

Is Hospital Autopsy Auditing Suitable for Clinical Risk Management? Actualities and Perspectives of Auditing in the Autopsy Room Following Italian Law 24/2017 on Patient Safety

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Abstract: Background: Autopsy is a valuable tool for understanding the physiopathology of any disease, and it is the gold standard to assess the cause of death. The clinical autopsy is the ultimate medical service for a patient and plays a crucial role in the context of quality control, education of physicians and other medical personnel, as well as mitigation of risk of malpractice claims.

Objective: This study aims to demonstrate the importance of improving an autopsy service and the relevance of this investigation procedure in daily clinical practice by evaluating the rate of major discrepancies between the assumed cause of death and the ascertained cause of death after a complete post mortem investigation. A further aim is to classify these discrepancies as class I or class II discrepancies according to the Goldman’s criteria in order to assess performance quality.

Methods: A retrospective study of the hospital autopsies performed from June 2018 to March 2020 was conducted by considering a diversified dataset, including age and sex of the deceased as well as the clinical and pathological causes of death.

Results: 362 cases were taken into consideration. Major discrepancies were found in 71.3% of cases, with a class I error of 22.7% and a class II error of 48.6%. The most frequent misdiagnosis were cardiovascular disorders, embolism, and aneurism rupture.

Discussion: The rate of major discrepancies and the rate of class I and class II errors are way above the rate found in the literature. Despite the high rate of a major discrepancy, evidence collected from hospital autopsies (*i.e.*, certainty of the cause of death, unknown comorbidities) has strengthened the legal defense in cases of medical malpractice litigation. In our experience, by accurately determining the cause of death, revealing new or unexpected findings, and any possible diagnostic or technical errors, post-mortem examinations can significantly contribute to the improvement of team performance and quality of care.

Conclusion: The presence of clinicians during an autopsy and the early sharing of results can be considered a new auditing strategy for hard clinical cases. Finally, by providing a clearer understanding of the nature and cause of the illness, the autopsy results assist in the grieving process by reassuring family members that action or inaction on their part had not contributed to the death.

ARTICLE HISTORY

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1. INTRODUCTION

The word autopsy comes from the ancient Greek word *αὐτοψία*. The word is made up of two words: “*αὐτός*” which means itself, and “*ᾄψις*,” which means to see; literal

meaning: to see for oneself. In medicine, an autopsy is still considered the gold standard to assess the cause of death and, thus, a good indicator of accurate clinical and surgical diagnoses and serves as a performance quality tool [1]. Autopsies are also an excellent educational tool not only for students and residents but also for physicians. Necropsies can also be a tool for medical research, particularly if done rapidly after death and for epidemiologic and public health issues other than for medico-legal investigations [2].

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Despite the role of autopsies, their rate has decreased worldwide in the last 50 years, and the autopsy rate is recently below 10% [3]. In the USA, the autopsy rate was between 40% and 70%, which has now fallen below 5%. The same trend was recorded in the UK with a decrease of autopsies from 25.8% in 1979 to 0.69% in 2013 of all hospital autopsies [4, 5]. In Germany, the rate of autopsies decreased from 8-10% in the '90s to almost 1% of all present-day deaths [6]. The same pattern could be seen in Switzerland, where a decrease in the autopsy rate of 72% has been observed in the recent decades. In the Netherlands, the autopsy rate decreased by 0.3% every year in the last 35 years [7, 8]. Other studies reported autopsy rates of less than 10% for teaching hospitals and less than 5% elsewhere [9-13]. The Italian autopsy rate is still unknown; in the past, an autopsy rate between 7-13% was calculated, but, in actual fact, pathologists do complain about a decrease [14]. Costs represent one of the most important causes of autopsy decline, followed by fear of litigation since an autopsy can reveal missed diagnoses and time to discuss necropsy with relatives [15, 16]. Furthermore, an overall lack of interest in autopsy findings, both on the part of pathologists and clinicians, contribute to the reasons for clinical autopsy decline. Finally, autopsies now contribute little to the scientific output of the pathology departments, with only 6% of the published articles being based on autopsy findings [17, 18].

In 2017, Italy enacted Law no. 24 on patient safety [19]. For the first time in Italy, patient safety was indicated as a fundamental right of each individual within any healthcare service and a primary goal of the national healthcare service. Italian Law no. 24 involves all healthcare providers in patient safety while supporting evidence-based practice and compliance with clinical guidelines and promoting a no-blame culture and error-reporting systems. Article number 4 of law no. 24 is dedicated to transparent relations with patients and regulates the modalities of access to medical records and to clinical autopsy. The discipline of the clinical autopsy was integrated twenty-six years ago after the mortuary police regulation enabled the relatives of the deceased to ask for a complete post mortem examination and representation by a doctor of their own choice [20]. Law 24/2017 seems to define a new role for clinical autopsy as a tool to promote transparency, prevent medical malpractice, litigation and loss, and improve patient safety by measuring the quality of performances and learning from errors.

2. MATERIALS AND METHOD

A retrospective study of clinical autopsies performed in the Azienda USL Toscana Nordovest of Lucca (Italy) from June 2018 to March 2020 was conducted with the aim of reviewing causes of death and validating discrepancies with post mortem diagnosis as a suitable indicator of the quality of clinical performance. The assumed cause of death was collected from the autopsy request and medical records, if available, while post mortem diagnosis of the cause of death was collected from the final autopsy reports. All data were collected in a dedicated dataset, including demographics, admitting diagnosis, major clinical findings, preexisting medical conditions, the presumed and ascertained causes of death. Diagnostic discrepancies were classified according to Goldman's criteria [21]. Class I includes missed diagnoses

with a potential negative impact on survival, which would have changed the patient management. Class II comprehends misdiagnoses that did not impact patient survival, which would not have changed their management because no effective therapy was available at that time or the treatment was appropriate even though the diagnosis was wrong [22].

3. RESULTS

A total of 362 clinical autopsies were performed from June 2018 to March 2020 (necropsy rate of 0.068%). 72.4% were men, and 27.6% were women. The mean age was 65.8 years (range from 24 to 98 years). 55.2% of autopsies were requested by the medical doctors who assisted the patients until death, 23.2% were requested by the emergency medical staff, 11.6% were requested by the medical doctors who ascertained the death, 9.4% were requested by the family doctor, and 0.6% were requested by the family of the deceased. Cardiovascular disorders (29.3%) and pulmonary disorders (12.7%) were indicated by medical doctors as the suspected cause of death. Infective complications were supposed to be involved with death in 11.6% of cases. In 35.9% of cases, the cause of death was labelled as "unknown" or "not defined" (Table 1).

The most frequent cause of death found after the autopsy was related to cardiovascular disorders (64.0%), followed by pulmonary disorders (14.9%) and infection disorders (5.5%). In 3 cases (1.7%), the cause of death was unknown, and in 4 cases (2.2%), was not reported. A summary of all the causes of death has been reported in Table 2.

Major diagnosis discrepancies were identified and classified according to Goldman's criteria. Major discrepancies were found in 71.3% of cases (discrepancy rate). Class I errors were identified in 22.7% of the cases, while class II errors in 48.6% (Table 3). Early acute cardiovascular disorders (*i.e.*, ventricular arrhythmia, myocardial ischemia, acute myocardial infarction, aneurysm rupture, aortic dissection, and massive pulmonary embolism, were mainly involved with diagnostic errors.

Diagnostic discrepancies were discussed with clinicians, and the retrospective analysis with medical records was performed to investigate the deeper causes of misdiagnosis. After auditing, all the involved clinicians considered that participating in a hospital autopsy would be a valuable educational experience. They also declared that they were far more motivated to compare the clinical diagnosis of death and post mortem diagnosis in order to enhance diagnostic accuracy and improve their knowledge of the disease. They also stated that autopsies raised opportunities to discuss the ethical and legal aspects of death and death certification, as well as increased empathy for dying patients and their families. They all concluded that autopsies could be considered beneficial and "educational" when findings are concordant by providing feedback on treatment decisions but complained about the possibility of legal claims in case of misdiagnosis or diagnostic errors. Of all 362 autopsies, only four cases were involved with medical malpractice suits, but the evidence collected from hospital autopsy (*i.e.*, certainty of the cause of death, unknown and severe comorbidities) strengthened the legal defense and were decisive for a positive conclusion of the litigation for healthcare providers.

Table 1. Summary of causes of death before autopsy.

	2018 (Jun - Dec) n = 90	2019 n = 202	2020 (Jan - Mar) n = 70	TOT n = 362 (%)
Infection disorders	16	22	4	42 (11.6%)
Sepsis/MOF	12	18	4	
Pneumonia	2	2	0	
Encephalitis/Meningitis	2	2	0	
Cardiovascular disorders	36	58	12	106 (29.3%)
IMA	16	24	4	
Aneurysm rupture/Aortic dissection	0	2	0	
Heart failure	18	30	6	
Arrhythmia	2	2	2	
Pulmonary disorders	8	26	12	46 (12.7%)
Acute respiratory failure	0	8	2	
Oedema	2	2	0	
Embolism	6	16	10	
Oncologic disorders	0	6	2	8 (2.2%)
Neurologic disorders	0	4	2	6 (1.7%)
Other	2	12	10	24 (6.6%)
Unknown	28	74	28	130 (35.9%)
Not Reported	0	0	0	0

Table 2. Summary of causes of death after the autopsy.

	2018 (Jun- Dec) n = 90	2019 n = 202	2020 (Jan - Mar) n = 70	TOT n = 362 (%)
Infection disorders	10	4	6	20 (5.5%)
Sepsis/MOF	8	0	2	
Pneumonia	2	2	0	
Encephalitis/Meningitis	0	2	0	
Endocarditis	0	0	4	
Cardiovascular disorders	46	140	46	232 (64.0%)
IMA	34	22	28	
Aneurysm rupture/ Aortic dissection	6	24	0	
Heart failure	6	28	8	
Arrhythmia	0	66	10	
Pulmonary disorders	10	32	12	54 (14.9%)
Acute respiratory failure	2	4	4	
Edema	0	2	0	
Embolism	8	26	8	
Oncologic disorders	0	6	0	6 (1.7%)
Neurologic disorders	8	6	4	18 (5.0%)
Other	6	12	0	18 (5.0%)
Unknown	4	0	2	3 (1.7%)
Not Reported	6	2	0	4 (2.2%)

Table 3. Major discrepancies according to Goldman's criteria over time.

	2018 (Jun - Dec) n = 90	2019 n = 202	2020 (Jan - Mar) n = 70	TOT n = 362 (%)
Class I	22	40	20	82 (22.7%)
Class II	28	112	36	166 (48.6%)
TOT (%)	50 (55.6%)	152 (75.2%)	56 (80.0%)	258 (71.3%)

4. DISCUSSION

Despite autopsy being the ultimate medical service for a patient, it could play a crucial role in the context of quality control, education of physicians, and mitigation of risk of malpractice claims [23]. Determining the cause of death, revealing new or unexpected findings, and possible diagnostic or technical pitfalls may be considered a source of information for clinical risk managers in healthcare institutions and an opportunity for colleagues to audit their performances [24].

Finally, it could be a valuable instrument for achieving cost-effective healthcare and the efficient allocation of resources within the public sector by indicating the location of the most productive investments in disease treatment and control. In the last decade, hospital autopsy has been presented as a quality management tool for systematic analysis of discrepancies between clinical (antemortem) and autopsy (post-mortem) diagnoses [25]. A major diagnostic discrepancy was found in 5%-40% of all hospitalized patients, with decisions affecting survival in up to 10% of patients [26-33]. Studies in adult intensive care units (ICUs) have reported rates of premortem to post-mortem discrepancies ranging between 7% and 32%, depending on the observed population [34, 35]. A recent Agency for Healthcare Research and Quality (AHRQ) report supported the practice of auditing hospital autopsy to measure outcomes and performances [36].

A French study by an intensive care unit reported clinically important missed diagnoses detected after clinical autopsy in 32% of the selected cases [37]. Another study by a Belgian intensive care unit reported missed diagnoses in 26% of necropsies [29]. It was postulated that discrepancies between antemortem and post-mortem diagnoses are due to selection bias, arguing that cases sent for necropsy are those in which there is diagnostic uncertainty. It could be plausible, but this view is not supported by the available evidence [38]. The basis of this theory is that autopsies are usually performed in cases in which doctors are unsure of diagnosis or cause of death or in complicated cases, so there is a higher possibility of finding discrepancies [39, 40]. Literature has shown that performing autopsies on every deceased patient at one hospital gives a diagnostic discrepancy rate similar to those found in studies in which autopsies were performed only after a physician's request. Thus, this theory does not have much support.

Healthcare organizations may also benefit from the use of autopsy in physician training. Diagnostic skills may be honed by comparing pre and post-mortem diagnoses and examining the factors (human and systemic) that contribute to diagnostic errors [41-43]. Autopsy findings could also be helpful in educating physicians in training, particularly if

they follow a patient's course through the entire medical experience and the autopsy is then used to clarify diagnoses, clinical trajectory, the usefulness of interventions, and to reveal any other factors that may have contributed to the clinical course and death [44-46]. Recently, Italian Law 24/2017 has given the families of the deceased the opportunity to request an autopsy. This supports the demand for transparency of healthcare institutions by the clarification of the suspected causes of death and to provide every effort to demonstrate that appropriate medical care was provided [47].

The overall rate of autopsy discrepancies obtained from our study (71.3%) is way above the data mentioned in the literature, with a prevalence for class II errors, which could be explained by the low necropsy rate and bias represented by patient selection (emergency department, medical wards, surgical wards, intensive care unit) with a prevalence for complicated cases or unexpected deaths and so the chance of finding discrepancies could be higher. In particular, in 23.2% of cases, deaths occurred in the emergency department or after a few hours from recovery, so that it is plausible that time significantly influenced the diagnostic pathway and final diagnosis of death. Physicians have complained of the difficulty in compiling death certificates when the cause is only suspected or unknown because of sudden or unexpected death. In these cases (sudden or unexpected death), cardiac arrest was mainly provided as the cause of death and classified as a class II discrepancy according to Goldman's criteria.

When comparing class I (22.7%) and class II (48.6%) discrepancies to data found in literature, we have found a class I discrepancy rate a little higher compared to the range given by literature of 2.0% - 18.3%. The class II discrepancy rate is way above the range observed in literature ranging from 5.0% to 20.4% [48-53].

In our study, the most frequent diagnostic discrepancies were related to cardiac disorders, pulmonary embolism, and aneurism rupture/aortic dissection. Data in the literature shows that diagnostic discrepancies are found mostly in cases of cardiovascular events, pulmonary embolism, infections, pneumonia, mesenteric ischemia, and neoplasia. On comparing the results, we have observed a good concordance rate for pneumonia and intestinal ischemia, which suggests satisfactory compliance with the existing clinical guidelines. Missed diagnosis of unsuspected acute cardiovascular events (myocardial infarction, aortic dissection, rupture of aortic aneurysm) and pulmonary embolism was discussed with the providers of emergency care who complained of a need for a shared diagnostic algorithm for thoracic pain in an emergency. Therefore, a high suspect level for these conditions.

Recognition of diagnostic discrepancies was perceived as being of fundamental importance to prevent “errors” in the future in order to improve medical skills. The risk of medical malpractice litigation has been complained by healthcare providers. Despite the high rates of diagnostic discrepancies, only a few cases were claimed in which the morphological evidence collected during autopsy strengthened the legal defense and contributed significantly in the exclusion.

CONCLUSION

Our results indicate that diagnosis discrepancies between clinical and autopsical causes of death still exist, despite the technological progress in imaging tools [54]. Autopsies are fundamental tools to assess the quality of medical performance and help identify where there is still a lack of ability to recognize a disease. Therefore, there is a need to maintain a high suspect of conditions such as pulmonary embolism and cardiovascular diseases, such as aneurysm rupture/aortic dissection and myocardial infarction [55, 56]. “Educational” autopsy has represented, in our experience, a new challenge for pathologists and clinicians to improve the quality of medical care by monitoring diagnostic accuracy and treatment of patients. A low necropsy rate (0.068%) represents a limit of the study, as well as the high percentage of autopsies performed in deaths that occurred in emergency departments (42.5%) as the recorded discordance rate (36.6%) is not representative represent the overall quality of healthcare. Anyway, the increasing number of clinical autopsies observed after the 24/2017 law is consistent with an enhanced awareness of clinicians with regard to the issue of transparency promoted by the law itself and supports the importance of promoting educational supports in the hospital context. Our experience confirms the suitability of clinical autopsy as an auditing opportunity for complex cases by reviewing diagnostic paths and therapeutic approaches, measuring the quality of performance (surgical in particular), and strengthening defensive strategies in medical malpractice litigations [57, 58]. All clinicians could benefit from experience in the autopsy room, Clinical risk managers need to be more confident with the learning opportunities offered by post-mortem investigations [59-61].

Great efforts should be made in the future to improve this virtuous practice, and general practitioners need to be involved by relatives towards an awareness of the importance of autopsy [62, 63]. The number of autopsies requested by families of the deceased is still low, and the promotion is needed in this respect.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

HUMAN AND ANIMAL RIGHTS

No Animals/Humans were used for studies that are base of this research.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this research are available within the article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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D.B., M.M. and S.D. conceived the research and contributed to the design of the work. M.Z, M.Mo, A.R, and A.M. provided the analysis of medical records and autopsy reports. E.V. provided the statistical analysis.

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