

Medical Negligence – is There a Defined Pattern?

ALEXANDRA LOSTUN¹, ARTHUR KERESZTESI², RAZVAN HAINAROSIE^{2,3*}, GABRIEL LOSTUN⁴

¹ University of Medicine and Pharmacy, Department of Forensic Medicine, 38 Gheorghe Marinescu Str., 540142, Tirgu Mures, Romania

² Prof. Dr. D. Hociota Institute of Phonoaudiology and Functional ENT Surgery, 21 Mihail Cioranu Str., 050751, Bucharest, Romania

³ Carol Davila University of Medicine and Pharmacy, 8 Eroii Sanitari Blvd., 050474, Bucharest, Romania

⁴ University of Medicine and Pharmacy, Department of Human Anatomy, 38 Gheorghe Marinescu Str., 540142, Tirgu Mures, Romania

During the last decades more and more complex and unexpected medical and surgical approaches to different pathology seem to appear. Living in this growing bubble makes the authors wonder about the importance of the human factor in solving the patients problem as the technology fast rate of evolution looks sometimes capable of substituting almost everything. The nowadays direction towards a patient customized medical act does not leave any doubt on the still high influence of the human factor on the outcomes of medicine. The authors state the above conclusion following a short interval of time studied (3 years). We have tried to highlight a pattern of evolution of the medical negligence cases in which the death of the patient was concluded to be in direct relation with iatrogenic pathology. 13 cases are discussed and selected by strictly applied criteria from a total of about 2000 autopsies. The main statements of the authors are that no matter the advances of medical technologies the human factor is at the top when discussing about iatrogenic pathology and more than that the evolution of the technical part seems to put even more pressure on the shoulders of the doctor. One of the important side effects are growing numbers of doctors practicing a defensive medicine as the state and medical law are not very well harmonized in order to clear these aspects for both medical and patient parts involved.

Keywords: forensic medicine, medical negligence, malpraxis, iatrogenic pathology

The iatrogenic pathology started to be studied as a separate entity in 1954 by Doerr and Stein, Meessen (1955) and Gianpalmo (1959). Only the side effects of drug therapy were considered iatrogenic, together with mutation potential of radiations and some other substances. J. Thurner releases a more complex book in 1970 and in his work he also approaches the paraclinic investigations pathology.

Nowadays the databases index shows an impressive number of articles that approach this subject from the perspective of the different medical or surgical/paraclinic specialties, country, gender etcetera. The frequency, diversity and importance of the iatrogenic lesions have seriously risen due to quick development of the therapeutic and diagnosis methods, especially the invasive ones.

Over the last years medical negligence has become an important issue. Medical negligence can be defined as a personal or health system failure to meet a standard level of care [1].

Unfortunately, the Romanian *standard of care* has only recently started to increase, probably due to the development of the private health sector. The laws that define malpractice in Romania are vague and interpretable. Only on a few cases of malpractice in the last 25 years a final sentence was passed.

There is a thin line between adverse events, medical negligence and system errors [2], the decision regarding these three is usually determined by forensic medicine.

The healthcare system faces two sensitive, worldwide issues: the patient's safety and the quality of the medical treatment. Not few adverse events occur in clinical practice, but a few of them are due to negligence. One study shows that 27% of adverse effects are due to negligence [3]. In general, no matter how we take a look at the problem the iatrogenic pathology has more side effects than one wants to accept [4]. The list is as long as

an enumeration of the medical specialties when talking about this subject – starting from first aid – emergency medicine where recognition of a certain condition can be a problem, going through apparently riskless administration of drugs and finishing with complex medical or surgical or combined acts the human factor can really turn a patient from its way on to relief [5-11].

The Romanian legal system has the difficult task of differentiating between adverse events and medical errors (negligence), because punishing adverse events would have an unfortunate effect: difficult procedures and complex cases would not be accepted by many physicians – the so called nowadays defensive medicine. This is only a reflection of a global phenomenon as the international literature regarding this subject shows it [12-15].

The Romanian law states that all sudden deaths, violent deaths or deaths that occur during or shortly after a medical or surgical procedure should undergo medico-legal autopsy [16].

The aim of the study was to detect medical negligence in a series of cases that underwent autopsy at an institute of legal medicine.

Experimental part

Material and method

A retrospective study was conducted on all consecutive autopsies performed between January 2007 and December 2009 at a chosen Institute of Legal Medicine. In the mentioned period, a total of 1993 autopsies were numbered. 13 cases were selected, based on the following inclusion criteria:

- in-hospital deaths;
- sudden deaths that occurred shortly (hours, days) after a medical examination/procedure;
- discrepancies between the history of the events that led to the person's death and the final autopsy conclusions.

* email: razvan@riacclinic.com, Phone: (+40)727224447

Exclusion criteria used:

- decomposing cases;

The selected cases were classified based on the errors that led to the patient's death, as follows: personal medical error (by providing a wrong diagnosis or performing an inappropriate surgical procedure) or medical system error (lack of medical personnel, nosocomial infections).

All patients were submitted to complete necropsy including histopathology exam.

The collected data were inserted into Microsoft Excel 2010, and EpiInfo 7 software was used for the statistical analysis.

Continuous variables are reported as mean \pm SD and categorical variables as observed number of patients.

Results and discussions

From the total of 1993 autopsies performed in the 3-year period, 13 cases met the selection criteria. The mean age of the cases was 52 ± 21 years, with a minimum age of 18 years and a maximum age of 77 years. The sex distribution of the cases revealed a male to female ratio of 0.6, five of the selected cases being male. The mean age of the male cases was 61 ± 15 years, while the female cases had the mean age of 46 ± 24 years. The area background of the selected cases revealed an urban/rural ratio of 0.6.

Based on the proposed classification, the personal error group included four cases, the rest being considered medical system errors.

We included in the first group of errors the following five cases:

First case

A 40-year old male, presents at the emergency room with 150/100 mm Hg blood pressure and is diagnosed with acute tonsillitis and laryngitis, for which he receives antibiotics and angiotensin converting enzyme inhibitor. Four hours after, at his residence, the patient dies, previously complaining of retrosternal and neck pain. The autopsy revealed the cause of death as being coronary atherosclerosis with a recent intramural clot.

Conclusion of the forensic report: The death of the patient was non-violent and it was due to the cardiac and respiratory failure as a consequence of atherosclerosis and coronary thrombosis.

Second case

A young woman (24 years) presents severe left lower limb pain after the last corticosteroid lumbar infiltration out of a series of six infiltrations performed in a private practice. The emergency neurological and CT exam performed at the County Hospital establish the diagnosis of *thoraco-abdominal posterior wall abscess post-infiltrations and toxico-septic shock*. Treatment is initiated immediately but the patient dies 33 days later. The autopsy confirms the diagnosis.

Conclusions: Death was violent. Death was due to acute cardiorespiratory failure after toxic septic condition possibly after paralumbar infiltrative injections.

There is a causal connection between the patient's death and her treatment [infiltrative injections].

Third case

A 51-year old woman underwent hip replacement due to congenital hip dysplasia. During surgery the external iliac vein is ruptured, causing hemoperitoneum, retroperitoneal hematoma leading to hemorrhagic shock. She dies later that day, after a new surgery to evacuate the hematoma and ligature the femoral and external iliac veins.

The autopsy confirmed the cause of death: hemorrhagic shock due to arterial-venous lesions during surgery.

Conclusions of the medico-legal report: The death of the patient was violent. The death was due to acute cardio-circulatory insufficiency as result of a massive bleeding in the small pelvis consecutive to sectioning of the branches of the internal left iliac and femoral artery and vein during trepanation of the bone in a left hip arthroplasty procedure.

Fourth case

This case refers to an 18-year old female who died 14 days after a C-section. The patient's history revealed that she developed eclampsia and, shortly after the C-section, she also suffered an ischemic stroke; during hospitalization she developed ventilation pneumonia leading to septic shock and death. The autopsy reveals an undiagnosed complication: the 18-year old female had an iatrogenic eso-tracheal fistula, considered an error of airway management during intubation/anesthesia. The autopsy report concludes that all of the above led to the cause of death, namely bronchopneumonia and multiple organ failure.

Conclusion of the forensic report: The death was violent. It was due to cardio-respiratory acute failure that appeared on behalf of the bronchopneumonia and MSOF, complications that appeared after hospitalization for multiple hypoxic-ischemic lesions. All of these might have appeared as a consequence of an error of airway management during intubation/anesthesia that led to eso-tracheal fistula and associated with a stroke as the patient suffered from pregnancy eclampsia.

Fifth case

The last case refers to a 71-year old male, who is admitted on the ENT ward presenting total dysphagia the initial suspicion being esophageal foreign body. The esophageal barium passage reveals no opacity of the esophagus, with the mention that the patient had contrast substance aspiration. He dies in the same day and the autopsy also confirms the diagnosis - massive aspiration of contrast substance but doesn't find any foreign esophageal body or any morphological changes at this level.

Conclusion of the forensic exam: The death was violent and it was due to massive tracheal and bronchi contrast substance aspirate in an old patient with severe cardiac and vascular disease. The patient was administered the substance for radiologic exploration as a suspicion of foreign oesophageal body was risen due to dysphagia.

The remaining 8 cases were included in the system error group:

Six of the cases were from the psychiatry ward of a small hospital from the same county. The patients were hospitalized either with schizophrenia, dementia (vascular, Alzheimer) or other mental diseases. In five of the cases the cause of death was mechanic asphyxia (two cases with food leftovers or food bolus, two cases with aspiration of gastric content in the respiratory tract and one case with asphyxia via hanging), while in one case, the death occurred due to a bilateral obstructive purulent bronchiolitis secondary to prolonged immobilization in context of the mental disease.

In another case, a 53-year old male required lumbar infiltration for pain in the lower back after a fall a few months earlier. One month later, the patient underwent surgery for removal of an extradural lumbosacral abscess and L5-S1 osteodiscitis with *Staphylococcus aureus*. Shortly after, a new surgery is performed to remove a paravertebral muscular abscess. Later he was transferred

in another medical facility, where he was admitted with Staphylococcal meningoenzephalitis for 2 weeks. A final transfer was made to a Neurology ward, where he died 5 days later. The medico-legal autopsy revealed a paravertebral lumbar scar, a partial purulent leptomenigitis, cerebral edema and cerebral ramolitio.

Conclusions of the forensic examiner: The death was non violent. The death was due to acute paralysis of the central nervous system subsequent to a partial purulent leptomenigitis acute cerebral edema and decrepitude as an evolution stage of a lumbar abscess that underwent surgery and which was complicated by an osteodiscitis (reintervention) and with sclerotic aspect at the time of the necropsy. No traumatic injuries on the head, trunk and limbs.

The last case included in the medical system errors is the case of a 25-year old female in need of a C-section. Shortly after, she complains of severe pain in the lower abdomen, and based on the negative evolution an exploratory laparotomy is decided. This reveals congestive bowels and peritonitis. The surgeons performed also a total hysterectomy and bilateral ovariectomy. The patient is transferred in the Intensive care unit where she died 16 days after admission. The medico-legal autopsy concluded that the cause of death was due to toxico-septic shock following generalised peritonitis after a cesarean section complicated with infection and abdominal wall abscess.

We considered the five cases in the first category as being personal medical errors.

For example in the first one, the diagnosis was missed because of unknown causes (either an ECG exam was not performed or it was not interpreted correctly). Under normal circumstances the patient diagnosed with an acute and possible life threatening ENT disease (acute tonsillitis and laryngitis can often cause acute respiratory insufficiency and death) should have been referred to a specialist. The initial diagnosis was clearly wrong, as the examiner seems to have forgotten out of the patient evaluation a measurement of the pulse and if possible blood oxygen level. In addition to that such a high blood pressure (150/100 mm Hg) asked for an ECG or a cardiologic exam as soon as possible as it came from a relatively young patient without any known preexistent heart conditions. The initial examiner was a family medicine specialist that might have lacked the technical means in its peculiar praxis but this does not exonerate him/her as the patient could have been saved if referred to an emergency service with more specialized possibilities of differential diagnosis.

We included the second, third and fourth case in the personal errors category possibly due to the lack of enough attention or lack of knowledge/experience regarding precise medico-surgical procedures. However these cases raise a big question mark because we are talking about common, daily-performed procedures, many of them considered and explained to the ill as low risk and still persons end up dead after them. There is no evidence that an informed consent explaining the full downsides and side effects of the medical act that was repeatedly performed was signed or even showed to the patient.

We included the last case in this category, involving the contrast substance aspiration, because we consider the treatment as being inappropriate. In the case of a patient presenting with dysphagia, the treatment should be immediate admittance, gastric tube complete rest and spasmolytic therapy for the first 24 hours. Barium ingestion or contrastography is an abandoned diagnosis method as it has exactly this aspiration risk. Furthermore, if the patient affirmatively describes total dysphagia as this was the case

this investigation was futile. After the attempt to clear the way by intravenous drugs if unsuccessful esophagoscopy/ videoesophagoscopy is advised for extracting the foreign body or food bolus. If this is impossible under safe circumstances (no tearing of the mucosa that will lead to strictures, bleeding) external combined surgery (thoracic surgery with ENT assistance) should be considered. The fault of the doctor in this case was possibly the urge to fully complete a differential diagnosis, to overdiagnose even if the clinical signs were quite enough in this particular situation. The final aspect of this case that should not be avoided is the blind listening of the involved radiology staff and also their insistence of completing their task even if in not so few other situations patients were thoroughly questioned before asking them to drink the contrast substance and many were refused as they could not properly ingest the substance and complained of total dysphagia.

The second group of patients, especially the psychiatric ones, gives us a complete x-ray of probably the most important problem that many Romanian hospitals face: the lack of medical staff, nurses, and auxiliary staff, few and overcrowded hospitals, lack of motivation of the staff. Patients are not properly cared for in terms of medical care as a nurse should administer drugs for at least 10 patients per shift, monitor their vital signs and evolution and also write all of these down on papers and in electronic archives. The lack of auxiliary staff brings up the other side of the problem – the lack of social care: patients end up tied up, lack adequate food, are not helped with eating, changing their clothes or lingerie and finally these little pieces of negligence lead to accidents and even suicide.

The last two cases in the second group show very well how a first act of medical negligence (poor surgical technique most probably) can roll over and produce a snowball build up effect that compresses the life expectancy of the patient. The individuals had no previous aggravating conditions but after an unsuccessful first surgical act the body seemed already too weakened for reintervention and short time after the patient dies. The other main problem that should be talked about in these cases is that of the nosocomial infections and surgical wound colonization with bacteria. Both patients died of toxico-septic shock due to subsequent generalized infection and this fact should not be forgotten, as it is not a normal evolution.

Because of the vague definition of malpractice/negligence in the Romanian law procedures, the medico-legal system can rarely support the existence of an error. We can only point them out.

Conclusions

The medico-legal autopsy is necessary in many cases of in-hospital deaths to point out many errors that otherwise would go undetected.

Our work unfortunately shows big problems in all sectors: the negligence or errors were present both for acute or chronic conditions, the poor medical act involved as well primary diagnosis, chronic treatment, surgical techniques for usual conditions such as C-sections and hip replacement and even the airway management for anesthesia.

The psychiatric cases show the real dimension of the lack of medical staff as individuals could not be cared for and monitored properly and found their death by food asphyxia.

The Romanian medical system is starving for doctors and as a counter measure the Health Department decided

a few years ago reducing by one year the training interval for most of the specialties. Under these circumstances the authors fear that even bigger problems than the ones we have described above may appear in the next time interval as more inexperienced medical staff may fill in some of the many free positions. The absence of a strict and reliable resident curriculum for residents deepens the problem.

The authors find of real importance and high impact renewing and conceiving medical and surgical protocols with indications and restrictions so the risk that medical malpractice decreases.

Another issue to be solved is the separation for the border type pathology and addressing it towards the most complete medical branch, both with diagnosis and therapeutic possibilities so that the patient would be as well as possible managed from the point of view of risks and cost/efficiency.

There should be an improvement of the relationship between clinician/surgeon, pathologist and forensic specialist for the better management of the clinical activity. The clinician/surgeon should constantly receive a feedback from the others regarding iatrogenic pathology and diagnosis discrepancies.

A higher rate of convictions might not be as good as supposed at a glance as it might lead to a more defensive medicine and therefore as the studies from other authors shows it might shatter the thin line between patient satisfaction and the quality of a complete and correct medical act.

The authors consider that some of the modern medicine tools (such as telemedicine, robotic surgery, video recording of the medical examinations or of the surgical procedures) are not used at their real value and this should be considered for the times to come as the age of the paper and pen notes seems to be over.

The better care for the future patient stands on a ledge. On one hand the medical system tries to reach optimization of the cost/efficiency ratio by almost any means and this while it should attract as many patients as possible. On the other hand the medical staff is literally compressed between the high volume of work and the increasing expectancies from the patient and the job provider. As a conclusion we state that a doctor is still a simple human being no matter all the incredible technological advances in nowadays medicine that are available and this is daily reconfirmed by the susceptibility of the individual to make mistakes.

Medicine develops faster and faster day-by-day and this irreversible process many times leaves far behind the human factor and its capacity to constantly include and correctly apply all of the medical progress during a life of hard work.

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