timeframe for requesting, performing, and interpreting imaging studies. Consequently, it can be hypothesized that abnormal secondary radiological findings—despite lacking clinical or therapeutic impact in the emergency context—were either downplayed or overlooked by radiologists focused primarily on the main pathology related to the patients' symptoms, given the urgent need to report critical results. Another limitation is the fact that several authors have affiliations with IMADIS-Groupe. To minimize biases, several safeguards in the study design and data interpretation were implemented. The AE-RADS grid was developed through a collaborative process involving both radiology experts working at IMADIS-Groupe for various proportions of their time, but also in classical radiological structures, ensuring diverse perspectives. Data collection and analysis followed strict methodological standards, with AE case evaluations performed independently and blindedly by multiple readers. As

teleradiology is a highly competitive field, we believe optimal patient care and quality assurance could be a key differentiator.

The typology of AEs and the performances of the AE-RADS and HAS grids may be different with another radiological population, such as oncologic CT-scans at a cancer center, or osteoarticular MRI in a private hospital. Lastly, it must be emphasized that the AE-RADS grid was not designed for interventional radiology and that specific AE reporting systems have been recently designed and recommended by experts in the fields [26, 27].

Conclusion

To conclude, AEs are an unavoidable aspect of diagnostic imaging, with significant human, financial, and legal implications. The AE-RADS grid effectively addresses these challenges by offering a structured decision-tree approach that accounts for both pure radiological AEs and radiological AEs with clinical impact, enhances classification consistency and reduces subjectivity, resulting in improved inter-reader agreement compared to the HAS grid alone. This study highlights that AE-RADS facilitates a more nuanced grading of AEs, reflecting a calibration better suited to the diagnostic radiology context and improved identification of AE sources, facilitating more targeted corrective actions, which could be directly used in addition to existing grids. Consequently, AE management is a growing concern in diagnostic imaging clinical workflows, evaluating its performance across diverse radiological populations and refining it through feedback and collaboration with health law experts. Lastly, as artificial intelligence tools evolve, they hold great promise for further improving AE management through automation and enhanced detection capabilities.

Abbreviations

α_K	Krippendorff's alpha
AE-RADS	Adverse events radiology system
AI	Artificial intelligence
CI	Confidence interval
CTCAEs	Common Terminology Criteria for Adverse Events
HAS	French 'haute autorité de santé;'
ICC	Intraclass correlation coefficient
IQR	Interquartile range
PACS	Picture archiving and communication system
RIS	Radiology information system
SD	Standard deviation

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Author contributions

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This observational study was approved by the Institutional Review Board of the French Society of Radiology (approval number: CRM-2306-350). The need for written informed consent was waived due to its retrospective nature and to the fact that data were anonymized.

Consent for publication

Not applicable.

Competing interests

J.F.B., A.C., F.G., B.P., N.L., R.P., P.E.: Stock of stock options from IMADIS Groupe.G.G.: Consulting fees from Philips; payment of honoraria for lectures, presentations, speakers bureau, manuscript writing, or educational events from Philips; support for attending meeting and/or travel from Philips; participation on a data and safety monitoring or advisory board for Agfa; and stock or stock option from IMADIS Groupe.M.S., S.L.N., V.F.: Employees of IMADIS Groupe.

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