



Malpractice claims in cardiology and cardiac surgery: A medico-legal issue

R. Montisci^a, M. Licciardi^a, R. Cecchi^{b,*}, T. Kondo^c, G. Gerosa^d, R. Casula^e, G. Cecchetto^f,
M. Montisci^f

^a Cardiac Surgery Unit, Department of Cardiac, Thoracic and Vascular Sciences and Public Health, University of Padua, Padua, Italy

^b Institute of Legal Medicine, Department of Medicine and Surgery, University of Parma, Italy

^c Institute of Legal Medicine, Wakayama Medical University School of Medicine Graduate School of Medicine, Japan

^d Department of Cardiothoracic Surgery, Imperial College Healthcare NHS Trust, Hammersmith Hospital, London, UK

^e Clinical Cardiology, Department of Medical Sciences and Public Health, University of Cagliari, Cagliari, Italy

^f Legal Medicine and Toxicology Unit, Department of Cardiac, Thoracic and Vascular Sciences and Public Health, University of Padua, Padua, Italy

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ABSTRACT

Medical liability has become a challenge in every physician's modern practice with the consequent loss of the physician's autonomy and an increase in "defensive medicine".

From this perspective, the role of Legal Medicine in assessing medical liability has become increasingly specific and a homogenization of the methods of ascertainment is increasingly necessary, since such a process can contribute to strengthening the guarantees in professional liability procedures.

Focusing on malpractice claims in the field of cardiology, the complexity of the management of cardiac pathologies and the frequency of severe adverse events implies the importance of a multi-disciplinary approach, together with the application of a shared ascertainment methodology.

In particular, it is essential for the forensic pathologist to collaborate with experts in cardio-pathology, cardiology and/or cardiac surgery in cases of alleged medical liability in the cardiology field and to follow the guidelines which have been produced to assist the expert dealing with deaths reflecting cardiac disease, in order to prevent criticism of case analysis in medico-legal environments and to promote the standardization of the structure of the juridical-legislative medical malpractice lawsuits.

1. Introduction

In the last decades, medical liability has become a challenge in every physician's modern practice. Nowadays, this phenomenon has taken on the dimension and the severity of a pandemic, whose transversal invasiveness does not spare nations, structures, politico-institutional regimes, social classes, professional contexts, or cultural and ideological orientations [1,2]. The main consequences are new economic pressures, loss of physician autonomy and an increasingly "defensive medicine", with increment of unnecessary diagnostic testing, referrals and treatment of low risk patients [3,4].

With time, the role of Legal Medicine in assessing medical professional liability (MPL) has become increasingly specific and a homogenization of the methods of ascertainment is necessary, since such a process can contribute to strengthen the guarantees in professional liability procedures. Therefore, in 2013 the European Academy of Legal Medicine (EALM) [1,5] published International Guidelines in the

International Journal of Legal Medicine, to be followed in the assessment of MPL cases, which were adopted, in 2015, by the International Academy of Legal Medicine (IALM) – these Guidelines have now been adopted in many countries all over the world.

The EALM Guidelines on Methods of Ascertainment and Criteria of Evaluation on Malpractice and medical liability provide 11 Steps to be followed for a correct ascertainment of a iatrogenic damage. It represents a shared methodology that consist of a previous ascertainment phase during which a comparative evaluation of clinical data regarding a patient is performed (Step 1) and the pathological features are identified (Step 2). If these steps document a damage to the patient (Step 3), the physio-pathological pathways are examined in order to reconstruct the ideal medical conduct (Step 4). If an ideal conduct is identified (Step 5), the real conduct of medical and healthcare personnel is reconstructed and compared to the ideal one (Step 6–7). If the comparison leads to the ascertainment of an error or non-observance, this has to be classified (Step 8) and evaluated ex-ante taking into account also the possible

* Corresponding author at: Viale A. Gramsci 14, 43126 Parma, Italy.

E-mail address: rossana.cecchi@unipr.it (R. Cecchi).

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causes of justifications (Step 9). Steps 10 and 11 regard the reconstruction of the causal value and causal link between error and damage/event, on the basis of the universal law, statistical law or criterion of rational credibility.

After the application of all the steps of the aforementioned guidelines on medical liability, in two cases (Case 1–2) no errors/inobservances were found, since the negative event was classified as a *no fault medical accident*. In the remaining three cases (Case 3–5) some errors in the conduct of the medical practitioners were identified, and in particular, in case 5: after the application of counterfactual reasoning, the causal link between the *diagnostic-prognostic-therapeutic errors* and death was recognized.

As expected by Gómez-Durán et al. [6], the implementation of the International Guidelines on Malpractice and Medical Liability in all specialties of medicine will bring improvements in claims relating to practice and in the liability system, ensure data for research for this field and consequently be the first step towards prevention and patient safety. As a result, the liability system should promote the quality of all health services and medical malpractice policies should be guided by the best evidence available.

With regard to cardiology, the complexity of the management of cardiac pathologies due to concomitant presence of multiple clinical features, such as metabolic, vascular and neurological pathologies and the frequency of severe adverse events and high-risk interventional procedures [7,8], makes the assessment of malpractice and MPL particularly challenging: it requires a multi- and *trans*-disciplinary approach, with the collaboration of experts in cardio-pathology, cardiology and/or cardiac surgery.

Therefore, the threat of such malpractice lawsuits is a critical issue for cardiologist and cardiac surgeons. A study of 40,916 physicians found that the annual percentage of cardiologists and cardiothoracic surgeons facing MPL claims was, respectively, 8.6 % and 18.9 %, compared with 6.6 % among general internists and 11.6 % among gastroenterologists [9]. These findings are similar to those of another study in which the percentage of cardiologists facing a malpractice claim each year was between 5 and 10 %. [10]. Moreover, another study showed that the average MPL defence costs were higher in cardiology than in other specialties [9,11,12]. Another study showed that amongst all specialties, cardiology had the smallest decline in paid malpractice claims reported from 1994 to 2014, which may be associated with the increase in the number of interventional cardiology procedures [13].

In order to improve the quality of care and risk management and to reduce the number of claims and lawsuits against cardiologists and cardiothoracic surgeons, a “culture of learning from mistakes” should be created and data about medical errors should be shared, in order to foster the quality of health through the improvement of the liability system [6,7,12,14].

In this paper we report the implementation of the EALM International Guidelines on a series of 5 autopsy cases performed at the Institute of Legal Medicine of the University of Padova, in which the presence of Medical Malpractice involving different fields of cardiology and cardiac surgery was suspected. The cases were selected based on significance and particularity of the conduct of the cardiologist/cardiac surgeon. Authors of other Italian, English and Japanese institutes contributed with their experience in applying the same guidelines. Some specific issues that should be applied in the assessment of cases pertaining to these fields were highlighted, with the aim of promoting the standardization of the structure of the juridical-legislative medical malpractice lawsuits.

2. Case series

A series of 5 “case examples”, in which the Public Prosecutor suspected the presence of Medical Malpractice involving cardiologists and cardiac surgeons, was selected from the autopsy cases performed at the Institute of Legal Medicine of the University of Padova during 2016.

Such selected cases were reviewed with respect to demographic data, medical history and autopsy findings. The assessment of medical professional liability was performed following the 11 Steps provided by the aforementioned EALM Working Group on Medical Malpractice Guidelines [5]. In all these cases the autopsy was performed by a forensic pathologist, with the collaboration of an expert cardio-pathologist, who dissected the heart and the vessels following the Guidelines for autopsy investigation of sudden cardiac death published by the Association for European Cardiovascular Pathology in 2017 [15].

2.1. Case 1

A 79-year-old diabetic, hypertensive and dyslipidemic man, who suffered from severe aortic stenosis treated with artificial mechanical aortic valve replacement 4 years before, was hospitalized for asthenia, malaise, lipotymic episodes and left scapula-humoral pain and died following hospitalization on the same day. The Public Prosecutor therefore ordered the autopsy in order to evaluate the possible correlation between the placement and functioning of the implanted valve and death. The necroscopic ascertainment revealed severe coronary artery disease with occlusion of the left anterior descending artery and right coronary artery and pseudoaneurismatic anterior left ventricle dilatation (Fig. 1). The precise placement and good functioning of the artificial mechanical aortic valve was also demonstrated. The histopathological examination revealed a widespread myocardial fibrosis with myocytes disarray and acute necrosis in the territory of right coronary artery.

The cause of death was identified as a cardiogenic shock due to acute myocardial infarction in severe chronic ischemic cardiopathy with pseudoaneurismatic anterior left ventricle dilatation and replacement of the aortic valve with a correctly implanted and functioning mechanical prosthesis.

The first steps of the guidelines, namely the process of analysis and comparative evaluation between *ideal* (Steps 1–5) versus *true* conduct (Steps 6–7) did not lead to the identification of a possible error and/or non-observance of required rules of conduct (Step 8). In fact, the almost complete occlusion of the coronary arteries determined a large ischemic area resulting in an irreversible cardiopulmonary insufficiency due to an acute contractile heart failure or a malignant arrhythmia completely independent of the presence of the replaced aortic valve, which was in place and functional, as demonstrated at the time of necroscopic ascertainment. Moreover, the literature reports that acute myocardial infarction is the most common cause of sudden deaths and is an unpredictable event (Step 9).

Therefore, given the correctness of the various diagnostic, prognostic and therapeutic phases, the negative event was classified, according to the guidelines, as a *no fault medical accident*, which implies no medical liability. In fact, when the negative outcome for the patient derives from an unpredictable event, or from an intrinsic therapeutic risk, such negative event must be classified as a *complication* and the healthcare professional cannot be held responsible for the event (Steps 10–11). The judicial decision was fully compliant with the medico-legal assessment.

2.2. Case 2

A 65-year-old obese woman suffering from psoriatic arthritis, hypertension and impairment of peripheral circulation was admitted to the hospital for acute low back pain. During hospitalization the patient suffered recurrent episodes of vomiting, hypertensive peaks, persistent fever, episodes of acute dyspnea, increase in index of myocardial necrosis with ischemic ECG changes, and new regional wall motion abnormality at echocardiogram, and a coronary catheterization with right femoral access was performed. The day following the coronary catheterization the patient suffered a hypertensive peak followed by hypotension, tachycardia, and pulseless electrical activity, after which she died. Therefore, the Public Prosecutor ordered the autopsy in order to



Fig. 1. Left anterior descending artery (a) and right coronary artery (b) occlusion.

evaluate the possible correlation between the recent coronary catheterization and the death.

The necroscopic ascertainment revealed a massive retroperitoneal bleeding infiltration extending from the right psoas muscle to the right iliac fossa and pelvic cavity with a massive infiltration of perivescical fat departing from the ipsilateral femoral vein, together with a transmural laceration in correspondence with the external right iliac vein bifurcation and a transmural tear in the superficial femoral artery at the point of the right external iliac vein bifurcation (Fig. 2).

The cause of death was identified in a haemorrhagic shock resulting from retroperitoneal hematoma due to the laceration of the vein, which was probably created during the puncture of the superficial femoral artery in recent cardiac catheterization, as a complication of an accidental tangential penetration of the needle through the venous wall, satellite to the arterial one. Therefore, it was first necessary to analyse the appropriateness of the indication to catheterize and then to evaluate

the possible complications associated with this procedure reported in the literature and their relative frequency.

The process of analysis and comparative evaluation between *ideal* (Steps 1–5) versus *true* conduct (Step 6–7) did not lead to the identification of possible error and/or non-observance of required rules of conduct (Step 8). In fact, given the presence of acute pulmonary oedema and the increase in the troponin level, an acute coronary syndrome was suspected, and the coronary catheterization was correctly indicated. During the catheterization a laceration of the left femoral vein was accidentally produced, and the blood made its way through the thin retroperitoneal space of the posterior abdominal wall (Step 9).

Despite the correct technical execution of the exam and the adequate post-surgery haemostasis, the literature reports an incidence of retroperitoneal haemorrhage of about 0.5 %. Such a low incidence makes the probability that the error occurs equally low, so it is possible to say that the predictability of this event is very low, to the point of framing it as



Fig. 2. Massive retroperitoneal bleeding infiltration extended from the right psoas muscle to the right iliac fossa and pelvic cavity with a massive infiltration of perivescical fat departing from ipsilateral femoral vein (a). Transmural tear in correspondence of both the external right iliac vein bifurcation and the superficial femoral artery at the point of the right external iliac vein bifurcation, before (a) and after formalin fixation (b, c, d).

unpredictable and, as such, it is inevitable or, in any case, a complication predictable but inevitable. Therefore, given the correctness of the various diagnostic, prognostic and therapeutic phases, the negative event was classified, following the guidelines, as a *no fault medical accident*, which implies no medical liability. In fact, when the negative outcome for the patient derives from an unpredictable and inevitable event, or from an intrinsic therapeutic risk, such a negative event must be classified as a *complication* and the healthcare professional cannot be held responsible for the event (Step 10). The judicial decision was fully compliant with the medico-legal assessment.

2.3. Case 3

A 63-year-old obese man suffering from obstructive coronary artery disease and atherosclerosis, was admitted to the hospital with an acute myocardial infarction complicated by left ventricular failure with pulmonary oedema, with hemodynamic and electrical instability. He was immediately intubated and treated with adrenaline and amiodarone, without any thrombolytic therapy via systemic fibrinolysis.

Three hours after the hospital admission, a coronarography study was performed, detecting a critical coronary artery triple-vessel disease with occlusion of two vessels considered at that moment not suitable for urgent percutaneous revascularization because of a high anatomical complexity and unstable clinical and hemodynamical situation. A decision to stage the revascularization, either percutaneous or surgical after discussion with the cardiac surgery team, was taken. However, after 6 days, a percutaneous myocardial revascularization was attempted: percutaneous transluminal coronary angioplasty (PTCA) and stent placement at the anterior descending artery and double stent placement at the circumflex artery was performed. However, after other six days, the patient, who was still hemodynamically unstable, was transferred to a non-equipped centre because of the need for free beds. Nevertheless, after three days the patient developed cardiogenic shock and was transferred again to the equipped centre. A coronary angiography was

immediately performed, during which an intrastent occlusion at the level of the anterior middle descendant artery was revealed. Thromboaspiration and subsequent PTCA with stent implantation in anterior descending artery was performed. After a month the patient died, and the Public Prosecutor ordered the autopsy in order to identify the cause of death and to evaluate the possible correlation between the hospitalization at both the equipped and non-equipped centre and death.

The cause of death was identified in a cardiogenic shock resulting from an acute-subacute haemorrhagic myocardial infarct in a patient with many previous myocardial infarctions and affected by three-vessel occlusive disease belatedly treated with stents implant on the left anterior descending artery and circumflex coronary artery.

In particular, the observation of a transverse section of the heart (previously fixed in formalin 10 %) revealed the presence of necrosis involving more than 50 % of the left ventricle myocardium, posterior and septal ventricular myocardial sclerosis and anterior-septal and posterior transmural haemorrhagic infarction of the left ventricle with papillary muscle involvement (Fig. 3a).

The histologic examination of the heart samples highlighted the presence of obstructive plaque of the right coronary artery (Fig. 3b) and coagulative necrosis of the myocardium (Fig. 3c) with neutrophil infiltration (Fig. 3d).

The process of analysis and comparative evaluation between *ideal* (Steps 1–5) versus *true* conduct (Steps 6–7) led to the identification, according to the guidelines, of *therapeutic/prognostic error* (Step 8) consisting in the delayed revascularization in a patient with acute myocardial infarction. In fact, such patients should be treated with coronary reperfusion therapy (either mechanical or pharmacological) at most within 90 min after the hospital admission and dual antiplatelet therapy (DAPT) especially after stent implantation to prevent stent thrombosis. In our patient coronary revascularization was postponed after a few days of acute ischemic event and the DAPT was not administered correctly. The second error consisted of the transfer of a hemodynamically unstable patient with severely impaired left ventricular

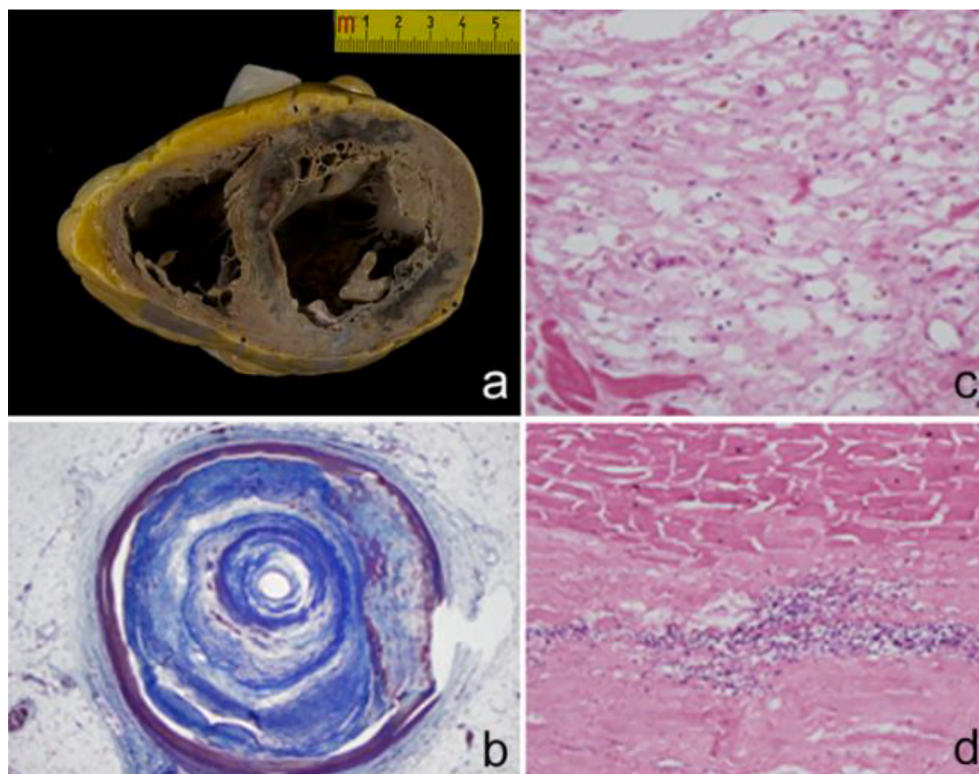


Fig. 3. Myocardium necrosis, sclerosis and transmural hemorrhagic infarction (a); Obstructive plaque of the right coronary artery (b; AZAN 15,6X); Coagulative necrosis of the myocardium (c; EE 160X); Coagulative necrosis of the myocardium with neutrophil infiltration (d; EE 80X).

function to a non-equipped centre, although he needed close monitoring in a suitable environment (Step 9).

However, after the application of counterfactual reasoning, the causal link between the errors and death was excluded, since the clinical situation was so strongly compromised at the admission and the probability of a successful revascularization so low that it was not possible to conclude, applying the criterion of statistical probability, in terms of near certainty, that an early revascularization would have saved the patient (Steps 10–11). The judicial decision was fully compliant with the medico-legal assessment.

2.4. Case 4

A 30-year-old pregnant woman (37⁺¹ weeks of gestation) was admitted to the emergency room after a lipothymic episode with loss of consciousness, dyspnea and dorsal pain during inspiration and, after a negative clinical examination, she was discharged. The following day she was admitted again to the emergency room for dorsal pain during inspiration and was discharged again after a negative clinical examination. On the third day she was rescued at home and the emergency medical services identified the presence of Pulseless Electrical Activity. The patient was therefore admitted again to the hospital and transferred to the operating room for an emergency cesarean. After the cesarean the patient died while the newborn, following resuscitation in Neonatal Therapy, survived, but he presented an anoxic cerebral palsy, which remained persistently unchanged until death occurred four months later.

During the autopsy of the woman, ordered by the Public Prosecutor, a cardiac tamponade was found together with both ascending aorta and aortic arch dissection with an intimal transverse tear, about 3 cm long, located 5 mm above the aortic valve plane and the cause of death was identified in a cardiac tamponade from type A aortic dissection with aspects of cystic degeneration of the tunica media in a pregnant woman.

Concerning the woman, the process of analysis and comparative evaluation between *ideal* (Steps 1–5) versus *true* conduct (Steps 6–7) led to the identification of a *diagnostic error* (Step 8), since the origin of the lipothymia and of the dorsal pain were not investigated, but the next evaluation of the causal link between error and death and the application of counterfactual reasoning excluded the causal link in terms of near certainty. In fact, it was not possible to state that the death would not have occurred if the diagnosis had been made correctly (Step 9).

On the contrary, concerning the newborn, the application of counterfactual reasoning, as indicated in the guidelines, highlighted the causal link in terms of near certainty between the identified *diagnostic error*, and the newborn death. In fact, considering the good conditions of the fetus at the time of the events, it was possible to state that the timely diagnosis of the mother's aortic dissection would have allowed an early caesarean section which would have avoided, in terms of high probability-near certainty, the severe perinatal asphyxia with the connected picture of lethal hypoxic encephalopathy (Steps 10–11). The judicial decision was fully compliant with the medico-legal assessment.

2.5. Case 5

A 63-year-old obese woman called the territorial emergency services because of gastrointestinal symptoms (i.e., diarrhea and vomiting) that had appeared 4 h previously. The emergency staff described the patient as moderately tachycardic with PA 95/60, sweating and asthenic and, as a result, she was transferred to the hospital. At the emergency room an ECG was performed, subjective chest pain was excluded without chest physical examination and vital parameters registration, and the patient was treated only with an antiemetic therapy. Two hours after the admission a marked increase of myocardial necrosis markers was detected and the repeated ECG revealed alterations indicative of inferior-posterior ST-segment elevation myocardial infarction (STEMI), which were already evident at the admission ECG, although they had not

been recognized. Therefore, the patient was immediately transferred to the cardiology department presenting with cardiogenic shock and was treated pharmacologically to support haemodynamic with adrenaline and norepinephrine. A coronary angiography was performed, revealing a complete thrombotic occlusion of the circumflex coronary artery in a left dominant circle, followed by coronary recanalization using thromboaspiration, PTCA and stent implant, at the end of which the patient died.

The autopsy ordered by the Public Prosecutor revealed severe coronary artery atherosclerosis, with calcification and rupture of plaques and critical stenoses in multiple coronary districts and the cause of death was identified in an acute cardiogenic shock with post-infarct electro-mechanical dissociation.

The process of analysis and comparative evaluation, indicated by the guidelines, between *ideal* (Steps 1–5) versus *true* conduct (Steps 6–7) led to the identification of a *diagnostic error* (Step 8), consisting in the lack of diagnosis of inferior-posterior STEMI, whose ECG alterations, already present at the hospital admission, were recognized only 4 h later, when the patient was transferred to the cardiology department. Such an error was followed by a *prognostic and therapeutic error*, consisting of the lack of rapid and timely revascularization (Step 9).

Moreover, given the known time-correlated association between infarct recognition and reperfusion treatment and between this and mortality, after the application of counterfactual reasoning, the causal link between the *diagnostic-prognostic-therapeutic errors* and the death was recognized. In fact, replacing the *real conduct* (i.e. missed diagnosis and reperfusion therapy of the inferior-posterior STEMI) with the *ideal one* (i.e. identification of the STEMI and a consequent targeted therapeutic approach, mechanical reperfusion and/or fibrinolysis, within 30–90 min), it was possible to state, in terms of high probability-near certainty, that the progressive functional-hemodynamic dysfunction would have been avoided by not increasing the mortality of the patient (7 %) (Steps 10–11). The judicial decision was fully compliant with the medico-legal assessment.

3. Discussion

The analysis of the bio-medicolegal literature shows that some fields of cardiology and cardiac surgery, which are detailed below, are more frequently involved than others in malpractice claims [9,16–27], as reported in Table 1.

1. *Acute coronary syndrome (ACS) and Myocardial Infarction (MI)*. Failure to diagnose and treat ACS has significant implications in medical liability because of its high disease burden, MI being one of the leading causes of death in most countries [28], also given the relative difficulty of diagnosis. However, due to its differences in symptoms, as a general rule cardiologists are unlikely to be liable for failing to detect MI in the absence of chest pain and if the patient's symptoms are not classic for coronary artery disease and are explained by another diagnosis [25,29].
2. *Interventional Cardiology (Coronary artery bypass and Percutaneous Coronary intervention/implantable cardioverter-defibrillator implantation)*. The relatively high incidence of serious adverse events may lead to litigation, particularly when combined with overly optimistic expectations on the part of the patients and the high percentage of early and late complications [20,30,31]. Interventional cardiologists have the highest rate of lawsuits amongst endovascular procedure operators such as interventional radiologists, vascular surgeons and cardiothoracic surgeons [32].
3. *Nontraumatic thoracic aortic diseases*, which are highly morbid conditions with devastating complications (death, stroke, paraplegia) including failure to diagnose (or delay in diagnosis) and significant implications in medical liability, especially in the event of delay in surgical therapy and error in surgical technique [18,19,26].

Table 1

The table shows an overview of the studies concerning cases of medical liability involving cardiologists and cardiac surgeons extracted from scientific bio-medicolegal literature. For each study the following parameters have been reported: *Year*, year of publication; *Collection Period*, period of time in which the study was carried out; *Database*, the database used for the collection of cases; *N° of cases*, the number of cases in which medical liability was suspected or lawsuit were claimed; *Field*, the field of cardiology/cardiac surgery involved; *Damage*, the damage reported at the end of the clinical history and the cause, when specified; *Medical Malpractice*, the presence of medical malpractice and, if present, the type of error identified.

Paper	Year	Collection Period	Database	Cases	Field	Damage cause	Medical Malpractice (type of error)
Rötter et al. [16]	2001	1989–1999	Lawsuits claims against Department	74 cases	30 Coronary Artery Bypass Graft 9 Valve Replacement 6 Pacemaker Implantation 4 Aortic Replacement 9 Others Cardiac 16 Others non Cardiac	n.s.	Present in 7 Cases (2 Diagnostic, 1 Prognostic, 4 Therapeutic)
Weintraub et al. [17]	2006	n.s.	Lawsuits Claims involving Tissue Plasminogen Activator therapy (case illustration)	9 cases	1 Stroke 1 Stroke 1 Stroke 1 Stroke 1 Cardiac Condition (n.s.) 1 Stroke 1 Stroke	Stroke sequelae Stroke sequelae Stroke sequelae Stroke sequelae Quadriplegy - Subdural hematoma	No Yes (Diagnostic) Yes (Therapeutic) Yes (Prognostic) Yes (Diagnostic) No
Eleftheriades et al. [18]	2008	2003–2006	Lawsuits Claims involving Thoracic Aorta-related diseases	33 cases	1 Stroke Aortic aneurysm or dissection	Stroke sequelae Stroke sequelae 30 Deaths 2 Paraplegia 1 Major cerebrovascular accident	No No Present in 22 cases (16 Diagnostic, 2 Prognostic, 4 Therapeutic)
Schulz et al. [20]	2009	1983–2007	Autopsy Study from University Database	15 cases	11 Pacemaker Implantation	Death – 2 Hemorrhagic shock; 2 Stroke; 2 Pericardial Tamponade; 3 Myocardial Infarction; 1 Pulmonary Thromboembolism; 1 Acute Cardiac Failure	No
Santiago Saez et al. [21]	2012	1992–2007	Lawsuit involving cardiologists from an Academic Database	32 cases	4 Implantable Defibrillator 16 Coronary Syndrome 2 Heart Failure 14 Others Conditions	Death – 2 Myocardial Infarction; 1 Acute Cardiac Failure; 1 Sepsis 24 Deaths 8 Lesions	No Present in 10 cases (n.s.)
Abbot et al. [22]	2013	n.s.	Lawsuits against Cardiologists (case illustration)	6 cases	1 Myocardial Infarction 1 Myocardial Infarction 1 Tissue Plasminogen Activator 1 Tissue Plasminogen Activator 1 CABG 1 PCI	Death Death Quadriplegy-Epidural Bleed Stroke sequelae (n.s.) Necessity for a Second Procedure Death	Yes (Diagnostic) No Yes Prognostic/Therapeutic Yes Prognostic/Therapeutic Yes (Therapeutic) Yes (Therapeutic)
Malangamurti et al. [9]	2014	1991–2005	Lawsuits against cardiologists from Insurer Database	530 cases	234 Myocardial Infarction 66 Nonvascular 17 Congestive Heart Failure 29 Arrhythmia 30 Perioperative 26 Cardiac Medications 18 Resuscitation 13 Aortic Dissection 11 Valvular Abnormalities 86 Others	304 Deaths Others (n.s.)	n.s.
Voudris et al. [23]	2016	1995–2015	Lawsuits from an Academic Database	17 cases	PCI	10 Deaths	Present in 5 cases (Therapeutic)
Kuan-Han Wu [25]	2017	2002–2013	3rd level civil and criminal verdicts Taiwanese ministry of Justice database	36 cases	All related to myocardial infarction	7 Deaths	Present in 7 cases (1 misdiagnosis, 5 delay diagnosis, 1 performance error)

(continued on next page)

Table 1 (continued)

Paper	Year	Collection Period	Database	Cases	Field	Damage cause	Medical Malpractice (type of error)
Wang et al. [24]	2018	2006–2016	Lawsuits against cardiologists from Insurer Database	1538 cases	n.s.	709 Death, 18 permanent grave, 103 permanent significant, 83 permanent major, 217 permanent minor, 214 temporary major, 84 temporary minor, 28 temporary insignificant, 63 emotional only, 19 legal issue only.	68 % dropped, denied, dismissed cases 30 % settled outside the court
Christopher Fernandez et al. [27]	2019	1983–2018	Lawsuit concerning cardiac tamponade from an Academic Database	77 cases	All related to cardiac tamponade	60 Death, 12 alive-disabled, 4 alive – disability unknown – 1 full recovery	Specified as number of physician who lost against the plaintiff in court: 30 (24 % out of 124
Krystina Choinski et al. [26]	2021	1987–2019	Lawsuits claims concerning Aorta-related diseases (20 % of lawsuits involving cardiologists).	346 cases	196 aortic aneurysms 150 aortic dissection	23 % Loss of consortium, 19 % emotional distress, 17 % bleeding complications, 13 % open heart complications	25 % in favor of plaintiffs 22 % went to settlement

PCI = Percutaneous coronary intervention; CABG = Coronary Artery Bypass Graft surgery; n.s. = not specified.

4. *Tissue Plasminogen Activator therapy* related injuries. Most of the literature regarding tPA-related malpractice is based on its use to cure acute ischemic stroke and to the realization of adverse events (i. e., acute epidural bleeding). However, the minority of cases of medical liability regarding tPA involve specialists in cardiology or cardiac surgery [17,22].

Our casuistry regards 5 cases of alleged medical malpractice, involving different fields of cardiology and cardiac surgery, among which one refers to cardiac surgical valve replacement (Case 1), one to coronary catheterization (Case 2), one to myocardial infarction and the targeted therapeutic approach (Case 3 and 5) and one to cardiac tamponade due to aortic dissection (Case 4).

Our casuistry, which covers the main areas reported in the literature as the most frequent object of litigation, demonstrated how the methodology proposed by EALM Working Group could be useful for the assessment of Medical Liability in the cardiology and cardiac surgery fields, with the application of some specific issues, described below.

The importance of the EALM guidelines lies in the fact that their application makes it possible to examine an event from all points of view and to reconstruct the causal link thoroughly. Once the causal link has been established, they make it possible to highlight not only the possible **justifying causes** of what happened, but also to establish their relevance in terms of foreseeability and avoidability. This provides the judge with all the elements needed to assess the case as malpractice or not.

For instance, the application of the EALM guidelines in case 1 obliges one to consider that, although the patient died in hospital, each action performed by the doctors corresponded to the requirements of ideal medical conduct. It was therefore an unforeseeable and non-avoidable event.

In case 2, although it is evident that the perforation of the left femoral vein was a technical error made during the cardiac catheterisation manoeuvre, the guidelines indicate to check how this error is described in the literature. It follows that, since it is considered to be extremely rare, the event must be regarded as not very predictable, or even unpredictable. Consequently, it also becomes unavoidable, which excludes the liability of the doctors.

In case 3, two erroneous medical acts were identified but, following the counterfactual reasoning indicated by the guidelines, the chances of survival were very low. It was therefore concluded that even if doctors had operated well, the patient would most likely have died anyway.

Case 4 is interesting in that a missed diagnosis was not considered to be the cause of the patient's death because the counterfactual reasoning, imposed by the EALM guidelines, showed that with high probability she would not have survived even if operated on in time. However, the foetus she was pregnant with would have been saved had the diagnosis been made in time and correctly. Malpractice was therefore established

with respect to the infant's death.

Finally, in case 5, a diagnostic error was considered to be causally linked to the patient's death since, by applying the chronological criterion laid down in the guidelines, it was ascertained that an operation performed within 30–90 min of admission to hospital would most likely have saved the woman's life.

With regard to the ascertainment methodology, the involvement of a specialized expert in cardio-pathology is highly recommended since the beginning of the ascertainment phases (i.e., examination of clinical and documentary data, execution of the autopsy and possible further analyses).

In general, during the evaluation of the clinical and healthcare documentation the need to involve medical specialists in the ascertainment phase could emerge, to ensure a better definition of the case. This is especially recommended for medical liability lawsuits in the cardio-pathological field, given the considerable complexity of these cases.

Therefore, according to the specifics of each case, the forensic pathologist should require the collaboration of multiple specialists, such as clinical and interventional cardiologists, cardio-pathologists, cardiac surgeons, geneticists and genetic counsellors [33] in order to determine the precise cause of death. This involvement should preferably take place before the autopsy, as the specialist may profitably contribute to the choice of pre-autopsy examinations, ascertainment, and possible integrative examinations.

Moreover, the autopsy is a moment of prime and essential importance in medico-legal ascertainment for medical liability on corpses, as indicated in Recommendation no. R (99) 3 of the Committee of Ministers to Member States on the Harmonisation of Medico-Legal Autopsy Rules, which deals in great detail with the question of autopsy procedures [34].

The investigation, description, documentation, and sampling during a medico-legal autopsy should primarily follow medical and scientific principles and simultaneously consider the judicial requirements and procedures.

Given the considerable variation in the way in which pathologists approach cases concerning sudden cardiac death, the Association for European Cardiovascular Pathology published the Guidelines for autopsy investigation of sudden cardiac death in 2017 [13,15].

In these guidelines the role of the autopsy in sudden death is precisely defined, and consists in establishing or considering:

- whether the death is attributable to a cardiac disease or to other causes of sudden death;
- the nature of the cardiac disease, and whether the mechanism was arrhythmic or mechanical;
- whether the cardiac condition causing sudden death may be inherited, requiring screening and counselling of the next of kin;

- the possibility of toxic or illicit drug abuse and other unnatural deaths [35].

Therefore, pathologists are responsible for determining the precise cause of sudden death and the guidelines represent the minimum standard required for the assessment of sudden cardiac death, including the protocols for heart examination, for histological sampling and for toxicology and molecular investigations.

Moreover, in 2015, the Royal College of Pathologists [36] has already published guidelines primarily addressed to consultants performing medico-legal autopsies, designed to be a focused bench-top guide with step-by-step examination suggestions. These guidelines have been created to address the needs of the autopsy pathologist dealing with deaths reflecting cardiac disease and to indicate a technical approach and investigation that should prevent criticism of case analysis in medico-legal environments.

Improvements in standards of practice will allow meaningful comparisons between different communities and regions and, most importantly, permit future trends in the patterns of diseases causing sudden death to be monitored [37].

At the end of the ascertainment phase, the forensic pathologist, together with the collaborators (i.e. cardiologists, cardio-pathologists, cardio-surgeons, clinical geneticists and genetic counsellors) [33], should conduct a comparative evaluation of all data collected and identify the pathological features which have led to the death of the patient. Subsequently, they should collegially reconstruct the physio-pathological pathways composing the actual chain of events, through the link between the initial, intermediate and the final pathological features.

Moreover, the *ideal medical conduct* which should have been followed by the physician during diagnosis, prognosis and treatment must be reconstructed. The reconstruction of the ideal medical conduct is carried out by analysing a hierarchy of specific scientific sources and the expert should take into account the so-called *pyramid of evidence* [38]. The scientific sources considered for the evaluation of the case must predate or be contemporary with the facts and accredited by scientific associations or institutions. *Guidelines* and *protocols* have particular importance and they are on the top of the scientific hierarchy of sources [39].

In the field of cardiology and cardio-pathology there are many useful guidelines and protocols in which diagnosis, prognosis and treatment of various problems (e.g. acute myocardial infarction, acute coronary syndromes) are described in detail [39–41]. However, the strict observance of such guidelines and protocols is not sufficient, because the cardiologist must take into account all clinical signs and all instrumental evidence, which could indicate the necessity to deviate from standard conduct.

Therefore, it is important to keep in mind that adherence to guidelines does not necessarily constitute a full defence against a claim of negligence, and on the other hand, that the decision to deviate from guidelines does not necessarily imply negligence, because some clinical situations may need a deviation from standard guidelines. The ultimate decision concerning the patient must be made by the physician [39].

Once the “ideal conduct” has been reconstructed, the forensic pathologist must conduct a comparative analysis between ideal conduct and true conduct.

The evaluation of the correctness of the various diagnostic, prognostic and therapeutic phases may lead to the identification of *errors* which must be classified according to the definitions given by the EALM Working Group on Medical Malpractice and/or *non-observances of rules of conduct* [5].

In the absence of errors and/or non-observances, the negative event is classified as a *no-fault medical accident* which implies no medical responsibility.

In case of error, it is important to verify whether there is a *cause for justification* of the error, for example, the special technical difficulty of a surgical operation.

Finally, the causal link between error and event must be identified, by means of the criterion of scientific probability described by universal scientific laws, statistical laws or rational credibility. Furthermore, the degree of probability of the causal link must be identified and counterfactual reasoning must be applied.

The conclusions must be expressed in terms of near certainty, probability or exclusion of the causal value-link.

4. Conclusion

Medical liability has become a fact of life in the physician's modern practice and each malpractice claim gives rise to a scientific challenge requiring specific expertise in the analysis and evaluation of the clinical case in question.

In this scenario, the role of the forensic pathologist and/or of the cardio-pathologist is divided into two phases and internationally shared guidelines related to both phases must be known and followed.

In the first phase, during the medico-legal autopsy, the pathologist should establish if death is related to cardiac disease or another process and the correlated nature of the cardiac disease, whether the cardiac disease is related to systemic disease, whether any cardiac disease is likely to be inherited, whether the cardiac disease is related to illicit activities, and whether the cardiac disease could have been treated.

In the second one, with regard to the evaluation of medical liability, the roles of the pathologist are to identify pathological features and damage, to reconstruct the physio-pathological pathways together with the *ideal* and *true medical conduct*, to identify and classify *errors* and *non-observances*, to evaluate the error *ex-ante* and to identify possible causes of justification and the causal value and causal link between error and damage/event and finally to identify the degree of probability of causal value and causal link.

Moreover, standardized data collection and reporting processes are needed to build up an accurate national and international picture of the problem. In fact, measuring the consequences of medical care on patient outcomes is an important prerequisite for creating a “culture of learning from our mistakes”.

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