

Mortal acute coronary syndromes in selected rulings of common courts in Poland

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Abstract: Cardiology is continually increasing its life-saving and healthcare capabilities for the benefit of patients with Acute Coronary Syndromes (ACS) through invasive surgical treatment methods. Nonetheless, ACS still involves the risk of death or complications related to the course of the disease itself, as well as to the imperfect nature of the treatment methods available. Frequently, both civil and criminal proceedings are instigated in Poland due to failed ACS procedures. All court proceedings related to medical errors constitute a valuable source of information about the course of a specific medical case and the treatment methods applied. The study discusses three cases of ACS investigated by Polish common courts, which despite treatment ended in patients' deaths.

Key Words: invasive cardiology, Acute Coronary Syndromes, Polish civil law, court judgement, medical malpractice.

INTRODUCTION

The subject of this study are three cases of acute coronary syndrome (ACS), which despite the rapid implementation of invasive treatment, led to patients' deaths. Each of them has become the subject of a civil lawsuit in connection with the claims of deceased patients' families who accused medical staff of malpractice during treatment. In all cases, based on the opinion of expert witnesses, the courts considered the treatment appropriate and dismissed the claims. The clinical descriptions were prepared on the basis of the justification of verdicts and were provided with a commentary on medical science (cardiology) and legal sciences (civil law, patient rights).

JUDICIAL ASSESSMENT OF THE MEDICAL ERRORS IN POLAND

For medical malpractice, the doctor may be called to disciplinary [1] criminal [6] and civil account - alternatively, face the common court or the provincial

medical committee for medical events ruling [2, 3]. At the beginning of each lawsuit, the competent authority is to determine whether actions of the doctor were correct from the point of view of the current medical knowledge. In the years 1989-2015, a total of 23.311 civil lawsuits were filed in courts of first instance for damages or compensation against a medical entity, where 32.4% of the cases ended with a total or partial settlement of the claim and in 4.1% of the cases an agreement was reached by parties [27]. In the majority of the settled claims, the court adjudicates based on the recognition that there is a significant probability of a link between the actions of medical staff and the resulting injury [22]. Moreover, given the nature of the knowledge needed to assess the actions of medical staff, courts appoint expert witnesses in relevant medical specialties and virtually rely on their opinion. Despite relatively mild evidential criteria, more than 60% of claims were dismissed in the indicated period as unjustified or rejected as unacceptable [27].

A medical error, which is the basis for the civil account of the doctor is, in principle, an un-intentional

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fault of failure to perform due diligence without an intention of causing the result-ant effect. In other words it's a negligence [19]. During a therapeutic activity, an error may occur at the stage of diagnosing or therapy, while misleading diagnosis almost always translates into improper treatment. If negligence is at least one of the causes, the appearance of other physician-independent probable causes of a medical event, in particular the patient's health burden, does not abolish the civil account of the doctor [25]. Secondly, a medical error usually leads to patient's suffering, disability, family inconvenience, material deprivation, and in extreme cases, death. As these situations are impossible or very difficult to redress because they concern special care goods, the above-average attention is required from the doctor when providing medical services [21].

CASES PRESENTATION

Case 1 (ST-segment elevation myocardial infarction and cardiogenic shock)

The Court of Appeal in Katowice [5] heard an appeal against the verdict of the District Court in Katowice [9] of 19 May 2015 dismissing the claim for compensation brought by the family of the deceased patient, who in July 2011 had ST-segment elevation myocardial infarction (STEMI) of the anterior-lateral wall with the features of cardiogenic shock. An Electrocardiogram (ECG) was performed within an hour of the onset of symptoms (severe chest and abdominal pain), and was followed by the immediate effective angioplasty of the left anterior descending artery. The procedure involves the implantation of four stents, as a result the normal thrombolysis in myocardial infarction (TIMI) 3 flow was restored, and an intra-aortic balloon pump. In addition, before and during the treatment, medications (such as pressure amines, abciximab, acetylsalicylic acid and clopidogrel) were administered to the patient. During the procedure, there was a haemodynamic table accident which did not interrupt the surgery and, in the opinion of expert witness, did not affect the course of treatment. The patient also suffered from peptic ulcer. After the first treatment, he twice vomited with blood (metoclopramide was administered), but there was no perforation of the gastrointestinal tract or peritonitis. In the face of dyspnea and epigastric pain, which occurred the following day, the patient was transported to a clinical hospital, where due to persistent shock, he was implanted with two additional stents into the right coronary artery (the circumflex branch was narrowed in 80% with the good flow). An intra-aortic balloon pump was exchanged due to its improper filling. During the transport of the patient, which lasted 30-40 minutes, one hospital building was mistaken for another, which had an influence on the duration of the transport. In the expert's opinion, the balloon could have been defective

during the transportation of the patient and his transfer, but it did not affect the course of the disease [8]. A follow-up test, which was performed the next day, showed the patency of all stents. The patient died in a clinical hospital one month after the procedure.

The plaintiffs accused the doctor, who carried out the coronary angiography for the first time, of medical malpractice and demanded compensation from the hospital which employed him. In the opinion of the plaintiff, the medical error included, among others, performing angioplasty instead of cardiothoracic surgery (bypass grafting), the implantation of too little number of stents, defective insertion of intra-aortic counterpulsation balloon pump, erroneous drug therapy and the lack of surgical consultation despite the medical history of peptic ulcer. In the opinion of expert witnesses, the conduct of medical staff from both centres was proper. There were no indications to cardiac surgery, and peptic ulcer was not an absolute contraindication to coronary angiography. At the same time, the widening of non-critically narrowed vessels during myocardial infarction complicated by shock would endanger the patient's life. According to the medical legal report, the death was caused by "progressive multi-organ failure which developed on the basis of advanced cardiovascular lesions, myocardial infarction and the accompanying cardiogenic shock with further complications". Following the expert's opinion, the Court of Appeal did not discern a medical error. By the verdict of 22 January 2016 the court dismissed the appeal brought by the family of the deceased patient and upheld the verdict of the court of first instance.

STEMI and the accompanying cardiogenic shock were a direct threat to life. Under such circumstances, angioplasty of the coronary vessel responsible for infarction is the first-line treatment [23]. During the surgery, anti-platelet drugs are administered which, as side effects, can cause hematemesis in patients with peptic ulcer. However, the medical history of peptic ulcer alone is not a contraindication to angioplasty which saves lives at the moment of myocardial infarction. The justification of the verdict does not state whether the patient was given proton pump inhibitors that should be administered while bloody vomiting. It has also not been specified whether the patient suffered from perforation of the gastrointestinal tract (gastroscopy or X-ray examination of the abdominal cavity should have been performed). In this case, surgical consultation would not have much contributed to the treatment because, due to the clinical condition, the patient would probably not be qualified for abdominal surgery, even more so considering its dubious goal at that time.

As for the patient's family allegations regarding the number of implanted stents and the method of infarction treatment (invasive cardiology or cardio-surgical treatment), the ESC Guidelines of 2012 on the management of acute myocardial infarction with

persistent ST-segment elevation are quite clear and precise. The initial cardiac intervention should involve only the artery responsible for the infarction. There is currently no evidence to suggest the appropriateness of emergency interventions which would include lesions in the blood vessels other than those responsible for myocardial infarction. The only exception for percutaneous coronary intervention (PCI) to be performed in acute (STEMI) is the procedure involving more than one vessel in patients with cardiogenic shock in the presence of many really critically contracted arteries, i.e. $\geq 90\%$ of the lumen. In the patient discussed, the circumflex branch was narrowed in 80%, but stenosis of the right coronary artery was not reported. The second exception relates to the situation when after PCI of the lesion, which is allegedly responsible for infarction, ischemia persists [13]. In this patient, the PCI of the right coronary artery was performed in the second stage in the clinical center. To sum up, doctors who performed PCI have followed the latest myocardial infarction treatment guidelines and standards.

Case 2 (Cardiac hypertrophy, myocardial infarction of the inferior wall and sudden cardiac arrest)

The District Court in Poznań [11] heard in first instance the claim for compensation and permanent allowance filed by the wife of the deceased who in September 2012 had acute STEMI of the inferior wall in the mechanism of vasoconstriction. The patient was cardiologically burdened and was treated for hypertension for 6 years, he was addicted to nicotine for 30 years (smoked about 20 cigarettes a day). While driving a car, he felt strong pressure in the chest, he pulled over and lost consciousness. After regaining consciousness, he still felt pressure in the chest. An ambulance took him to an emergency department, where he was diagnosed with acute STEMI. The doctor prescribed him aspirin, clopidogrel and heparin. Then, about an hour after the onset of symptoms, the patient was transported to another hospital for invasive treatment. At the admission room, he still felt pressure in the chest. On physical examination, the circulatory and respiratory systems were efficient, with low blood pressure. The laboratory tests revealed leucocytosis, mild anaemia, the elevated levels of D-dimers, C reactive protein (CRP), troponin and normal creatine kinase – myocardial band (CK-MB) values (the test was performed twice at 4-hour intervals). The coronary angiography showed atherosclerotic lesions in the coronary arteries with their slight narrowing (30% and 40%). 5000 units of heparin were administered. After the procedure, staying in a forced lying position, the patient reported pain typical after puncture and compression of the femoral artery. The echocardiography performed after the surgery demonstrated symmetrical hypertrophy of the left ventricular muscle and diastolic dysfunction due to long-term hypertension,

but the absence of cardiac tamponade. The chest X-ray showed nothing relevant. As the patient still reported chest pain, he was given morphine and low molecular weight heparin (80 mg); the treatment with clopidogrel (75 mg) and acetylsalicylic acid (75 mg) was continued. He was constantly monitored in terms of ECG, heart rate and measurement arterial blood pressure (ABP), which was repeated every 30 minutes. Thanks to the lowering of the systolic pressure, the general condition of the patient normalized. The next day, at 5.00 a.m. he had sudden cardiac arrest. The medical staff started resuscitation (intubation, artificial breathing, external heart massage). For the duration of the resuscitation, the patient's pupils in both eyes were enlarged. He died 31 minutes after the start of resuscitation. The causes of death included in the medical records were as follows: ACS (aborted), sudden cardiac arrest in the mechanism of electromechanical dissociation, the medical history of hypertension and sudden stoppage of breathing.

The autopsy also showed the presence of 200 ml of blood in the pericardial sac, haematoma at the base of the heart occupying the adipose tissue in the area of the right coronary artery and the left circumflex artery, a significant degree of cardiac concentric hypertrophy (heart weight 600 g), mainly within the intraventricular septum (the thickness in the upper section of 3.0 cm) and the inferior wall of the left ventricle (the wall thickness of 2.5 cm), an ischemic focus in the upper part of the anterior wall of the left ventricle, minor atherosclerotic lesions (mainly in the aorta), fresh passive hyperaemia of the lungs, renal cortex ischemia, passive hyperaemia of the liver and the state after coronary angiography. It was found that the cause of death was acute cardiopulmonary insufficiency associated with bleeding into the pericardial sac (probably from a thin-walled blood vessel), but there were no signs of damage to the continuity of the walls of the main coronary arteries and the blood vessels of the base of the heart. In the opinion of the pathologist, fresh ischemic lesions and hypoxia of the myocardium due to tamponade and acute left ventricular failure overlapped with the earlier ischemic heart disease.

An expert witness in cardiology explained that the patient was heavily burdened by cardiac hypertrophy which may cause sudden cardiac arrest and reduce cardiac susceptibility to resuscitation and indirect massage. He declared that a decision to perform coronary angiography was proper and did not find the complications of this procedure in this case. If the operators had refrained from coronary angiography, this would have posed a risk of leaving an unstable atherosclerotic plaque with active thrombus in the coronary arteries and their critical stenosis. The expert attributed the symptoms reported by the patient and by the medical staff to abortive myocardial infarction. Abortion - the expert explained - consisted in a change of the ECG record presenting a closed coronary artery (suggesting the closure of the right coronary

artery) into the ECG picture of changes after restoration of patency of the coronary artery [24]. In the expert's opinion, there was no need to repeat the diagnostic tests because the clinical condition of the patient stabilized and improved. The medical staff could not predict sudden cardiac arrest that could have been caused by hypertrophy of cardiac cavities or their ischemia. As myocardial infarction developed in the mechanism of vasoconstriction, there was a risk of another infarct, especially in the morning. However, the expert witness was not sure about the cause of sudden cardiac arrest and merely pointed out the possible impact of cardiac hypertrophy and ischemia. He also failed to determine the cause of cardiac hypertrophy indicating the possible coexistence of primary hypertrophic cardiomyopathy. He pointed out to a half-hour resuscitation (about 3000 chest compressions of the precordial area with a large displacement of the thorax in the sagittal dimension) as the only probable reason for the presence of blood and hematoma in the pericardium [18], but excluded myocardial hypertrophy as a cause of hematoma and the presence of blood in pericardial sac as a result of coronary angiography. The patient also had no typical symptoms of tamponade, such as low ABP values and rapid heart rate. The expert also ruled out mechanical damage to the chest as a consequence of a possible hit on the steering wheel of the car, which he was not sure about.

The plaintiff accused the defendant hospital of the malpractice of ignoring the complaints of the patient after coronary angiography. In the opinion of the plaintiff, during coronary angiography, the aortic lumen fused with the pericardial sac producing pain, pressure and expansion of the chest. The defendant hospital argued that no vessel was damaged during coronary angiography and that it was impossible to make a diagnosis of pericardial tamponade during the procedure. In the defendant's assessment, the injuries found during an autopsy were a consequence of cardiac massage. Having accepted the expert's opinion, the District Court did not discern a medical error. By judgment of January 20, 2015, the court dismissed the lawsuit brought by the deceased patient's wife (the verdict is not final).

Also in this case, errors can not be found in the decisions taken by doctors. In any clinical case suggesting STEMI (the ECG record showing ST-segment elevation and typical clinical symptoms, such as chest pain and dyspnea), coronary angiography is the first-line treatment, while emergency PCI is carried out in critical stenosis of the coronary vessels.

The justification of the verdict did not specify the time after which the echocardiography was performed in this patient. In cardiac tamponade as a complication of coronary angiography (what the plaintiff suggested), echocardiographic characteristics of tamponade (fluid in the pericardial sac) should be visible, and that was not the case here. As for spinal pain or pain radiating from

the vertebral column to the chest, the complaints are often reported by patients after coronary angiography performed from the femoral access. This pain is caused by the adoption of the forced lying position. Here, experienced nursing and medical staff can differentiate the source of pain.

It is difficult to unambiguously determine what was the cause of patient's death. Myocardial infarction in the mechanism of vasoconstriction and cardiac hypertrophy caused by untreated hypertension or previously undiagnosed hypertrophic cardiomyopathy (HCM) should be taken into account. It ought to be added that in this first case no atherosclerotic lesions are visible in the coronary angiography. In the majority of the contemporary groups of adults with HCM, the annual mortality rate due to cardiovascular problems is estimated at 1-2%, with major causes of death being sudden cardiac death (SCD), heart failure and thromboembolic events [14].

Case 3 (Chest pain with the normal ECG result)

The Court of Appeal in Katowice [4] heard the appeal against the verdict of the District Court in Katowice of 5 May 2014 [10] dismissing the claim for compensation and damages brought by the wife and children of the deceased patient who in May 2009 had myocardial infarction of the inferior wall of the heart. An emergency doctor reported blood pressure of 200/80 mmHg which decreased to the value of 170/80 mmHg after the administration of captopril. The patient was transported to the hospital due to dyspnoea and chest pain, where the following examinations were performed: blood pressure measurement (ABP 170/100 mmHg) and ECG (regular sinus rhythm, the record was normal, no features of acute myocardial ischaemia); the results of laboratory tests were normal. The level of troponin was not determined because of the lack of appropriate reagents available in the hospital. At the admission room, the patient did not report any complaints and the on-call doctor did not find the grounds for hospitalization. While awaiting for a blood pressure check-up and his daughter's arrival, the patient lost consciousness without any preceding symptoms. Sudden cardiac arrest was diagnosed and immediate resuscitation was initiated (external cardiac massage, artificial respiration, intravenous infusion of fluids and medications and anaesthetic consultation). The spontaneous heart rhythm was restored, however, the patient did not regain consciousness. It was decided to transport him to an intensive care unit of another hospital with a diagnosis of the state after sudden cardiac arrest and effective resuscitation, acute circulatory-respiratory failure, myocardial infarction without the ST-segment elevation, head trauma and hypertension in the medical history. The patient died after a few weeks without regaining consciousness. According to the expert's report prepared for the purpose of the criminal proceedings,

in this case myocardial infarction overlapped with intracranial haemorrhage as a complication of untreated hypertension, which led to the loss of consciousness, collapse and coma. In the absence of chest pain, there was no basis for doing enzyme tests at the admission room (it was considered necessary when the patient reported chest pain). In the opinion of expert witnesses, the rescue actions were conducted in a proper manner.

Before hearing the claim, the disciplinary and criminal proceedings took place in this case. In the disciplinary proceedings, by ruling of 30 March 2010, the Supreme Screener for Professional Liability did not discern the failure of the medical personnel. On 20 July 2010, the Supreme Medical Court dismissed the appeal filed by the patient's daughter. In the opinion of the Supreme Medical Court, there were no grounds for claiming that the patient reached the hospital with myocardial infarction. The expert witnesses declared that chest pain caused by myocardial ischaemia subsided spontaneously as the coronary flow improved. The criminal proceedings also ended with a decision to dismiss the investigation. In the civil trial, giving up additional diagnostic tests (in particular the level of troponin) was a basis for the plaintiffs to accuse the hospital staff of the defendant hospital of negligence and omission resulting in death. The hospital argued that the patient suffered myocardial infarction and intracranial haemorrhage already after the examinations. Adhering to the expert's opinion, the Court of Appeal did not discern a medical error in this case. By judgment of January 20, 2015, the court dismissed an appeal of the family of the deceased patient and upheld the verdict of the court of first instance.

As for the actions undertaken by the doctors, it should be emphasised that when the patient reports chest pain and non-ST-elevation myocardial infarction (NSTEMI) is suspected, a determination of cardiomyocyte damage biomarker, preferably using the high-sensitivity cardiac troponin test, is mandatory [15]. Even though the omission of this test in this case could not have influenced the course of treatment, it was a risky decision. The lack of reagents in the laboratory does not absolve the medical staff of responsibility to consult the patient at another facility. Having no result of coronary angiography, it can not be clearly determined whether NSTEMI was an immediate cause of death.

It's worth noting that "the strength of the relationship between hypertension and coronary heart disease is only about 2/3 of the link between hypertension and stroke. [...] Diastolic blood pressure smaller by 5 mmHg or systolic blood pressure smaller by 9 mmHg is associated with the risk of stroke lowered by 1/3" [20]. Due to the coincident risk factors, cardiologic intervention is often accompanied by neurological intervention.

CONCLUSIONS

Presented cases shows medical problems and legal consequences possible in therapy of ACS. With the development of medical knowledge and therapeutic methods, more and more patients have a chance to be cured, but in some situations, medicine will remain helpless. In the described cases, ACS led to the patients' deaths despite the proper medical management confirmed by the opinions of expert witnesses and the current guidelines for the treatment of cardiovascular diseases. It should be emphasised that ACS is characterized by a rapid course and that invasive treatment should be implemented within 2 hours of the onset of the symptoms [12]. 30-day mortality is less than 2% and 6-month mortality is even up to 12% [7]. Nevertheless, these cases are not representative in this respect due to the overlap of additional dis-eases and complications.

The patient's right to health care services provided with due diligence [2] cannot guarantee the expected results, because the outcome is always to a certain extent independent of the medical personnel. The lack of expected treatment outcomes in some cases becomes the subject of a civil or criminal lawsuit. In medical malpractice lawsuits, like presented cases, we can observe three points of view: of the patient or his/her family filing a specific claim (not always motivated only by a sense of justice), of a medical entity or its employees who seek to demonstrate the correctness of their actions or omissions, and of lawyers who face an unknown domain of knowledge and the emotions of the parties. As lawyers have problems with medical issues, they completely rely on the opinion of expert witnesses, which are often ambiguous and indicates only possibilities without quantitative characteristics of probability [26]. It is true the significance of different evidences should be more unambiguous for judge and parties [17]. On the other hand, many physicians use in their everyday work a variety of ways to protect themselves against possible liability, which often hinders their own practice and the work of others. The current compromise between the patient's right to a civil and criminal trial and the right of doctors to decent working conditions and mental comfort at work increasingly requires more effective legislative solutions in Poland, among other full and correct implementation of European Guidelines on Methods of Ascertainment and Criteria of Evaluation formulated by Working Group on Medical Malpractice operating at European Academy of Legal Medicine [16].

Conflict of interest. The authors declare that there is no conflict of interest.

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