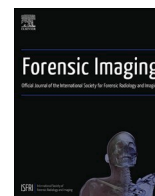




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Claimed medical malpractice in fatal SARS-CoV-2 infections: the importance of combining ante- and post-mortem radiological data and autopsy findings for correct forensic analysis

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ABSTRACT

We present the case of an elderly woman who died from COVID-19 during the first wave of the pandemic. The physicians in charge of the patient were later accused of medical malpractice resulting in the death of the patient. The article reviews the comprehensive medico-legal investigations into this case that included an analysis of the medical history, clinical imaging, post-mortem imaging, autopsy, histopathology, and microbiology as well as an assessment of the medical knowledge regarding transmission of the SARS-CoV-2 virus and the management of COVID-19 at the time of the patient's death. The investigation resulted in a verdict of not guilty. This case highlights the value of clinical and post-mortem imaging as well as various challenges of medico-legal investigations of COVID-19 related deaths.

Introduction

The COVID-19 pandemic has had a significant impact on healthcare facilities and professionals, leading to several challenges concerning not only direct patient care, but also the reorganization and allocation of human and non-human resources [1]. As a consequence, the pandemic has several interesting medico-legal implications, due to the lack of preparedness and the failure to promptly adopt effective prevention and control measures for COVID-19 in many countries (including many highly-developed countries) and hospitals [2]. Therefore, issues have arisen globally regarding the legal liability of healthcare institutions and professionals for avoidable errors [2-6]. Particularly during the first wave of pandemic in Italy, the lack of hospital/intensive care unit (ICU) beds prompted the government to reallocate COVID-19 patients to long-term care facilities (LTCF). In Italy, many LTCFs for elderly patients

with physical and/or psychiatric impairment (in Italian: "residenze sanitarie assistenziali" or "RSA") have become COVID-19 hotspots since the beginning of the pandemic [7-8]. In these facilities, during the first wave, the prevalence of deaths related to COVID-19 was reportedly 40–51.3% in the Italian epicenter of the pandemic (Lombardy region), and it has been claimed that political decision-makers are liable for these hotspots [7].

In this paper, we present the case of an elderly resident of an LTCF who died due to COVID-19, in which the physicians who were in charge of the patient's treatment were accused of causing her death. We were asked to evaluate whether COVID-19 had played a causative role in the death, and if the medical personnel who were in charge correctly managed and treated the patient. We provide a complete documentation with ante- and post-mortem imaging and autopsy findings. The aim is to depict imaging and autopsy evidence of a fatal SARS-CoV-2 infection as

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a case example of complete ante- and post-mortem documentation for COVID-19 deaths for which a claim of medical professional malpractice was made.

Case details

An 85-year-old LTCF resident was transferred to an ICU due to the onset of acute and severe respiratory failure. At admission, the patient's blood pressure was 90/60 mmHg, with 96% oxygen saturation; the patient had a respiratory rate of 22–23 breaths per minute and the body temperature was 37.4 °C. Oxygen therapy was initially administered at 2 L/min using a Ventimask. Oropharyngeal swab test results indicated the presence of SARS-CoV-2 infection.

The patient was affected by chronic atrial fibrillation, anemia and severe sarcopenia and had a history of cerebral ischemia.

Lung auscultation revealed bi-basal rhonchi. Computed Tomography (CT) of the chest on the first day of hospitalization showed multiple, diffused, bilateral areas of consolidation, patchily-distributed in the whole parenchyma, but more evident dorsally (Fig. 1). Lopinavir/ritonavir was initially prescribed, and, in case of QTc abnormality, hydroxychloroquine and intravenous ceftriaxone were recommended. Three days after hospitalization, despite the use of non-invasive ventilation, the clinical condition of the patient drastically worsened and the patient subsequently died of respiratory failure.

A public prosecutor requested a forensic team (composed of a pathologist and a radiologist) to investigate whether the infection was the cause of the death and if the physicians from the LTCF and hospital were responsible for her death. Both the post-mortem CT (PMCT) and forensic autopsy were performed at the Section of Legal Medicine of Università Cattolica del Sacro Cuore (Rome, Italy), a public institution.

A PMCT scan was performed before autopsy using a 16-slice scanner (Philips Medical Systems, Best, The Netherlands), with the following parameters: slice acquisition 1.25 mm, pitch 0.5, rotation time 0.5 s, tube voltage 120 kVp, tube current-time 400 mAs/rotation. No contrast medium was administered. Image reconstruction was carried out at a slice thickness of 1 mm (0.6 mm increment), with soft tissue and sharp bone kernel. PMCT showed massive consolidation of the whole right and left lung, with the exception of the anterior and part of the apico-posterior segment of the left upper lobe, which showed marked ground glass densities with internal septal thickening in a crazy-paving pattern (Fig. 2). These pulmonary alterations were interpreted as evidence of acute respiratory distress syndrome (ARDS). Fluids led to complete obliteration of the lumen of the trachea and the bronchial structures of the whole right lung and almost all of the left lung, with the exception of the above-mentioned regions (Fig. 2). Scant bilateral pleural effusion was detected. The post-mortem swabs of the rhino-pharyngeal/tracheal tract and both lungs were positive for SARS-CoV-2. At autopsy, both lungs showed a pronounced lobar architecture with a solid, airless appearance and an increased weight (the left lung weighed 970 g, while the right lung weighed 1100 g). The cut surface was variegated and contained multiple hemorrhages, both in subpleural and intraparenchymal areas, without apparent vascular distribution (Fig. 3). On histopathological examination, multiple areas of intra-alveolar hemorrhage were observed along with foci of the initial

organizing phase of diffuse alveolar damage. Interstitial lymphocytic infiltrate was also seen, with interstitial/perivascular distribution (Fig. 3). The cause of death—in the absence of any other major pathological findings—was attributed to respiratory failure caused by SARS-CoV-2-related pneumonia. The physicians of the LTCF and the hospital who were in charge of the patient's treatment were judged not to be responsible for her death.

Discussion

In this paper, we present the case of an elderly resident of an LTCF who died due to COVID-19, in which the physicians who were in charge of the patient's treatment were accused of causing her death. The cause of the death was identified by combining the data obtained from ante- and post-mortem microbiological testing, ante- and post-mortem CT scans and a full forensic autopsy. Despite the fact that SARS-CoV-2 infection had already been detected before the death, we performed post-mortem swabs in the rhino-pharyngeal and tracheal tract and the lungs to confirm the ante-mortem result and to assess the biological risk for the pathologist, as recommended by forensic guidelines [9]. Multiple post-mortem swabs were performed to avoid the risk of false negatives [9].

Despite the high risk of infection for the operators, in the scenario of the COVID-19 pandemic autopsies must be considered essential to ascertain the severity of pulmonary damage and thus to evaluate whether pulmonary impairment could have played a causal role in the death [10–15].

Many forensic institutions have continued to regularly perform autopsies since the beginning of the pandemic, despite recommendations from some authors and scientific societies, such as the Italian Society of Anatomical Pathology (SIAPEC), to restrict autopsies to selected cases [10, 16].

In general, finding an infectious cause of death at autopsy can have important medico-legal implications when the victim has been infected in a hospital or LTCF. Residents of LTCFs are generally fragile and, especially during the first phase of the COVID-19 pandemic, have been exposed to a high risk of infection, mainly due to crowding, shared rooms and bathrooms, and the lack of proper infection control measures [11]. Moreover, in some cases, due to the lack of hospital/ICU beds, some patients affected by SARS-CoV-2 infection were transferred to LTCFs during the first wave of pandemic. The issue of liability in the case of errors committed by hospital/LTCF managers and healthcare professionals during the first wave is therefore particularly complex and controversial [8].

In the case presented, the death was attributed to SARS-CoV-2 infection and the health professionals were judged not to be responsible for the death. In the determination of the cause of death, the combination of radiological and autopsy data was particularly important.

The pulmonary CT manifestations of the SARS-CoV-2 infection in the ante- and post-mortem CT imaging in this case deserve some consideration. The ante-mortem CT imaging of the lungs showed multiple, diffused, bilateral areas of consolidation, patchily-distributed in the whole parenchyma, but more evident dorsally (Fig. 1). In accordance

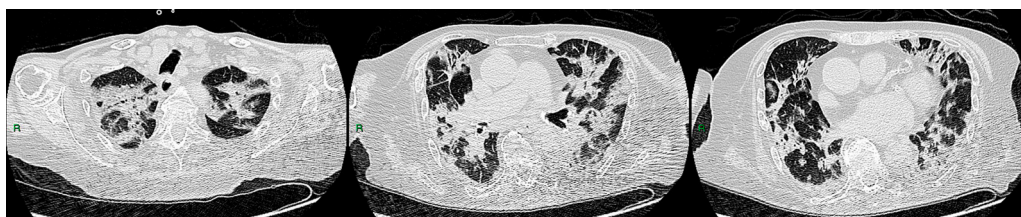


Figure 1. Axial ante-mortem CT images of the thorax, with the lung window at the level of the apex (a), hila (b), and bases (c). The images show multiple, diffused, bilateral areas of consolidation, patchily-distributed in the whole parenchyma, but more evident dorsally.

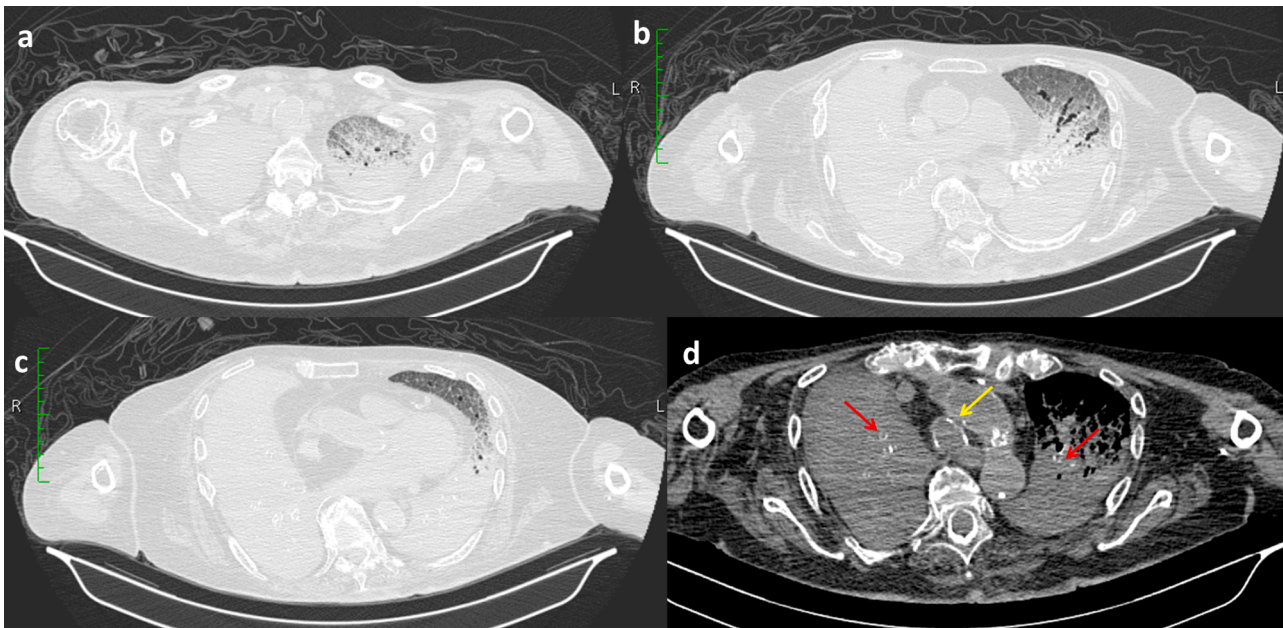


Figure 2. Axial post-mortem CT images of the thorax, with the lung window at the level of the apex (a), hila (b), and bases (c), and with the soft tissue window at the level of the medium III of the trachea. The images a, b and c show consolidation of the whole right and left lung, with the exception of the anterior and part of the apico-posterior segment of the left upper lobe, which showed marked ground glass densities with internal septal thickening in a crazy-paving pattern. In c, the trachea (yellow arrow) and bilateral segmental bronchi (red arrows) are completely fluid-filled.

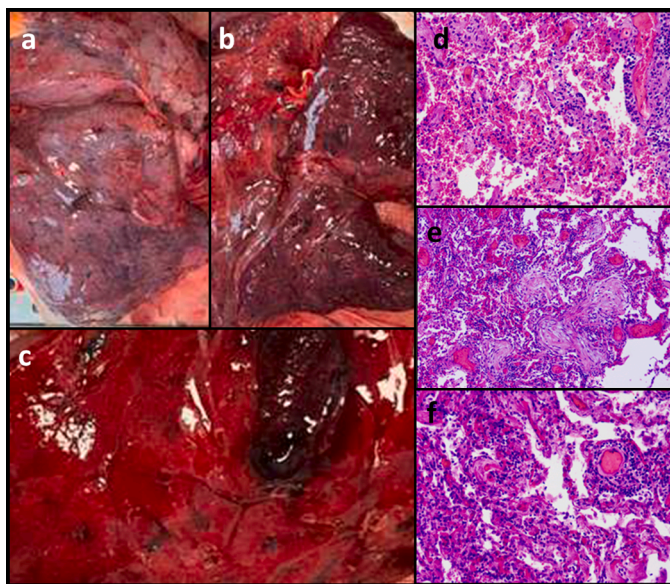


Figure 3. At macroscopic autopsy examination (a, b and c) the lungs showed an increased weight (the left lung weighed 970 g, while the right lung weighed 1100 g) and a pronounced lobar architecture with a solid, airless appearance. The cut surface (c) was variegated and contained multiple hemorrhages, both in subpleural and intraparenchymal areas. The histopathological examination (d, e and f) showed multiple areas of intraalveolar hemorrhage, along with foci of the initial organizing phase of the diffuse alveolar damage. Interstitial lymphocytic infiltrate was also seen, with interstitial/perivascular distribution.

with the available clinical literature [17], consolidation, linear opacities, crazy-paving pattern, and extensive involvement of both lungs had a significantly higher incidence in severe/critical patients, than in non-critical cases. Consolidations in both lungs have been identified as the main pulmonary CT pattern in the clinical literature in the late and critical phases of the disease [18-20].

Moreover, clinical factors such as age over 50 years, comorbidities,

dyspnea, chest pain, cough, expectoration, decreased lymphocytes, and increased inflammation indicators have been demonstrated as risk factors for severe/critical COVID-19 pneumonia and are associated with more severe lung CT alterations, as described above [17].

In the PMCT images, severe involvement of both lungs was found, with massive consolidation of the whole right and left lung, with the exception of the anterior and part of the apico-posterior segment of the left upper lobe (Fig. 2). This pulmonary PMCT pattern was attributed to ARDS and confirmed by histopathological analysis of the lungs. These pulmonary alterations seen on PMCT largely resemble those reported in the literature for SARS-CoV-2 positive patients studied using PMCT [21-27].

Post-mortem imaging, particularly PMCT, has been already proposed as a rapid and non-invasive method of post-mortem investigation to augment the number of cases examined and reduce the risk of infection for the operators [21]. Some evidence on the value of PMCT in COVID-19 cases has been reported [22, 24-27].

Although not specific for SARS-CoV-2 infection of the lungs, in the presence of ante- and post-mortem swabs positive for SARS-CoV-2 infection, these pulmonary findings on PMCT are highly suspicious for severe lung involvement by the pathogen, resembling a severe ARDS pattern, as seen in the clinical literature.

Concerning the possibility of attributing the cause of death by PMCT imaging of the lungs alone, with the support of post- ante-mortem swabs, we maintain that there is currently insufficient published literature [22, 24-27] and the findings reported for assessment of SARS-CoV-2 infection of the lungs using PMCT are not sufficiently specific to propose this post-mortem imaging modality as an alternative to classical autopsy and histopathological analysis.

In this case, histopathological and autopsy data in a subject positive for SARS-CoV-2 infection confirmed the hypothesis of death due to COVID-19. However, the physicians of the LTCF were not considered liable for the death of the resident, because during the first wave (the period in which this case occurred) there was poor knowledge of the measures to prevent and control the transmission of the disease. It was shown that the physicians and LTCF managers had done everything they could to avoid the transmission of the infection. According to the

treatment administered and planned after the hospitalization, the hospital physicians in charge of the patient's treatment were also judged not to be responsible for the death.

The issue of liability in cases of errors committed by hospital/LTCF managers and healthcare professionals during the first wave of the COVID-19 pandemic is particularly complex and controversial [8]. In Italy, this issue has been widely discussed, revealing two main critical points: i) in Italy, the pandemic has had an extremely high incidence, leading to an extraordinary burden on healthcare resources (in particular, lack of hospital/ICU beds and equipment has been reported); and ii) at that time, the understanding of COVID-19, its treatment, and adequate preventive measures to reduce its risk was extremely limited [8]. In other words, in the first phase of the pandemic, the national healthcare system showed a clear lack of preparedness, thus limiting the legal responsibility of the hospital/LTCF managers and the healthcare professionals only to cases of gross negligence [8].

In conclusion, this case of a malpractice claim in a death related to SARS-CoV-2 infection is presented as a case example, where the combination of all data (in particular PMCT and autopsy findings) is crucial for finding the exact cause of the death in patients infected with SARS-CoV-2. Thus, we provide a comprehensive basis for forensic investigations in cases of malpractice claims surrounding SARS-CoV-2-related deaths.

Declaration of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] D.M. Hartley, E.N. Perencevich, Public health interventions for COVID-19: emerging evidence and implications for an evolving public health crisis, *JAMA* (2020), <https://doi.org/10.1001/jama.2020.5910>.
- [2] SG Parisi, G Viel, R Cecchi, M. Montisci, COVID-19: The wrong target for healthcare liability claims, *Leg. Med. (Tokyo)* 46 (2020), 101718. Sepdoi: 10.1016/j.legalmed.2020.101718. Epub 2020 May 16. PMID: 32512463; PMCID: PMC7229443.
- [3] C Martín-Fumadó, EL Gómez-Durán, J Benet-Travé, E Barbería-Marcailain, J. Arimany-Manso, Liability claims in Spain post-COVID-19: A predictable scenario, *Leg. Med. (Tokyo)* 47 (2020), 101745. Novdoi: 10.1016/j.legalmed.2020.101745. Epub 2020 Jul 2. PMID: 32650232; PMCID: PMC7331512.
- [4] AM. Kelly, COVID-19 and medical litigation: More than just the obvious, *Emerg. Med. Australas.* 32 (4) (2020) 703–705. Augdoi: 10.1111/1742-6723.13548. Epub 2020 Jun 3. PMID: 32386246; PMCID: PMC7272927.
- [5] K Duignan, C. Bradbury, Covid-19 and medical negligence litigation: Immunity for healthcare professionals? *Med. Leg. J.* 88 (1 suppl) (2020) 31–34, <https://doi.org/10.1177/0025817220935892>. NovEpub 2020 Jul 23. PMID: 32700595.
- [6] C. Tomkins, C. Purshouse, R. Heywood, J. Miola, E. Cave, S. Devaney, Should doctors tackling covid-19 be immune from negligence liability claims? *BMJ. (Clin. res. ed.)* 370 (2020) m2487. 10.1136/bmj.m2487.
- [7] S. Logar, Care home facilities as new COVID-19 hotspots: Lombardy region (italy) case study, *Arch. of Geront. and Ger.* 89 (2020), 104087, 10.1016/j.archger.2020.104087.
- [8] E. De Angelis, S. Renzetti, M. Volta, et al., COVID-19 incidence and mortality in lombardy, italy: An ecological study on the role of air pollution, meteorological factors, demographic and socioeconomic variables, *Env. Res.* 195 (2021), 110777, <https://doi.org/10.1016/j.envres.2021.110777>. Advance online publication.
- [9] I Aquila, MA Sacco, L Abenavoli, et al., SARS-CoV-2 pandemic: Review of the literature and proposal for safe autopsy practice, *Arch. Pathol. Lab. Med.* (2020), <https://doi.org/10.5858/arpa.2020-0165-SA>.
- [10] A. Sapino, F. Facchetti, E. Bonoldi, A. Gianatti, M. Barbareschi, Società Italiana di Anatomia Patologica e Citologia - SIAPEC, The autopsy debate during the COVID-19 emergency: the italian experience, *Virchows. Archiv.: An Int. J. of Path.* 476 (6) (2020) 821–823, 10.1007/s00428-020-02828-2.
- [11] P.M. Davidson, S.L. Szanton, Nursing homes and COVID-19: We can and should do better, *J. Of Clin. Nurs.* 29 (15-16) (2020) 2758–2759, 10.1111/jocn.15297.
- [12] ECDC Public Health Emergency Team, K. Danis, L. Fonteneau, S. Georges, et al., High impact of COVID-19 in long-term care facilities, suggestion for monitoring in the EU/EEA, *May 2020, Euro Surveillance : Bulle. Euro. Sur. Les. Mala. Transmi. = Euro. Commun. Dis. Bulle.* 25 (22) (2020), 2000956, 10.2807/1560-7917.ES.2020.25.22.2000956.
- [13] J. Wang, W. Yang, L. Pan, J.S. Ji, J. Shen, K. Zhao, B. Ying, X. Wang, L. Zhang, L. Wang, X. Shi, Prevention and control of COVID-19 in nursing homes, orphanages, and prisons, *Env.l pollu. (Barking, Essex : 1987)* 266 (Pt 1) (2020), 115161, 10.1016/j.envpol.2020.115161.
- [14] P. Gualniera, C. Mondello, S. Scurria, A. Oliva, S. Grassi, J. Pizzicannella, A. Alibrandi, D. Sapienza, A. Asmundo, Experience of an italian hospital claims management committee: A tool for extrajudicial litigations resolution, *Leg. Med. (Tokyo, Japan)* 42 (2020), 101657, 10.1016/j.legalmed.2019.101657.
- [15] L.F. Tan, S. Seetharaman, Preventing the spread of COVID-19 to nursing homes: Experience from a singapore geriatric centre, *J. of the Ameri. Geri. Soci.* 68 (5) (2020) 942, 10.1111/jgs.16447.
- [16] J.P. Spherhake, Autopsies of COVID-19 deceased? Absolutely!, *Leg. Med. (Tokyo, Japan)* 47 (2020), 101769, 10.1016/j.legalmed.2020.101769.
- [17] K Li, J Wu, F Wu, D Guo, I Chen, Z Fang, C. Li, The clinical and chest CT features associated with severe and critical COVID-19 pneumonia, *Invest. Radiol.* 55 (6) (2020) 327–331, <https://doi.org/10.1097/RLI.0000000000000672>. JunPMID: 32118615; PMCID: PMC7147273.
- [18] M Carotti, F Salaffi, P Sarzi-Puttini, A Agostini, A Borgheresi, D Minorati, M Galli, D Marotto, A Giovagnoni, Chest CT features of coronavirus disease 2019 (COVID-19) pneumonia: key points for radiologists, *Radiol. Med.* 125 (7) (2020) 636–646, <https://doi.org/10.1007/s11547-020-01237-4>.
- [19] S Salehi, A Abedi, S Balakrishnan, A Gholamrezaezhad, Coronavirus disease 2019 (COVID-19): a systematic review of imaging findings in 919 patients, *AJR. Am. J. Roentgenol.* 215 (1) (2020) 87–93, <https://doi.org/10.2214/AJR.20.230342>.
- [20] Q Zheng, Y Lu, F Lure, S Jaeger, P Lu, Clinical and radiological features of novel coronavirus pneumonia, *XST.* 28 (3) (2020) 391–404, <https://doi.org/10.3233/XST-200687>.
- [21] A. Malizia, L. Filograna, C.P. Ryan, G. Manenti, Post-mortem investigation through virtual autopsy techniques: Proposal of a new diagnostic approach to reduce the risks of operators during emergencies, *Int. J. of Safet. and Sec. Engin.* Vol. 10 (No. 4) (2020) 535–541, <https://doi.org/10.18280/ijse.100413>.
- [22] Schweitzer W, Ruder T, Baumeister R, et al. (2020) Implications for forensic death investigations from first Swiss post-mortem CT in a case of non-hospital treatment with COVID-19 forensic imaging; 21: 200378. Published online 2020 Apr 18. doi: 10.1016/j.fri.2020.200378.
- [23] T Kanchan, A Saraf, K Krishan, S. Misra, The advantages of vrtopsy during the Covid-19 pandemic, *Med. Leg. J.* 88 (1 suppl) (2020) 55–56, <https://doi.org/10.1177/0025817220943035>. NovEpub 2020 Aug 6. PMID: 32758010.
- [24] PM Leth, CH Rasmussen, M. Pagh, [Findings in post-mortem CT and autopsy in a 53-year-old-man with COVID-19], *Ugeskr. Laeger.* 182 (28) (2020). Jul 6V04200289. Danish. PMID: 32734876.
- [25] I Kniep, A Heinemann, C Edler, JP Spherhake, K Püschel, B Ondruschka, AS. Schröder, COVID-19 lungs in post-mortem computed tomography, *Rechts. (Berl.)*. (2021) 1–3. Feb 15doi: 10.1007/s00194-021-00462-z. Epub ahead of print. PMID: 33612977; PMCID: PMC7884063.
- [26] M Ducloyer, B Gaborit, C Toquet, L Castain, A Bal, PP Arrigoni, R Lecomte, R Clement, C. Sagan, Complete post-mortem data in a fatal case of COVID-19: clinical, radiological and pathological correlations, *Int. J. Legal. Med.* 134 (6) (2020) 2209–2214. Novdoi: 10.1007/s00414-020-02390-1. Epub 2020 Aug 6. PMID: 32767018; PMCID: PMC7410356.
- [27] E Helmrich, L Decker, N Adolphi, Y. Makino, Postmortem CT lung findings in decedents with Covid-19: A review of 14 decedents and potential triage implications, *Foren. Imag.* 23 (2020), 200419, <https://doi.org/10.1016/j.fri.2020.200419>.