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Research Paper

Infective endocarditis and litigation for compensation on healthcare-associated infections: An Italian sample analysis

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ABSTRACT

Background: Litigation related to Healthcare-Associated Infections (HAIs) in Italy represent a growing field of interest in establishing the medico-legal link between infection and the healthcare environment and practices for compensation; it is little explored in the cardiovascular surgery regarding infective endocarditis (IE).
Methods: We retrospectively analysed the civil judgements on infective endocarditis in the Italian region Emilia-Romagna from 2016 to July 2024 using Ministry of Justice national official database. The search was conducted on the online database on July 31, 2024, using the free word "endocarditis". Two authors independently analysed the full-text judgements: , those IE without relevance in the reason for the claim were excluded. Main items were the timeline and outcome, with complaint motivation and liability ascertainment. In-court confirmation of healthcare causal link was reported.
Results: Twenty-five judgments were retrieved. After screening for inclusion, nineteen judgements (11 of first instance and 8 of appeal) were included, for overall 15 cases of infective endocarditis. Of the fifteen cases, median age 60.5 years, 73 % males, median time for claim 6 years, for judgement 10 years and, if appealed, 16.5 years. Annual distribution of the claims was linear over time. Eleven (67 %) infective endocarditis were confirmed as healthcare-associated in trial. The prevalent reason for liability was improper or delayed diagnosis and/or treatment of the IE. Valvular surgery resulted in 40 %, while the more frequent pathogens were *Staphylococcus aureus* (40 %) and epidermidis (30 %). Of fifteen cases, 73 % was decided in favour of the patient-claimant, with an average cost of €289.872, plus an additional €55.296 in case of appeal. Only in 25 % the appeal's judge changed decision. In all cases, technical advisors were appointed.
Conclusions: This sample provides an initial insight into litigation for compensation related to infective endocarditis, highlighting specific characteristics compared to HAIs management in court. Medico-legal reasoning should be integrated into infection prevention and control policies and overall clinical risk management strategies.

1. Introduction

Healthcare-associated infections (HAIs) are defined as those infections that have occurred and can be causally traced back to the healthcare setting, after medico-legal ascertainment, depending on the ecosystem, behaviours, vectors, healthcare technologies and devices.[1–3] In the specific field of cardiovascular surgery, infective endocarditis (IE) within a year after surgery (early endocarditis) and even more so within 3 months after surgery (very early endocarditis) is most typically brought back to the healthcare setting, as far as thorax surgical site

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infections. However, a consensus on the definition of healthcare-associated infective endocarditis (HA-IE or HCA-IE) is lacking, as usually remains complex the reconstruction of the overall case in its context and the source of the infection.[4,5] In fact, HA-IE widely differs from other types of HAI, such as pneumonia or surgical site infection, as any source of bacteraemia, also without clinical relevance, could be a source for infection, depending on several practices, devises, habits and behaviours. IE, in particular if associated with the care, represents a key indicator for cardiac surgery centres.

From an epidemiological point of view, the rate of IE stands at 3 cases (1.4–6.2)/100,000 inhabitants in the general population. The rate in the hospitalized cardiovascular patients is extremely wide (2–25 %), as suffers from several selection biases due to the heterogeneity of the population.[6–8] Looking to Italian registries, 4.365 patients with IE resulted from 2000 to 2021 in the INFECT-REGISTRY endorsed by the Italian Society for Cardiac Surgery and the Italian Group of Research for Outcome in Cardiac Surgery (24 Italian cardiac surgery centres),[9] while 677 patients between July 2007 and December 2010 in the Italian Registry of Infective Endocarditis RIEI (17 centres).[10]

However, even when forensic evaluation is considered, the data on IE tend to be underestimated.[11] The post-mortem changes in the microbiome, which are strictly related to the post-mortem interval and the autopsy arrangement, limit the diagnostic power to the clear presence of valvular vegetations or coarctation.[12] The incidence is also similar in the transcatheter approaches, probably reflecting the same higher risk conditions - also of infection-that contraindicate the traditional approach.[13,14]

The phenomenon of HAI litigation in the framework of healthcare malpractice in Italy represents a growing field of insight between medicine and law, in particular to assess the causal link with the healthcare setting and to consequently build risk prevention strategies, but it is still little explored specifically in the cardiovascular field.[15–18] The relationship of the infection with the healthcare environment - including any facility providing healthcare services - could in fact represent a source of user complaint, a burden for compensation and an issue for healthcare service accountability.[19–21]

The 2023 report by Marsh, a leading broker operating in the health insurance sector in Italy, details on the overall issue of litigation for HAI.[22] It is a growing phenomenon (9 % of the total cost of claims in 2023, compared to 4.7 % in 2012), with costs per case among the highest (more than 142.000 euro), median claiming time from the event 3.5 years, median settlement time from the claim to the judgement 3 years. In the study of one-year judgements for healthcare malpractice –including those for infections - by the Civil Court of Rome the median claiming time was 5.3 years,[23] while in the study of five-year judgments of the same Court specifically focused on infections, the data is not reported.[17] Critical factors include the foreseeability of the infection, the ability to prevent and control those infections with the subsequent burden of proof, and the link between the infection and the responsibilities of all healthcare providers and facilities.

To date, reliable and targeted data on IE in Italy, and even more so on the associated litigations for compensation, is almost missing. When compared to the general context, IE cases are widely different and involve additional complexities. At first, a longer period between the healthcare act and the onset of symptoms and a heightened risk of litigation in very early-onset endocarditis. Moreover, a higher risk of severe or fatal outcomes, which increase the likelihood of claims for damages by heirs, leading to significant compensation demands. In such way, the restorative burden could exceed the average insurance deductible or Self-Insurance Retention (SIR) thresholds of healthcare facilities (between €250.000 and €500.000), with the interplay of multiple stakeholders.

Hence the interest in exploring how infective endocarditis is addressed in courts of merit, within the broader context of HAIs from the official data source of the Ministry of Justice. Analysing the clinical cases in trials, the evidence presented, the errors identified, and the behaviours observed in an unbiased manner—alongside the risks of litigation and potential losses —offers critical insights. These insights are essential for improving patient care, enhancing risk management strategies, optimizing healthcare organization, and refining litigation approaches.[19,24] No less, the in-depth analysis is useful to provide some initial elements for the discussion and further investigation of the phenomenon.

2. Materials and methods

This study is a retrospective analysis of civil judgments concerning cases of infective endocarditis in the Italian region of Emilia-Romagna from 2016 to July 2024. Cases were retrieved from the online public database of civil judgments provided by the Italian Ministry of Justice (Portale dei Servizi Telematici del Ministero della Giustizia), accessible through digital identification.[25]

The database includes only judgments of merit from the civil courts of Italy (first instance and appeals) starting from January 1, 2016. It excludes ruling decrees and judgments related to family, children, and personal status, while includes case law records for medical malpractice in civil courts. The choice of this database was based on the need to use an official national source. The database allows searches by free text, keywords, date, legal field, and Court of Appeals district, but retrieved judgments must be downloaded individually as PDF files. The search could be done by “at least a word”, “the exact sentence” or “all the words”.

The search, conducted on July 31, 2024, used the free word "endocarditis” searched in the database limiting to the “the exact sentence”; in this way, the search engine searches for the word in the text. The search was restricted to the Bologna Court of Appeals district, which corresponds to the Italian region of Emilia-Romagna. This region had a population estimate of 4,459,477 in 2019, accounting for approximately 7 % of Italy’s population.[26] Full texts of civil judgments retrieved were downloaded and independently analysed by two authors for inclusion. Judgments mentioning infective endocarditis but without relevance to the clinical history or the reason for the claim were excluded, as discussed in the results. Any discrepancies between the authors were solved through discussion.

The primary items analysed included the timeline of each case, the reasons for the complaint (and appeals, if applicable), and the liability assessment, along with the judge’s motivation. Additional data retrieved included demographic details, the date of the infective endocarditis event, the date of the claim, the year of any conciliatory or mediatory procedures (if available), and the year of the legally relevant event (e.g., the death of the patient or the alleged malpractice). These details were recorded in locked fields to ensure accuracy. Data regarding the surgical approach or pathological condition in IE, whether it was early IE, death (if applicable), the IE pathogen (if identified), the involvement of court-appointed technical advisors, the year and outcome of the ruling, and the overall trial costs in euros were also collected and reported. Confirmation of healthcare association with the case was included.

The main items analysed were reported in an Excel program sheet (Microsoft Office 365) for basic statistical, medico-legal, and clinical analysis. Locked fields were used to minimize errors in reporting binary and numerical data, while timelines, reasons of complaint and liability were narratively reported.

Continuous variables were expressed as means, or median with range according to their distribution. Categorical variables were expressed as frequency and percentages.

Some limitations must be acknowledged for a better comprehension and generalisation of the results. The time intervals between the event and the claim (considering the ten-year statute of limitations for contractual relationships in Italy) may be influenced by numerous factors. First, the individual must become aware of having suffered an unlawful act before filing a complaint. Complaints are often made after partial stabilization of the clinical condition or, in some cases, by family

members following the patient's death. Additionally, mandatory mediatory and conciliatory procedures, which are procedural prerequisites under Italian law, may also affect case retrieval. Cases resolved during these preliminary stages without progressing to court may create a bias in the analysis. Nevertheless, the extended study period enhances understanding of this phenomenon over time, also given the timing of the process.

3. Results

The research yielded 25 judgments, 17 of first instance and 8 of appeal. After study, 6 judgements were excluded because incidentally mentioning IE or IE was irrelevant in the claim motivation or IE was mentioned as clinical condition apart from healthcare malpractice. In detail, the reasons for exclusions were:

1. Case of myocardial infarction and sepsis, IE only initially mentioned in differential diagnosis, furtherly excluded.
2. Claim concerning malpractice in hip prosthesis surgery, with transient IE during hospitalization treated without sequelae and not relevant in the claim issue. (It was mentioned the role of pre-surgical nasal swabs for *Staphylococcus aureus* carriers and proper antimicrobial prophylaxis).
3. It mentioned IE risk associated with pacemaker (PM) implantation in a patient who underwent several PM removals and surgical revision for PM pouch complications and infections.
4. Occupational law: public employee with past clinical history of IE found unfit for work.
5. Occupational law concerning work injury: evaluation of the relationship between occupational trauma with elbow excoriation and olecranon bursitis, subsequently with *Staphylococcus aureus* over-infection and, after years, IE. It discusses the unlikely relationship between phenomena.
6. It mentioned IE risk and its prophylaxis following repeated extensive treatment and the improper management of a maxillary *Proteus mirabilis* abscess that led to brain abscess.

Finally, 19 judgements were included, 11 of first instance and 8 of appeal, for a total of 15 clinical and judicial cases. In fact, 4 of the 8 cases of appeal were ruled in the first instance before January 1°, 2016, so were not available in the database and the timeline was retrieved, if possible, from the appeal judgements (see Fig. 1, Supplementary material). Of the 15 cases, 73 % were males (11/15 males), median age 60.5 (min 19 - max 80) years. Main items retrieved were summed in Supplementary Table 1 (Supplementary Table 1: Cases synthesis Insert here, with Legend: NA not applicable; _ data not retrievable or available from the judgment analysis.).

In 80 % of cases (12/15), a surgical approach was performed, with 67 % (10/15) involving cardiac surgery (8 of which (80 %) could be defined as early endocarditis, but 1 was not confirmed as healthcare-associated at first instance and 2 at appeal). Among the 8 clinically defined early endocarditis cases linked to cardiac surgery, 6 (75 %) were confirmed as healthcare-associated following liability ascertainment (Supplementary Table 1).

Overall, of the 15 cases of IE, 73 % (11/15) were confirmed as healthcare-associated after liability ascertainment at the first instance, 67 % (10/15) were confirmed at the appeal stage.

When the sample was grouped into five-year periods for better representation, a trend in the number of IE cases and claims emerged, with a median time of 6 years between the occurrence of IE and the first instance claim. This shift is also evident when including appeals, where the median time between the IE event and the appeal claim was 11.5 years (Fig. 1).

In most cases (87 %), the legally relevant event corresponded to the year of the endocarditis itself, except for case 5 (where the relevant event was the patient's death) and case 15 (where the malpractice dated back to before the IE event).

Consequently, the distribution largely overlaps with the timeline of the infective endocarditis cases.

As for the time to file a claim, the distribution appears homogeneous, as illustrated in Fig. 2.

Median year for claim and for decision, and in the 53 % of cases for appeal claim and appeal decision related to infective endocarditis was shown in Fig. 3.

Regarding the type of surgery or pathological condition related to infective endocarditis in the sample, single mitral or aortic valve replacement accounted for 40 % of the cases (6/15). Transcatheter valve replacement was not mentioned, suggesting that traditional surgical approaches to valve replacement were predominantly employed (Fig. 4).

The most frequently involved pathogen was *Staphylococcus aureus*, accounting for 40 % of cases (6/15), including one case of methicillin-resistant *Staphylococcus aureus* (MRSA). This was followed by *Staphylococcus epidermidis*, which was identified in 20 % of cases (3/15) (Fig. 5). In 20 % of cases (3/15), the pathogens were not specified. Additionally, *Enterococcus faecalis* and *Staphylococcus capitis* were each identified in one case.

In the first instance, judges ruled in favour of the claimant-patient in 73 % of cases (11 out of 15 cases, and in 8 out of 11 judgments at first instance). On appeal, judges sided with the claimant-patient in 62.5 % of

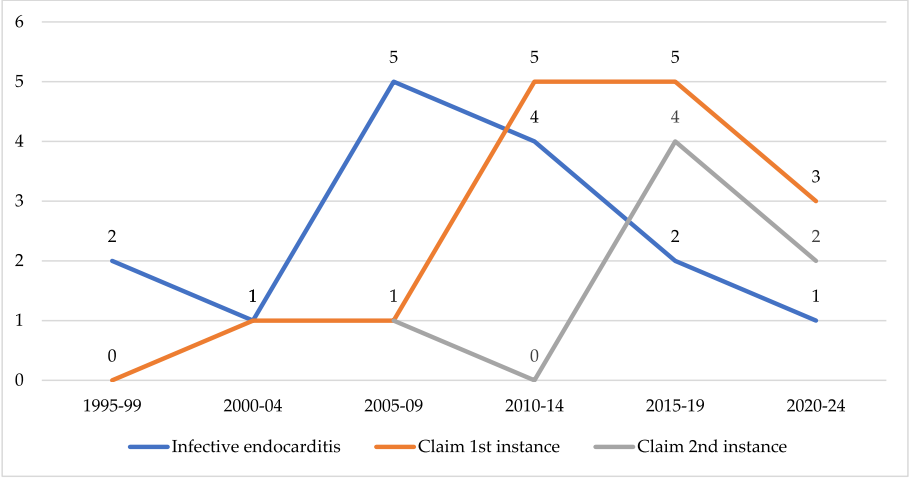

Fig. 1. Distribution of infective endocarditis and claims over time.

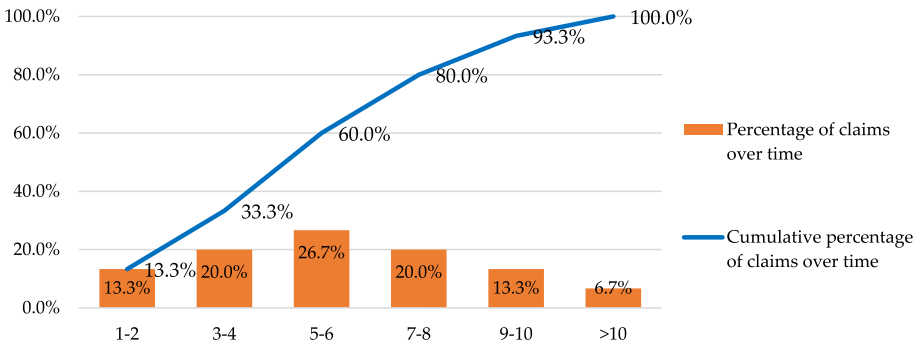

Fig. 2. Percentage and cumulative percentage of first instance claims for infective endocarditis over time.

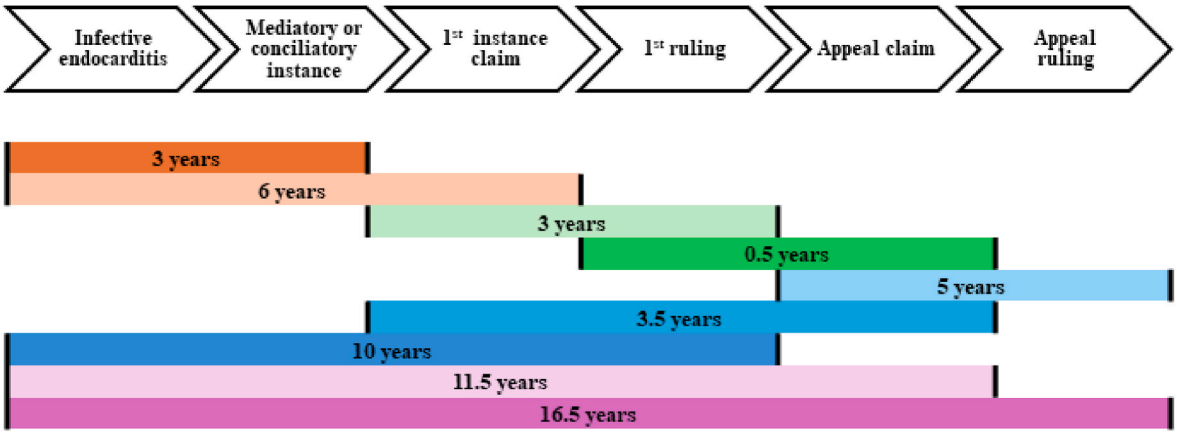

Fig. 3. Timeline of infective endocarditis and trial.

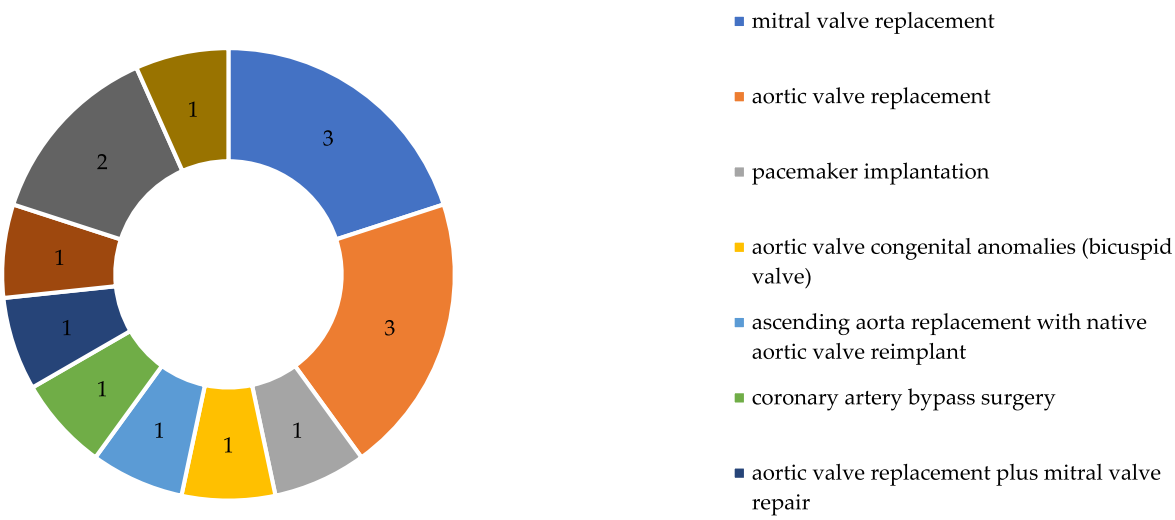

Fig. 4. Surgical approach or pathological condition in infective endocarditis.

cases (5 out of 8 appeals). In 25 % of cases appealed (2 out of 8), the first-instance decision was overturned. In the first case (case n. 1), the decision was reversed because the causal link between negligence and harm was not sufficiently established, a burden previously placed on the health facility. In the second case (case n. 13), the court of appeal recognized a reduction in the claimant's quality of life due to negligent professional conduct, which was deemed relevant for compensation, contrary to the initial judgment.

Then, after the appeal decision, the outcome was 73 % (11/15) in favour of the patient-claimant with liability confirmation, while looking at the single judgements, 68.4 % was in favour of the claimant (13 of the 19 judgements). Timeline and claim description are summed in Supplementary Table 1.

The liability profiles identified included: improper or delayed diagnosis of IE (5 cases), with one misidentification of echocardiographic findings and 3 cases with further improper antimicrobial treatment, improper antimicrobial therapy (2 cases), where non-specific or inadequately timed treatments failed to eradicate the infection, omitted prophylaxis (2 cases). Improper surgical option as a non-resolving procedure, with delayed infectiology consultations. In one case (case n. 1),

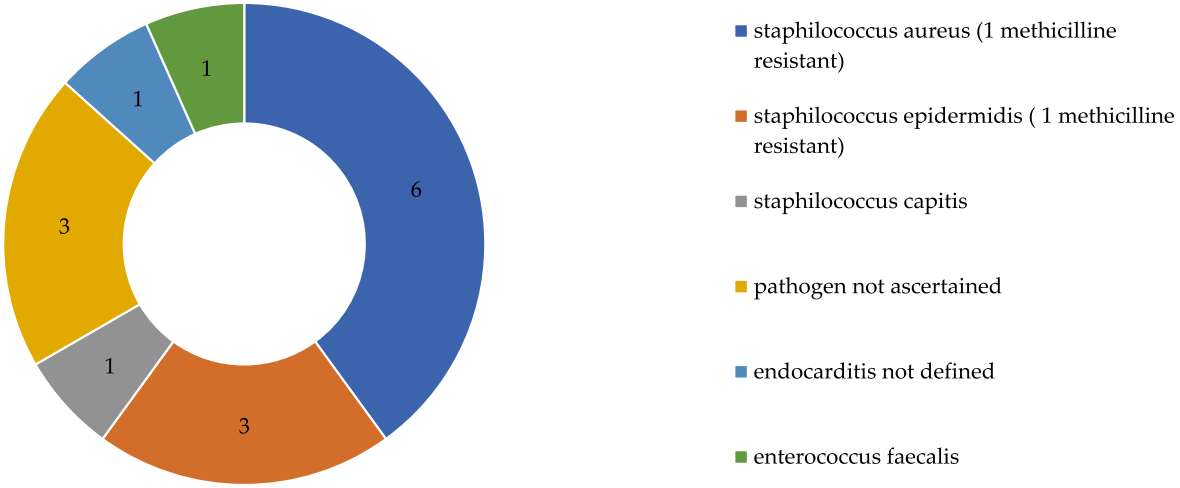

Fig. 5. Pathogens involved in infective endocarditis.

improper antimicrobial therapy was identified, but the causal relationship between professional negligence and the patient's death was not attributed to the healthcare facility after the appeal. Specific informative and consent deficit was detailed (2 cases, cases n. 12 and n. 15). Additionally, the judgement cited the Court of Cassation, III civil section, ruling March 3, 2023, n. 6386 which set a legal precedent regarding infections in healthcare settings and the burden of proof. In one case (case n. 15) the healthcare facility was specifically condemned, as not having organized a system that secure transmission and tracking of information functional to the care.[27] Another judgement (case n. 11) included autopsy findings.

Technical advisors were appointed by the judge in all cases. In 55 % of cases (6 out of 11), two or more advisors were appointed, typically a legal doctor and a cardiovascular or infectiology specialist. In 45 % (5 out of 11), the technical advisors were not further specified. At the appeal stage, in 50 % of cases (4 out of 8), technical advisors were reappointed, while in the other 50 %, the judges relied on the first-instance advisors' reports. In one case (case n. 4, 7 % of the total), the judge chose not to follow the advisors' report, a decision later upheld on appeal. This was because the IE was not microbiologically confirmed and healed without sequelae, meaning no harm occurred.

Cases were further subdivided accordingly to the harmful consequences: 7 are associated with death, 8 with transient or permanent sequelae, as in Table 1, with mean costs. The overall mean cost per case was €289.872, plus an additional €55.296 in case of appeal. The overall cost for all the cases was €3.630.955.

4. Discussion

This study analysed 15 cases of infective endocarditis (IE) judged over a nine-year period (2016–2024) in the Courts of merit of Emilia-Romagna, representing around 1 % of the estimated annual IE cases in the Italian region.[28] For contextualisation, in 2021 Emilia-Romagna recorded 5.2 million hospitalizations, for overall 38.565.940 bed-days, including 21.142 cardiac valve surgeries, 109.158 percutaneous cardiovascular interventions, and 33.958 pacemaker implantations (according to Diagnosis Related Groups reporting).[29]

Although limited in sample size, this case law series is original due to its homogeneity and time span, allowing for valuable and focused insights in the field of cardiac surgery.

The findings of this study reveal a specific divergence from what has been addressed in relation to healthcare associated infections, both from a medico-legal perspective and in the context of infection prevention policies. Certainly, the most interesting data concerns the number of cases compared to the number of judgements for infective endocarditis. However, what should not be underestimated and further deepened, also with respect healthcare facilities and professionals' perception, is the real incidence of compensation claims for IE, and among these, those resolved in a mediative/conciliatory phase. This data is neither available nor extractable at an Italian level, to date, and therefore this study stands as a first picture of a larger phenomenon.

As shown in Fig. 3, another peculiar finding is the processual trend when four main outcomes are considered: 3 median years from IE to a mediatory or conciliatory procedure (when data available), 6 median

Table 1
Harmful consequences of the cases described and related costs.

Harmful consequences	Number	First instance	Cost (in euro)	Appeal	Cost (in euro)
Death	7	6 with first instance in favour of the claimant	mean amount: 500.422 (min 84.236 - max 1.252.658)	1 not uphold in appeal with claimant refund and further expenses	84.236 refunds and further expenses of 10.000
		1 in favour of the defendant health facility	Only expenses on the claimant 23.937	-	-
Transient or permanent sequelae	8	3 in favour of the claimant	Mean amount 97.188 (min 31.387 – max 163.632)	1 appealed by the claimant, uphold for the claimant with further compensation	107.261
		2 in favour of the defendant health facility	Mean amount of expenses on the claimant 7.400	2 appealed by the claimant, uphold for the defendant health facilities	Mean amount of expenses on the claimant 8.750
		-	-	3 rulings of appeals in favour of the claimant (1 not upholding previous judgement in favour of healthcare professionals)	Mean amount 76.901 (including further expenses on the defendant health facilities)

years from IE to the claim, 3 median years from the claim to the judgement and finally 10 median years from IE to the judgement. Overall, with the investigation window set for judgments in 2016–2024, the study looked back IE of around 10 years. This would therefore explain the apparent peak of IE in Fig. 1 and the shifted forward peaks of the first instance and appeal claims.

The study moreover describes an almost homogeneous development of the process and in general a longer litigation processes than the average for HAIs. The distribution of the claims for IE appears linear and progressive (within 5 years only 40 % claimed), differently to what reported on malpractice in general, with 50 % of the claims within 2 or 3 years and 90 % within 6 years.[22] This extended timeframe reflects the complexity of IE cases, which often require stabilization and detailed medico-legal investigation.

The study found that 75 % of early IE cases and 67 % of all IE cases were confirmed as healthcare-associated after liability ascertainment in trial.[30] The legal definitions of healthcare associated infection often diverge from the clinical criteria due to the broader reconstruction of patient history and stricter evidentiary standards. In fact, the epidemiological definition investigates a single case in a definite chronological horizon, by emphasising the specific and fixed major health fact (the surgery or the hospitalization) in which many facts can happen to the patient, at home and in healthcare settings, evidently not traceable or documented. The aim is also to guide preventive health policies at various levels. The legal one, on the other hand, evaluates precisely all the facts that happen to the patient, with a more stringent criteria for healthcare-association in link with possible liability profiles, based on documental and testimonial sources.

In a timeframe as long as that of early infective endocarditis, which spans about a year of the subject's life, the context is not necessarily and predominantly healthcare related. This introduces a further layer of complexity in the reconstruction of the clinical history, the identification of the hypothetical infectious source, and the tracing back to the medical act and/or the care. In contrast to peri-prosthetic infections that occur within a few weeks after surgery and in a kind of microbiological *enclave*, any source of bacteraemia can pose a risk for infective endocarditis, particularly when a foreign body – the valve or the pacemaker - is introduced into the bloodstream.[31]

But the most relevant finding is how clinically defined HA-IEs, as overall IEs in the sample, were judged as healthcare-associated in trial.

Nonetheless, the challenge lies in establishing a principle that *a priori* correlates the clinical criteria for healthcare association with the legal ones. It is important to note that the latter also depends on more stringent evidentiary requirements, procedural mechanisms, and a shift towards specificity.[30,32] It is evident that the legal definition of healthcare-associated infection remains conjectural and is subject to judicial scrutiny, thereby underscoring the absence of *a priori* responsibilities for healthcare providers. The medico-legal method and its criteriology therefore appear to be fundamental both *ex post facto* to ascertain its origin and whether there is any misconduct.[21] On the other hand, *ex ante*, to structure infection prevention and control systems that can serve as sources of evidence, i.e. guaranteeing the correct traceability of pathways and activities in the single care path towards the clinical records.[33]

It is also pivotal to emphasise the significance of addressing the human natural microbiota and, by extension, the partially contaminated anthropic environment. The healthcare environment is not sterile, differently for instruments, materials, and devices for surgery, and meet specific microbiological thresholds set by regulatory references 34.

Certainly, it must be considered that the cases detected in each year and analysed represent about 1 % of the annual clinical cases, which could reasonably represent that more serious and complex portion of HA-IE, such as to push the plaintiff to sue. Hence the high verdict rate in favour of the patient. The concomitant presence of other adverse events (surgical site infection, haemothorax, pneumothorax, reporting and identification errors, counselling delays) can then account for a lowering of the subject's tolerance threshold and an increase in the subject's desire for payback and reparation, primarily emotional.[35]

The median age and the male prevalence are in line with the literature on infective endocarditis.[36] The prevalence of valvular surgery and among the pathogens of *Staphylococcus aureus* and *epidermidis* emphasise the value of resident skin flora together with preoperative clean-up practices, intraoperative asepsis and certainly prophylaxis, in particular in high-risk patients.[37] These pathogens' prevalence is consistent with the literature, however much epidemiological variation is taking place.[38,39] Of interest is the absence of cases related to *Mycobacterium chimaera*, a pathogen associated with some clusters of surgical site infections due to the contamination of heater-cooler units and/or sanitary water.[40] An explanation would be the resolution of the dispute at the pre-trial stage with the alternative extrajudicial dispute resolution due the high probability of defeat in trial assessed by the Hospital Claims Management Committees or by the Insurance companies experts.[41] Newly, a share of the IE that does not reach judgment.[41] No cases revealed issues of environmental sanitation deficiency.

The judgment's motivations for liability imputation found specific diagnostic, prophylactic and/or treatment issues. For comparison, in the study of 41 Italian judgments on HAI issued from 2020 to 2021, the prevalent motivation was the lack or non-adherence to protocols of prophylaxis and/or infections prevention.[15] The discrepancy may be ascribed to the prevalence of surgical site infections. Rather than being attributable to a single, identifiable improper action, these infections are typically the result of a multitude of improper behaviours and actions. Hence, the liability is distributed and compensation finally and indirectly attributed to the healthcare facility. The enterococci are relevant as a growing pathogen in transcatheter approaches, even not mentioned here.[42] However, if gram-negative infections in cardiac surgery patients can be partially linked to bacterial translocation from the mucosal site of colonisation, also linked with extracorporeal circulation timing, the proper management of catheters, skin – mainly at inguinal site-antisepsis and invasive practices must also be considered and therefore properly documented.[43,44]

In death cases the average cost in cases in favour of the patient claimant is equal to that of big claims, while in permanent or transitory damages the average is just under €100.000 in first instance and a further €50.000 in appeal.

The rate of judgement in favour of the patient claimant is comparable with the literature,[15,23] including foreign literature,[45] and partly underlines a jurisprudential orientation in favour of the compensation for confirmed healthcare-associated infections. On the other hand, it still highlights the need to strengthen functional healthcare IPC actions also as sources of evidence for discharge by the healthcare service in the case of litigation.[46] It is imperative to acknowledge that the present analysis is based on a selected sample of cases of IEs that were more likely to be attributable to healthcare for some criticalities in the care pathway. The greater clinical and legal complexity of the cases described could explain both the longer time taken to initiate and manage judicial cases in general and, above all, the apparent ineffectiveness of the strategies to contain the process, although only five cases disclose a mediatory/conciliatory phase. However, further reflections on the actual opportunity and capacity for settlement, both at the corporate and pre-trial stages, are necessary.[41]

Also of foremost importance is the presence in all trials of the technical advisors, with only one case in which the judge does not sustain technical report at first instance and at appeal, and 50 % technical advisors' re-appointment. Regarding the court-appointed advisors, the differences of specialisations (infectiology's physician, cardiac surgeon, cardiologist, etc) may also depend on the parties' consultants and the point at issue in the clinical case. Apart from the mention of the ruling 6386/2023 and of informative and consent deficit, one case discusses the relevant issue of distinguishing the role – from which the fault-of the healthcare facility with its organisation and that of the practitioner.

In fact, in the Court of Appeals of Bologna Ruling N. 1128/2021 -

Proceeding N. 2412/2015 court-appointed consultants have identified responsibility on the side of health practitioners: the revision surgery with mitral ring cleaning was not in accordance with guidelines, and the antibiotic management was inadequate, both preoperatively as prophylaxis and, more notably, postoperatively. The health facility, on the other side, was burdened together with the professionals of the improper management of the cardiac surgery patients. In detail, negligence in taking the patient's medical history, which led to ignoring the existence of a severe form of aggressive periodontal disease, incompleteness of the bacteriological diagnosis, which neglected the culture test for HACEK bacteria (*Haemophilus*, *Aggregatibacter actinomycetemcomitans*, *Cardiobacterium hominis*, *Eikenella corrodens*, *Kingella kingae*), failure to prescribe antibiotic therapy (broad-spectrum and adequate duration) in a case of possible IE. Moreover, information and consent disclosure deficit has been ascribed to both.

Another judgement of the Court of Reggio Emilia, Ruling N. 559/2024 - Proceeding N. 1877/2022 is relevant regarding causal assessment related to two healthcare-associated infections and the death. The case law in fact distinguishes and weighed the causal value of the two infections occurred in two different healthcare facilities in sequence with each other (previously a Staphylococcal endocarditis then a multi-resistant Candida systemic infection). The consultants and the judge considered how the first HAI – with liability profiles - led to a condition of immunocompromise, even once Staphylococcal endocarditis had resolved. A second severe and resistant opportunistic infection, leading to multi-organ failure and death, developed on top of this condition. Then, the second infective cause was not considered to absorb by itself the previous cause and was related to the conditions brought by the previous healthcare-associated infective endocarditis. Then, the second healthcare facility, even if it has still determined a clinical HAI, was not considered liable and the death entirely attributed to the first healthcare facility.

In terms of limitations, apart for sample sizing, we conducted the research on the national and official database of the Ministry of Justice, but as far as other online legal databases are concerned, completeness could not be guaranteed. We avoided the selection of "legal field" as "healthcare malpractice" because the flags are not precise or could overlap within fields. The two-author assessment sought to avoid single-author cognitive bias in inclusion and analysis. However, it should be noted that excluded cases were discussed in the results to highlight the reasoning for replicability. For the causal attribution of the infection to the healthcare setting, that is HA-IE confirmation, authors reported and discuss the court decision.

5. Conclusions

The study offers an initial perspective on infective endocarditis litigation in an Italian sample, which presents specific features compared to the general management in court of healthcare-associated infections. The question of what is meant by *healthcare-associated,* especially from a legal point of view, remains fundamental to understand the breadth of its meaning and its implications, especially for health professionals and the citizens, to avoid reducing access to any kind of healthcare setting to be a mere condition, or even a mere risk, that gives rise to civil responsibility. It is needed to understand the legal implications of a naturally colonised substrate and therefore of the partially contaminated anthropic environment.

The question of the epidemiological trace of the pathogen is still not fully answered, while simple antimicrobial resistance is no longer limited to acute care. The medico-legal reasoning, especially in a phenomenon of social relevance such as that of infections, deserves to be taken into account in IPC policies and in general clinical risk management.

Informed consent statement

Not applicable.

Author contributions

All authors have read and agree to the published version of the manuscript. Conceptualization, Livio Tronconi, Giuseppe Basile, Luca Bianco Prevot and Vittorio Bolcato; Data curation, Gerardo Lo Russo; Formal analysis, Elisa Mikus, Carlo Savini, Diego Sangiorgi and Vittorio Bolcato; Funding acquisition, Giuseppe Basile; Investigation, Elisa Mikus, Luca Bianco Prevot, Carlo Savini and Vittorio Bolcato; Methodology, Elisa Mikus, Luca Bianco Prevot, Carlo Savini, Gerardo Lo Russo, Diego Sangiorgi and Vittorio Bolcato; Project administration, Vittorio Bolcato; Resources, Livio Tronconi and Giuseppe Basile; Software, Diego Sangiorgi and Vittorio Bolcato; Supervision, Vittorio Bolcato; Visualization, Livio Tronconi and Giuseppe Basile; Writing – original draft, Elisa Mikus and Vittorio Bolcato; Writing – review & editing, Livio Tronconi, Giuseppe Basile, Luca Bianco Prevot, Carlo Savini, Gerardo Lo Russo, Diego Sangiorgi and Vittorio Bolcato.

Institutional review board statement

Not applicable.

Data availability statement

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Declaration of competing interest

The authors declare no conflicts of interest.

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none.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jflm.2025.102861.

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