

Biosafety procedures for handling intraoperative surgical samples during COVID-19 pandemic: an Italian pathology laboratory experience

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Summary

Up to now, Italy is one of the European centers with the most active Coronavirus cases with 233,836 positive cases and 33,601 total deaths as of June 3rd. During this pandemic and dramatic emergency, Italian hospitals had also to face neoplastic pathologies, that still afflict the Italian population, requiring urgent surgical and oncological treatment. In our Cancer Center Hospital, the high volume of surgical procedures have demanded an equally high volume of intraoperative pathological examinations, but also posed an additional major challenge for the safety of the staff involved. The current commentary reports our experience in the past two months (since March 9th) for a total of 1271 frozen exams from 893 suspect COVID-19 patients (31 confirmed).

Key words: COVID-19, frozen samples, biosafety, pathology laboratory

As is known, a novel viral pandemic, driven by the 2019-nCoV, also known as severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), started from the initial epicenter in Wuhan (China) and spread all over the world with dramatic healthcare consequences^{1,2}. On January 31st 2020, the number of positive patients in Europe and mostly in Italy significantly increased. Then the infection rapidly spread in Northern Italy where 11 municipalities were placed under quarantine. On March 9th 2020, given the persistent and steep increase in deaths and positive cases, the Italian Prime Minister, Giuseppe Conte, imposed a lockdown on all of Italy and placed more than 60 million people in quarantine. Up to now, Italy is one of the European centers with the most active Coronavirus cases with 233,836 positive cases and 33,601 total deaths as of June 3rd. The pandemic growth congested Italian hospitals with symptomatic patients and turned most medical and paramedical staff to this dramatic emergency^{3,4}.

At the same time, unfortunately, neoplastic pathologies, requiring urgent surgical and oncological treatment continue to affect Italian population. Our hospital, Policlinico Gemelli (Rome, Italy), represents one of the biggest Italian referral centers for oncological patients, including also a large number of gynecological cancers. The high volume of surgical

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Conflict of interest statement

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procedures demanded an equally high volume of intraoperative pathological examinations (frozen) but posed an additional major challenge for the safety of the staff involved. In agreement with Internal and National guidelines for biosafety in containing the pandemic spread, our pathology laboratory adopted further safety procedures for processing fresh surgical samples from suspect patients who are also affected by severe neoplastic pathologies. The current commentary reports our experience in the past two months (since March 9th) for a total of 1271 frozen exams from 893 suspect COVID-19 patients (31 confirmed with PCR). Patients characteristics and frozen section details are summarized in Table I. It is mandatory to ensure that all the possible biosafety conditions are met for the medical and technical staff involved in this procedure.

According to the recent WHO recommendations, all samples sent to the histopathology laboratory should be considered as potentially infectious ⁵. Moreover, the Centers for Disease Control and Prevention (CDC) released an Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) ⁶.

Adapting the indication from both guidelines, we developed an internal protocol for intraoperative examination of fresh specimens from patients with suspect or proven COVID-19 infection in order to reduce the risk for laboratory personnel.

We defined the following internal protocol for the management of frozen exams.

Table I. General characteristics of patients undergoing frozen section in our Laboratory.

Parameter	N.
Total no. of patients	893
Number of COVID-19 + patients	31
Median age of patients	52
Total no. of intraoperative exams	1271
Total no. of intraoperative exams according to anatomical site	
Central nervous system	25
Head and neck	208
Pulmonary-thoracic district	83
Breast	313
Gastro-enteropancreatic tract	175
Urinary system	17
Female genital system	450
Mean time of diagnosis	29.38 minutes (range 17-49 minutes)

Surgical planning

- Only undeferrable surgical procedures involving COVID-19-positive/suspect patients should be performed.
- Surgical procedures involving COVID patients should be planned and scheduled in order to avoid cross-contamination between patients; if possible, they should be performed in a dedicated operative section.

Specimen transport

- All specimens should be considered as possibly positive for COVID-19.
- The hospital should designate a well-defined path, ensuring dedicated corridors and elevators to COVID patients/specimens.
- Specimen transit from operating room to the COVID-dedicated frozen section room (FSR), must be as short as possible in a pre-defined direct path and away from other people within the hospital in order to minimize the chances of outbreak.
- Specifically trained transport personnel, equipped with personal protective equipment (PPEs), should be the same from origin to destination.
- Utilized lifts must be sanitized.
- A dedicated specifically trained 24/7 cleaning team is suggested.

Frozen section Room and intraoperative examination

- Adequate training of all the involved personnel is mandatory.
- Once the specimen has been admitted to the FSR, the door must be kept closed.
- Frozen room should have controlled inward directional airflow: high FSR air exchange cycles are recommended (> 25 exchanges/h), contributing to effectively reduce the viral load within FSR.
- Personnel involved in the FS processing should not leave the room during the procedure.
- One technician and one pathologist only are allowed in the FSR.
- The frozen-dedicated personnel wear protective equipment such as disposable gloves; solid-front or wrap-around gown; scrub suit, or coverall with sleeves that fully cover the forearms; head covering; shoe covers or dedicated shoes; safety goggles or face shield; EU FFP2 or surgical masks (Tab. II).
- Dedicated freezing microtome for specimens of suspect or proven COVID-19 patients.
- Dedicated certified Class II Biological Safety hood for sample grossing.

Table II. Personal protection equipment.

EU FFP2 facial mask for residents/physician and lab technician
Surgical mask for lab technician, accepting and registering the sample
Disposable long sleeves fully covering the forearms
Waterproof coats, solid-front/wrap-around gowns / scrub suits or coveralls
Head coverings
Disposable double pair of nitrile gloves
Protective eye-goggles or face-shield
Disposable head caps
Disposable long shoe covers or dedicated shoes
Alcoholic hand hygiene solution

- Separate sample storage in a dedicated certified Class II Biological Safety cabinet.
- Dedicated hand-wash sink.

Instructions for PPE removal

All possible sources of infection while removing PPE should be avoided; therefore an adequate procedure must be adopted by the healthcare operators. Please consider the following order of actions:

- At first, remove the first pair of gloves, which is likely to be highly contaminated.
- Subsequently, remove with care all other PPEs during the doffing procedure, according to this order: protective suite, shoe cover, head cap, face mask and glasses, taking care to handle the face mask by the ear laces, without absolutely touching its external side.
- The second pair of gloves must be removed as the very last PPE.
- Finally, proceed immediately with hand disinfection with hydro-alcoholic solution.

Removed PPE must be placed outside the FSR in dedicated areas ensuring the virus is not transmitted to the healthcare worker.

Environmental sanitization

- Disinfection of external and internal cabinet components must be performed daily with 99% ethanol or 0.5% chloro-derivate (Tab. III).

Table III. Surface and medical devices, work instruments, cabinet sanitization.

1. Clean with chloro-derivate solution
2. Rinse and dry
3. Disinfect with 99% ethanol and chloro-derivate solution at 0.5%

- Hood and frozen microtome should be sanitized after every use.
- FSR and surrounding donning/doffing areas must be disinfected as soon as possible after each procedure.
- Well identifiable containers for infectious-risk health waste (IRHW) should be dedicated for single-use potentially infected disposables (sharps and other material). Reusable materials should be decontaminated, washed, dried, and or disinfected/sterilized.

The COVID-19 epidemic has not yet shown signs of receding despite a recent apparent drop in the number of new cases. In fact, starting on May 4th, Italy entered in Phase two, and relaxed the lockdown, similar to other European countries. We retain that our laboratory protocols were useful to control and limit the possibilities of infection in personnel. In fact, to date, no infected workers have been recorded in our unit. Moreover, despite all adopted biosafety procedures, the mean time of intra-operatory diagnosis was 29.38 minutes (range 17-49 minutes). Therefore, if the personnel is well trained, our suggested protocols are able to ensure a good balance between laboratory security and rapid diagnostic times.

In our opinion, also in phase two, we must not lower our and evaluation of intraoperative surgical samples should still be limited to what is strictly necessary. Our protocol together with the current guidelines⁵⁻⁸ may provide further safety for pathology laboratory workers and prevent infection diffusion. Although the pathologist has limited direct contacts with patients, the intraoperative exam of fresh, potentially infected specimens carries high infectious risk and needs to be performed in safe conditions. The resiliency of our universal healthcare system is based on the strength on the safety of all the system components for the best possible patient care in conditions of stress.

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