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J Public Health Res 2021 [Epub ahead of print]

*Citation*

Cernigliaro M, Negroni D, Sassone M, et al. **Observational study on healthcare workers protection in the angiographic suite during the SARS-CoV-2 pandemic: before and during vax era.**

J Public Health Res 2021;xx:2265

doi: 10.4081/jphr.2021.2265

**Observational study on healthcare workers protection in the angiographic suite during the SARS-CoV-2 pandemic: before and during vax era**

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**Key words:** COVID-19, interventional radiology, management protocol, healthcare safety.

**Contributions:** Massimiliano Cernigliaro is the main author of this original article. Davide Negroni and Miriana Sassone collected, organized, and analyzed the data utilized in this article and drew the conclusions from the results of the data analysis. Andrea Paladini, Alessandro Carriero, Luca Saba e Giuseppe Guzzardi supervised the article.

**Conflict of interest:** The authors declare no conflicts of interest.

**Funding:** The authors declare that there was no outside funding for the writing of this paper.

**Data Availability:** All data is available on public databases with no access restrictions.

**Acknowledgements:** This study could not have been done without the support of Carmelo Stanca, Marco Spinetta, Serena Maria Tettoni, Vittoria Melissa e Andrea Galbiati.

**Abstract**

*Background:* Since the first case of Coronavirus Disease 2019 (COVID-19) in Italy, all the hospital facilities had to reform their daily activities. Amidst them, the Interventional Radiology Department in the “Azienda Ospedaliera Universitaria” of Novara (Italy) had to create a dedicated protocol for the patient’s management during the pandemic.

*Design and Methods:* The time interval between February 2020 and March 2021 was divided into three different periods and we reported the evolution of our safety protocol, the changes in our daily activities and the rates of SARS-CoV-2 infection among the healthcare workers (HCW) of the

Angiographic Suite. Personnel who had positive partners/family members or who had established close contacts of another nature outside the workplace were excluded from the study, in order to reduce any bias.

*Results:* A total of 35 HCWs served in 355 patient procedures on SARS-CoV-2 positive patients from February 2020 to March 2021. During the year there was a reduction in the morbidity rate first from 7.9% to 1.4% and then currently reaching 0%.

*Conclusions:* Dedicated routes, elevators, establishing Filter Areas and a clear demarcation between clean and contaminated areas, Dressing and undressing procedures, Cleaning procedures and the obligation to always wear a surgical mask during the working shift are essential to prevent in-hospital infection. The vaccines' arrival seems to further reduce the risk for healthcare workers, but it is still necessary to take docile precautions in view of the new mutations of the virus.

### **Significance for Public Health**

During the last year, about 3.26 million infections for SARS-CoV-2 have occurred in Italy.

Interventional Radiology has been placed in the second line due to its irreplaceable urgency activity (e.g. stroke and arterial bleeding). Currently, we are facing a new wave of infections, which, unlike the previous ones, is part of an active vaccination campaign on the population. Furthermore, the arrival of new SARS-CoV-2 mutant strains such as United Kingdom, South African and Brazilian variants, show different rates of virulence and contagion capacity. Through this study, a management model of the Angiographic Suite (aimed at the protection of personnel and for patient management) is proposed to face the new airborne pandemic. This protocol could be a precious hint for further and institutional regarding public health measures.

### **Introduction**

In December 2019, in Wuhan, Hubei Province, China a cluster of patients with pneumonia of unknown cause were hospitalized (1). The cause was later found out to be SARS-CoV-2, and it soon became an international emergency. The "Ospedale Maggiore della Carità" in Novara started immediately to take precautions.

The main aim was to grant the continuous radiologic diagnostic and interventional assistance for the whole healthcare emergency, assuring the safety for the staff and both infected and un-infected patients (2).

Within the Radiology Department, the Interventional Radiology (IR) staff (radiologists, nurses and radiographers), being in close contact with patients were the most at-risk category (3).

In order to provide continuity to the interventional service in full safety, changes to patient management protocols and organization inside the angiographic suite were necessary.

We had different problems to address: environmental issues, cleaning and disinfection procedures, personnel formation, organization inside the angiographic suite, operating room daily routine with patient selection through rapid/molecular swabs.

Since the beginning of the SARS-CoV-2 pandemic, the main tools to detect the presence of SARS-CoV-2 were molecular swabs, antibodies tests and more recently the rapid antigenic swab tests. The most used test is the molecular swab test, with an overall sensitivity of 94% (95% confidence interval 86 to 98) and an overall specificity of 100% (99 to 100)(4). The rapid Ag swab is the latest tool introduced that played a significant role in surveillance of COVID-19. Rapid Diagnostic Test Ag-RDTs correctly identify more cases than what they miss (sensitivity  $\geq 80\%$ ) and have very high specificity ( $\geq 97-100\%$ ) (5). Antibodies detected in serum are used to investigate the immunity state. A cumulative sensitivity of 82% for IgM, and 85% for both IgG and total antibodies. Pooled specificity was 98% for IgM and 99% for both IgG and total antibodies (6).

In Italy, the vaccination program was introduced on 27<sup>th</sup> December 2020. The first available vaccination was Pfizer-BioNTech COVID-19, that consists of two doses (30  $\mu\text{g}$ , 0.3 mL each) administered intramuscularly, three weeks apart. Polack *et al.*, in a clinical trial, reported that the Pfizer-BioNTech COVID-19 vaccine was 95.0% effective (95% confidence interval = 90.3%–97.6%) in preventing symptomatic laboratory-confirmed COVID-19 in people without evidence of previous SARS-CoV-2 infection (7). Consistent high efficacy ( $\geq 92\%$ ) was observed across age, sex, race, and ethnicity categories and among people with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection (7).

Last data found in literature show that the seroprevalence of SARS-CoV-2 in Italy is closer to 7-8%. (8). By now, in Italy 2.003.391 have been vaccinated, and 572252 doses were given in Piedmont (9).

The aim of this study is to describe the evolution of the protocol, the one currently in use in our interventional radiology department and the infection ratio among our healthcare workers.

## **Design and Methods**

To evaluate the effect of the protocol in use, we described the number of SARS-CoV-2 infection among our employees. The study period from February 2020 to March 2021 was separated in three time-range: from February 2020 to April 2020 (COVID-19 breakout period or period 1), from May 2020 to December 2020 (COVID-19 steady period or period 2) and from January 2021 to March 2021 (COVID-19 Vax period or period 3). Every patient was considered as positive if one of more of these criteria were present at the moment of the angiographic procedure:

- Suggestive clinical symptoms (high temperature over 37.5°C, cough more than 3-day, dyspnea) (10).
- COVID-19 related - CT findings classified as “indeterminate appearance” or “typical appearance”, according to RSNA consensus statement (11).
- Positive molecular swab (from the second half of March 2020) and/or positive rapid swabs (from July 2020) (12).

The HCWs are considered positive if the monthly screening swab or the swabs for flu-like symptoms found positivity vs COVID-19 antigens.

Personnel who had positive partners / family members (two HCWs) or who had established close contacts of another nature outside the workplace (one HCW) were excluded from the study, in order to reduce biases.

## **Protocol evolution**

### *Environmental issues*

In order to protect both patients and the involved personnel, it was necessary re-organize all the working environment. According to literature, exposure sources to SARS-CoV-2 are various. The main two are through droplets and through direct or indirect contact(13).

Moreover, the virus can spread through aerosol in certain conditions, for example during intubation and in all the maneuvers involving the upper airways (14,15).

Our angiographic suite is located in a different block than the emergency room and all the other departments who were being set up to host the COVID-19 positive patients.

We only have two angiographic suites but none of them had a filter area between “clean” and “contaminated” areas. Each operating unit had to be arranged in progressively less contaminated areas, from the reception area to the operating theatres. Following this principle, in order to treat this type of patients we had to set up and build a separate room before entering the angiographic suite, to be used mainly for undressing and keeping the used Personal Protective Equipment (PPE) that has to be thrown away or disinfected for reuse.

Trolleys, and all the non-essential equipment have been moved in the “clean” area. Ventilators, pedalboard, mattress, C-arm have all been protected and covered with disposable plastic hoods. At the end of each procedure all these are disposed by a dedicated cleaning crew.

HEPA filters were mounted to have a better air filtration rate and to reduce the spreading as much as possible (16,17).

### *Personnel training*

The protocol in use was taught to all HCWs. Each time a patient is treated we establish who is the “clean” and the “contaminated” healthcare personnel, which has to stay under a 1.5m distance from patients. The latter, after entering the “SARS-CoV-2” area, cannot go out without a dedicated undressing procedure.

Routinely, the medical staff wears surgical masks at all times during their working shift (3). The dressing procedure is started before patient’s arrival in order to be able to attend to his needs as soon as he arrives.

We used the hospital’s protocol for dressing and undressing procedures, but we had to add a few modifications in order to fit the lead aprons (Fig. 1 & Fig.2).

<b>Dressing procedure</b>
Wear in Order: Make sure not to wear jewellery and tie hair <ul style="list-style-type: none"><li>• Wear Lead apron</li></ul> Perform hand hygiene <ul style="list-style-type: none"><li>• Put on FFP2 mask, make sure it is correctly fit.</li></ul>

- Cap
- Googles
- Long OverBoots

Second Hand Hygiene

- Sterile Coat
- Long sleeved Gloves
- Short Gloves

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For Surgeons only after the patients has entered.

- Sterile Coat and sterile Gloves

### **Undressing procedure**

It needs someone (wearing PPE) helping from outside with a pack of short gloves and sodium hypochlorite spray for hand hygiene.

Remove in Order, without making sudden moves and throwing everything inside the bin cautiously to avoid spreading of droplets.

For Surgeons – Sterile Coat and Gloves

- Short Gloves and Sterile Coat simultaneously

Hand Hygiene

- - *Wear clean disposable Short Gloves*
- Remove Goggles and place them in the appropriate container for cleaning. Spray them with sodium hypochlorite.
- Remove cap
- Remove over boots- when doing so, exit one step at a time out of the “Dirty” Area.
- Short Gloves

Hand Hygiene

- - *Wear disposable Short Gloves*
- Remove FFP2 mask

The mask in use are the FFP2, which have a high filter capacity (closer to 94%) (3)

While the dressing procedures can be performed by a single person, a dedicated colleague checks that the procedure is followed correctly, in order to prevent mistakes.

Dressing and undressing procedures were taught in a short training session in classes of four people lasting about 30 minutes.

Surgical masks always must be worn during working shifts. Healthcare providers with flu-like symptoms should refrain from coming to the workplace as not to infect healthy patients.

#### *Cleaning and disinfection procedure*

All equipment used for interventional radiology maneuvers inside the operating room is covered with plastic sheets and dedicated disinfection must be done after every patient.

All the corridors leading to the operating rooms need their access to be restricted and then disinfected after the passage of the patient in order to reduce droplet spread.

Our standard cleaning procedure involves the use of sodium hypochlorite and a quaternary ammonium compound for the angiographic suite and the staff (18).

Once the sanitization is over, radiographers take care of cleaning the C-Arm and electronic instrumentation as well as the HEPA filters when needed (using the appropriate PPEs).

All the protective face masks are a single use device, and they don't need a specific cleaning procedure. Goggles and any other PPE reusable are cleaned twice by their own users and placed in a tank with sodium hypochlorite.

Until everything is done the operating room remains closed (est. duration 30 min).

#### *Organization inside the Angiographic Suite*

During airway management of patients who require emergent intubation there is a high risk of aerosol and droplets dissemination (14–16). Measures to protect the resuscitation equipment and mechanical ventilators are necessary. All non-essential catheterization tools, guidewires, needles, devices are removed from the angiographic suite, or covered with plastic sheets (Fig.3). Everything must be ready before the patient is brought to the Interventional room. Only essential personnel should be involved in the procedures at closed doors. If any device is needed from outside, a dedicated person, who is wearing PPE passes it through the filter area between the “clean” area and the angiographic suite.



### *Angiographic Suite daily routine*

We regularly had to change patient selection criteria in order to abide by the Government rules regarding RT rates of infection in Piedmont. We went from treating only emergencies and oncologic patients during February-June, to returning to our normal routine until the second wave in October, when fewer procedures were allowed again. Measures in use keep changing as R number values vary over time. During the COVID-19 steady period, except for emergencies all patients were required to have a molecular negative swab test in order to access to treatments.

All HCW must undergo monthly screening with molecular antigenic testing and are isolated at any sign of flu-like symptoms and tested if come in contact with anyone infected.

At the beginning of the pandemic not every patient underwent a throat swab for SARS-CoV-2, as they were not readily available, and sometimes we got to know about their infection accidentally from chest CT-scan. From July we have been doing regular molecular testing on Hospital arrival and rapid antigenic test in order to admit patients to the angiographic suite. In emergencies if patients are positive to the antigenic test, but the molecular test results are not yet available, we treat patients as if they were positive, as we have initially found out discrepancies between the tests in our earlier experience, and to maximize HCW protection. The implementation of all safety protocol throughout the Hospital, all personnel formation took from the end of February 2020 until April 2020. From May 2020 till December 2020 on we continued with this protocol.

At the beginning of the COVID-19 vax period, we witnessed an increase in the Italian territory of viral mutants, including United Kingdom and South Africa. Currently the protocol has abolished the use of rapid tests and patients are considered negative only in the presence of a molecular test result.

### *Vax schedule*

From the 20<sup>th</sup> of December 2020, the Pfizer-BioNTech vaccine program started for all the personnel, achieving immunity with the double dose of vaccine at the second week of January 2021. No serologic test has been performed to evaluate the acquired immunity. The HCW that had COVID-19 in the past months has been vaccinated too, in according with the Ministry of Health recommendations (9). Although the vax covered the 100% of our HCW, the angiographic suite protocol has not changed.

## Results

A total of 355 SARS-CoV-2 positive patients were treated from February 2020 to March of 2021 (period 1-2-3). Mostly emergencies - 88 (25.1%) strokes procedures, 134 (38.3%) embolizations for arterial bleeding, 104 (29.7%) Acute Limb Ischemias, 24 (6.9%), different planned procedures such as Acute ruptured Cerebral Aneurismal Embolizations, superior mesenteric artery acute ischemias, biliary drainage positioning, suppurative collection drainages, cholecystostomies as shown in [Table 1](#). Thirty-five out of thirty-eight HCWs satisfied the inclusion criteria.

From February 2020 to April 2020, 63 procedures (the 18% of 355) were performed in the angiographic suite. In this period, five of the 35 HCWs, resulted positive to SARS-CoV-2 (morbidity tax of 14,3%). From May 2020 to December 2020, we implemented our Safety Protocol. In this period, on a total of 216 procedures (61,7%), only three HCWs resulted positive (morbidity rate of 8.6%). Since the vaccine in January, no HCWs resulted positive (morbidity rate of 0%). The ratio between HCWs infected and procedures number is about 7.9% (5 infected on 63 procedures) for the period 1 (COVID-19 breakout period), about 1.4% (3/216) for the period 2(COVID-19 steady period) and about 0% (0/71) for the period 3 (COVID-19 Vax period).

	Period 1 February-April 2020	Implementation of Safety Procedures	Period 2 May-December 2020	Vaccine	Period 3 January-March 2021
Stroke	27		50		11
Bleeding	17		91		26
Acute ischemic limb	17		60		27
Other	2		15		7
Total	63		216		71
<b>Infected HCW</b>	<b>5/35</b>		<b>3/35</b>		<b>0/35</b>

*Table 1: Number of procedures on COVID-19 positive patients and HCWs Infected before the implementation of safety procedures and after the vaccine.*

## Discussion

Despite the regulations that the Italian and European governments have implemented to contain the COVID-19 pandemic, we are witnessing a new increase in positive cases as for the beginning of a new wave of infections (19,20). In the last year, we have seen the development of different technologies such as rapid antigen swabs and, more recently, the worldwide launch of several highly effective vaccines (7,21–23).

The aim of the study is to describe the evolution of the management protocol of the angiographic suite and the number of infected among the healthcare workers in the three periods that characterized the pandemic caused by the Sar-Cov-2 virus: COVID-19 breakout period (period 1, February 2020 to April 2020), COVID-19 steady period (period 2, May 2020 to December 2020) and COVID-19 Vax period (period 3, January 2021 to March 2021).

Of these time intervals, the COVID-19 steady period (period 2) is the largest and with approximately three times the number of procedures performed on COVID-19 positive patients.

Despite the high number of interventions carried out on infected patients, the infection rate among the HCW was lower than in the period 1, the COVID-19 breakout period (1.4% vs 7.9%). The modification of the angiographic suite management protocol, which took place after the introduction of molecular swabs, allowed for a better classification of patients with consequent better management of cases. The latest update of the COVID-19 patient management protocol in angiographic suite improved the vaccination's awareness. Among our personnel, the vaccine adherence rate was 100%. Although the number of procedures on COVID-19 positive patients, between the period 1 and the period 3 (the current one), did not substantially change (63 vs 71 procedures, respectively), no operator has been infected since January.

Compared to the main protocols reported in the literature (17,24–27) regarding patient management in the angiographic suite, no substantial differences in patient management are reported. However, to our knowledge, no proposals for updated protocols have been found for vaccinated personnel and for COVID-19 mutant variants.

In Literature, there isn't enough evidence on the effectiveness of vaccination using Pfizer BioNTech (administered at 100% of the HCWs) in the COVID-19 variants. Particularly, Xuping et al. reported a similar efficacy of BNT162b2 vaccine (Pfizer) in United Kingdom and South African variants. However, the article concludes with the necessity to confirm the vaccine effectiveness against variant viruses with further clinical data (28). Moreover, Madhi et al. reports the Oxford/Astrazeneca efficacy of

10.4% against the South African variant B.1.351 (29) . For this reason, our center has chosen to keep a strict protocol, without reducing the protection standards for patients who result or wait for molecular swab's results.

Further studies are required to increase the degree of evidence about the safety of this protocol.

Multicenter studies are recommended, both retrospective and prospective, combined using a common protocol.

Particular attention should be paid to controlling any biases as the possibility of an outer source of out-of-hospital infection and/or the possibility of new viral mutants.

## **Conclusions**

Interventional Radiology (IR) is an essential service for the population, delivering minimally invasive care for patients both in emergency and elective procedures. Even during the SARS-CoV-2 pandemic these procedures should not be delayed.

Safety protocols are a mandatory means to protect HealthCare Workers. The presence of dedicated routes for infected patients, PPEs, cleaning protocols are as important as personnel training to avoid any risk of infection and guarantee continuity of care.

The arrival of the vaccine seems to further reduce the risk for healthcare workers.

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Fig.1. Interventional radiologist equipped with personal protective equipment



Fig. 2. Focus on face masks that we usually use during our angiographic procedures on COVID-19 positive patients.





Fig.3 Angiographic room prepared with plastic covers on monitors, ventilator, X-Ray detector and lead protection