International Journal of Community Medicine and Public Health
John PH et al. Int J Community Med Public Health. 2020 Dec;7(12):4927-4933
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20205164

Original Research Article

COVID-19: Ultraviolet-C device for protecting operation theatre personnel: a pilot controlled study

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Received: 28 August 2020
Revised: 17 October 2020
Accepted: 28 October 2020

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ABSTRACT

Background: Covid-19 is currently wide-spread in urban and rural India. Health care workers (HCW) contract disease when exposed to inoculum in enclosed spaces namely operation theatre (OR) or Intensive care unit (ICU). 1.8-5 % of health care workers (HCW) tested positive in Delhi and Dutch experience is similar. 8% of HCW who contract COVID-19 die. Commercial filters have been advocated by various surgical societies and despite routine use of these filters, HCWs continue to get infected. Ultraviolet C (UVC) irradiation has been in use for bacterial and viral decontamination of surfaces, liquid and gaseous media.
Methods: In this study, we describe a closed UVC chamber with built-in HEPA filters to decontaminate and sterilize effluent gases from patients undergoing laparoscopic or open surgical procedures to make it free of SARS-COV-2 virus and minimize risk of infection for the OR crew. We also report an adaptation of this device for anesthesia. We compare SARS-CoV-2 infections in HCW in our hospital, where this device is routinely used, with outcomes from another hospital with identical personal protection measures, performing similar surgical procedures but without the device.
Results: COVID-19 incidence is significantly reduced with the use of this device compared to a similar hospital with similar surgical protocols but without the device
Conclusions: In the current pandemic situation where a number of HCWs get infected or succumb to SARS CoV2 infection, measures such as UVC chamber described in this paper provide additional protection to HCWs in the OR. They are of considerable public health importance and serve to boost the sagging morale of HCWs.

Keywords: COVID-19 prevention, HEPA filters, Health care workers, Minimal access surgery, SARS-CoV-2 decontamination, Ultraviolet C radiation

INTRODUCTION

COVID-19 is now a global pandemic. India with a population of 1.38 billion has nearly 55-65,000 new cases and 800 to 1000 deaths every day.[1] Sero-prevalence study in the National capital shows nearly 23 % have positive IgG antibodies indicating that there are a large number of asymptomatic individuals who are infected with the virus and recover spontaneously.[2] In contrast to Wuhan, China and Netherlands where the incidence of COVID-19

among HCW was <1%, 1-5.8% of HCW in Delhi had the infection.[3-5] While state government reports on the incidence among HCW are awaited, the Indian Medical Association (IMA) reports 1279 cases of COVID-19 and 99 deaths among doctors.[6] The large proportion (nearly 40%) of infected but asymptomatic individuals can spread the disease to HCW particularly when they are admitted for or operated upon for non-COVID illness. In OR, procedures like endotracheal intubation, use of high speed drills in orthopedic or neurosurgery theatres and release of pneumo-peritoneum during laparoscopic surgery are aerosol generating and pose a special risk to HCW.

Reverse transcriptase polymerase chain reaction (RT-PCR) test used to diagnose COVID-19, was used exclusively for case detection and contact tracing in the first 3 months of the epidemic in India.[7,8] During this time period, essential surgical procedures were conducted with only thermal screening and history suggestive of the clinical syndrome as screening tools without preoperative RT-PCR testing for the virus.[9] Subsequently, with wider availability of RT-PCR testing in private laboratories, routine pre-operative screening for the virus is practiced widely in the country to minimize risk to surgeons, anesthetists and all other OR personnel.

The Indian Council of medical research (ICMR) recommends prophylactic hydroxychloroquine for HCW.[3] However the RT-PCR test has a false negative rate of about 30%, which means that 30% of infected individuals will not be picked up by the screening test.[10] Therefore, additional protective measures are mandatory for HCW in OR and ICU. While personal protective equipment (N95 masks or respirator masks) and strict protocols for surgical smoke evacuation are the corner-stones of preventing spread of this viral infection to HCW, continuing occurrence of SARS-CoV-2 infections in HCW despite these precautions, indicates the need for innovations to further minimize risks to HCW. Objective of the study was to demonstrate the efficacy of UVC to decrease the incidence of covid19 in HCW and to compare with a similar hospital without UVC chamber.

In this prospective controlled pilot study we used a metallic chamber fitted with UVC source, HEPA filters in the smoke/aerosol evacuation system for a period of three months.SARS-CoV-2 infection rates in our hospital are compared to those from a similar hospital in the same state, with similar lock-down situation imposed by the state government.

Comparable protective steps in theater such as PPE, respiratory mask with HEPA filters, smoke evacuation systems for laparoscopic surgery were in place in both hospitals. The ventilation systems in the OR in the two hospitals were also similar. The only difference was deployment of UVC decontamination chamber for decontamination of surgical smoke and aerosols in the OR in the study hospital.

METHODS

This was a prospective observational control study. Two similar non-COVID hospitals where no COVID cases were admitted were chosen in Tamilnadu, South India, subject to the same standard government regulations. Pre-operative RT-PCR testing for SARS-CoV-2, choice of cases, standardized protocols for entry and exit of OR Personnel, use of personal protective equipment were very similar in the two hospitals. Duration of the study was for 3 months from April 2020 to June 2020. During the early part of study when RT-PCR testing was unavailable for preoperative screening, thermal screening and signs and symptoms of COVID-19 clinical syndrome were used and suspected cases referred to COVID-19 care centres from both the hospitals.[14]

Inclusion criteria

In both hospitals, details of the number of surgeons, surgical nurses, anaesthetist and technicians who entered OR, and the duration in the OR were recorded. The protocol for OR entry was as follows. Anesthetist with technician entered theatre first and exited last. Surgical nurses entered next, followed by surgeons.

Exclusion criteria

Age, co-morbid situations were not applied. Ethical approval was not required as the study did not involve patients.

Procedure

Preoperative RT-PCR testing was done in all 19 patients in control hospital and in 16 out of 35 patients in study hospital.

Both hospitals adopted similar practices in theaters, limiting the number of staff in theater to the minimum, proper donning and doffing of PPE, usage of N95 respirator masks and smoke evacuation systems with HEPA filter for laparoscopic surgery. In study hospital, smoke evacuator system was through the additional UVC chamber, HEPA filters. Surgical team followed other identical preventive steps and protocols.

Description of the UVC chamber with HEPA filters

The cylinder for UVC chamber device was fabricated by Atatri Industries Pvt Ltd, Coimbatore. HEPA filters were obtained from Hengst Luman India Private limited.

The UVC chamber (Figure 1) with inlet and outlet vents (*Technical details and mathematical model are presented in the addendum) has all its components contained within an opaque metallic UVC proof cylinder (which prevents exposure of OR personnel to UVC). The cylinder contains within it a UVC source, a low pressure mercury vapour discharge lamp with tubular glass envelope which

emits short wave ultraviolet radiation with peak at 253.7 nm (UVC) for germicidal action.[11,12] UVC acts on microorganisms like bacteria and viruses by disrupting the nucleic acid in the cell thus eliminating their infective potential.[12,13] UVC has been proven to destroy viruses including SARS-CoV-1.[11-13] Two HEPA filters, also contained within the chamber, distal to the UVC source, filter the particulate matter.

Figure 1: UVC chamber with HEPA filters.

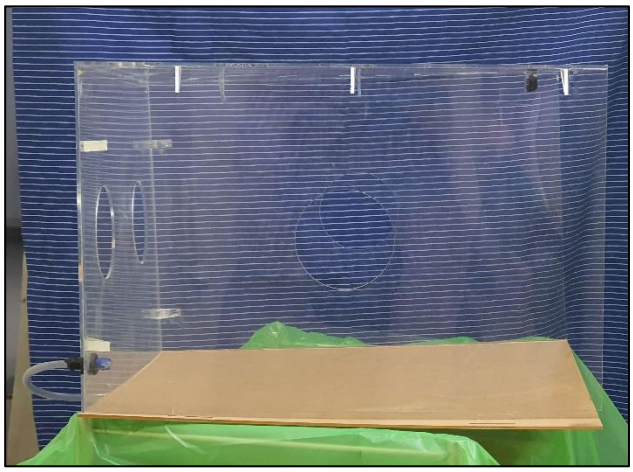

Figure 2: Acrylic hood for anesthesia.

The inlet vent is connected through a sterile air tight tube to the patient's end; acrylic hood in anesthesia, laparoscopic trocar in minimal access surgery (MAS) or to the diathermy pencil in open surgery. The inlet leads to the UVC chamber. The gas effluent or aerosol from patient that enters the chamber passes through the UVC chamber and the two HEPA beyond.

The UVC generator, housed inside the cylinder, passes UVC rays over the gas mixture inside the closed chamber. Outlet vent from the chamber is connected to theater central suction system. The time required for UVC irradiation to render the virus inactive inside the chamber has been calculated to be 0.663 seconds (formula described in Addendum).

In the study hospital, UVC chamber with HEPA filters was used in the following situations to treat the effluents gases from the patient, namely anesthesia, laparoscopic surgery and open surgery.

Figure 3: Use of UVC chamber in MAS.

Method of use of UVC chamber with HEPA filters in anesthesia

The modification of the device for anesthesia (Figure 2) consists of an acrylic hood at head end, with holes to access airway and for suction catheter.The hood is fitted over the patient's head, to minimize escape of the aerosol into the OR environment. The hood is partly in place at the time of intubation and after intubation fully in place. It is removed at the time of extubation of the patient. Throughout the operative procedure, the hood is maintained in place at the head end both in general and spinal/ regional anesthesia. The hood is connected to wall suction so as to generate negative pressure inside the hood. The patient is intubated by the anesthetist in full respiratory protective gear including N95 mask, goggles and head cover. The potentially contaminated exhaled air gas mixture is sucked into UVC chamber and the UVC treated effluent gas mixture is drained swiftly through central suction.

Use of UVC chamber with HEPA filters in Minimal Access Surgery (MAS)

The outer end of the laparoscopic trocar is connected by a sterile tube to the inlet of the UVC chamber via a valve so as to let the effluent gases from peritoneal cavity to be sucked into UVC chamber. The outlet vent from UVC chamber is connected to the central suction. Smoke generated during MAS enters the chamber where it is exposed to UVC irradiation, filtered by HEPA filters and exits into the central suction. The very short exposure time required for inactivating 99.9% of SARS-CoV virus (0.663 seconds) ensures rapid sterilization of the smoke generated during MAS. Use of the device during laparoscopic surgery is shown in Figure 3.

Use of UVC chamber with HEPA filters in open surgery

In open surgery, the diathermy tip is mainly used for cutting or for coagulation using appropriate current. A standard sterile suction tube is perforated 1 cm before its distal end to admit diathermy electrode tip. The tip of electrode is introduced through this opening and pushed through such that it projects by one centimeter outside the tip of the suction tube. The diathermy pencil is secured in place with two ties. The other end of the sterile suction tube is attached to the inlet vent of the UVC chamber. The outlet is connected to wall central suction. This enables the smoke created during the use of diathermy (for cutting, dissection or coagulation) to be carried through the UVC chamber HEPA filters before it is sucked into the central suction. Commercial diathermy pencils with suction tips, available in the market were not used in this study.

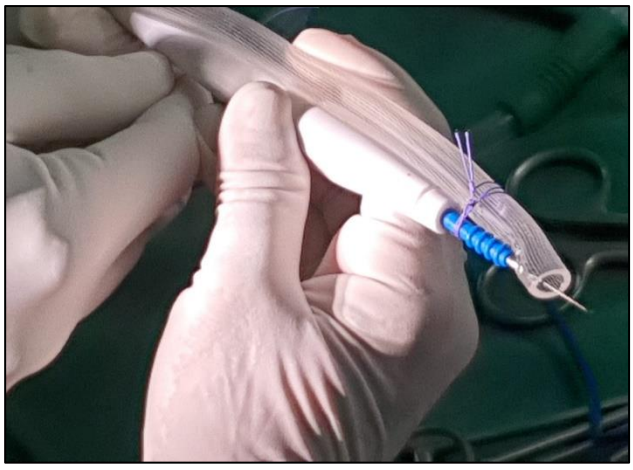

Figure 4: Method to attach suction to cautery tip at open surgery.

Statistical methods

Categorical variables were compared using two tailed Students''t' test. Proportions were compared with Chi^2 test. Results were considered to be significant if $p<0.05$.

RESULTS

The personnel in the study hospital consisted of 5 surgeons (2 of them age>60 years, 4 nurses, 3 technicians and 6 anesthetists (one of them age >60 years). The personnel in the control hospital consisted of 3 surgeons (2 age>60 years, 1 had diabetes mellitus and hypertension), 5 nurses, 6 technicians and 4 anesthetists. All the pre-operative RT-PCR tests done on patients for COVID-19 were negative in both the hospitals. The age, female:male ratio and the type of surgery (open or laparoscopic) are shown in Table 1. (The details of the surgical procedures in the study hospital and control hospital are provided in the addendum). The study hospital had a greater number of procedures overall and a significantly greater proportion of laparoscopic procedures ($p=0.02$) compared to the control hospital (Table 1).

Table 1: Female:male ratio, age range and type of surgery for patients in study and control hospitals.

Factors	Study hospital	Control hospital
Females: Males (Total)	18:17 (35)	11: 8 (19)
Age (Mean, Range)	49 (20-83)	54 (26-85)
Open surgery	17	16
Laparoscopic surgery	18	3*

*Chi 2 with Yate's correction: *(1, N =54) X2: 5.17, p=0.02

There was significantly greater number of laparoscopic surgical procedures in the study hospital compared to the control hospital $p<0.005$

Table 2 compares the number of exposures to the OR of different categories of OR personnel and cumulative duration of exposure to OR in the two hospitals. The incidence of COVID 19 in the control hospital and study hospital are compared.

As shown in Table 2, the number of OR exposure of personnel of different categories such as doctors, nurses, technicians and anesthetists were significantly greater in the study hospital than in the control hospital ($p<0.05$). The cumulative duration of exposure of different categories of OR personnel to the OR environment while the patient was inside the theatre was significantly greater in the study hospital than in the control hospital ($p<0.001$). In spite of the greater number of episodes of personnel exposure to OR and the significantly greater duration of exposure to the OR, the incidence of COVID-19 in the study hospital was significantly lower than in the control hospital ($p<0.05$). The only difference in protocol between the study hospital and the control hospital was the consistent and regular use of UVC chamber with filters for treatment of effluent gases and aerosols during anesthetic and operative procedures.

Table 2: Comparison of Covid-19 occurrence in personnel and operation duration between control and study hospitals.

	Control Hospital@			Study Hospital@		
	Number of OR exposure of Personnel	**Hours exposed to OR**	**COVID-19 infections***	**Number of OR exposures of Personnel****	**Hours exposed to OR*****	**COVID-19 infections**
Surgeons Open/lap (total)	39/9(48)	26.35	2	33/41(74)	42:25	0
Nurses Open/lap (total)	34/6 (40)	29.1	2	29/35(64)	46:00	0
Technicians Open/lap (total)	14/3 (17)	32.05	0	24/39(63)	52:10:00	0
Anesthetists Open/lap (total)	16/3 (19)	32.05	1	17/18(35)	52:10	0
Total	124	119.55	5*	236	192.45	0

*Chi-square 8.22, p-value 0.042. The result is significant at p <0.05** t-value 2.46208, p=0 .048981. The result is significant at p<0.05.*** t-value 6.54244, p=0 .00061. The result is significant at p < .001; @: Control hospital had 2 surgeons age > 60 and 1 had diabetes and hypertension; @: Study hospital had 2 surgeons and an anesthetist age>60 but n other comorbidity.

DISCUSSION

The large number of daily new cases reported from every country and the wide-spread occurrence of asymptomatic infections as evidenced by sero prevalence studies portend a very high risk for all HCW, in particular those working in ICUs and OR all over the world.[1,2] Covid-19 is currently wide-spread in urban and rural India.[7,8] Around 1-5.8% of all HCW get COVID-19 infection and those in high risk areas have a greater proportion of infections.[3,4] Eight percent of HCW who contract COVID-19 die of the disease.[5,6] The OR, a closed space where the viral load is likely to be very high poses a particular threat to the health and welfare of surgeons, anesthetists, nurses and technicians. Based on guide-lines drawn up by different surgical societies protocols have been standardized in operation theaters to minimize exposure risk to HCW.[14,15] These include pre- operative testing with RT-PCR, negative pressure theaters, minimizing the number of personnel inside theater during surgery, avoiding change of personnel during a procedure, and restricting the presence of anesthetic crew (excluding the anesthetist) to intubation and extubation time. However use of UV radiation for sterilizing the micro-environment in the OR is not widely practiced though char-coal filters to minimize the emission of particulate matter and the smell of burning tissue is in use for laparoscopic surgery.[11-13] Other important personal protective measures include N95 masks, respirator masks, PPEs, facial visors, double gloves and hand hygiene.[16] In view of the false negative rates of about 30% for RT-PCR testing for the virus, these precautions are mandatory for every surgical patient and for every procedure under any type of anesthesia (regional or general).[10] As the COVID 19 pandemic is not likely to end in the near future these protocols are mandatory perhaps for the next several months. Despite these measures, COVID-19 infections do occur in members of the operating team. Therefore there is an urgent need for innovations to make the OR safe for personnel.

Covid-19, caused by SARS-CoV-2 virus which is positive sense single stranded RNA is a very small virus (diameter 50 - 200 nM).[17] The envelope is made of a lipid bilayer with embedded proteins. The virus uses extended spike proteins to attach to and to get into the cells through a specific receptor ACE 2 present in respiratory epithelium.[18] The spikes made up of glycoproteins give the appearance of a crown and hence the name corona.

UVC rays work by disrupting the spike proteins and the RNA inside the virus thereby inactivating the virus and its ability to attach to cells.[11,12] The potential harm from UVC to OR personnel was eliminated in this study by housing the UVC source in a metallic chamber.

The best way to decide whether this chamber is effective in eradicating live virus would be to culture the gaseous effluent from patients (anesthetic aerosol, and smoke emanating from laparoscopic or open surgery) before and after passage through the device. Unfortunately this verification can only be done in level 3 bio-safety laboratory which is available only in select institutes in the country. The commonly available RT-PCR test for COVID-19, which tests for only viral RNA, is unsuitable for this purpose, because it will be positive even if the virus is dead.

The UVC radiation and the 2 HEPA filters in the UVC chamber that we deployed are mutually complimentary, the filters serve to contain the virus inside the chamber and the UVC radiation inactivates the virus. The HEPA filter which filters 99.7% of particles size >0.3 µm, and the ULFA filter which filters 99% of particles >0.1µm are inadequate for containing the SARS-CoV-2 virus with a size ranging from 0.05 to 0.2 µm particularly because in an aerosol the virus exhibits Brownian motion20and may wriggle through these filters.[19] Further when one attempts to evacuate the aerosols and smoke mixtures using a suction device, the negative pressure in the suction

system can hasten movement of the viral particles through these filters making them ineffective. Even though multiple national and international associations advise the use of HEPA and ULPA filters their efficacy in containing the spread of the virus within the OR environment is questionable.[21]

Surgical smoke contains particulate matter, the size of particles varying with electro-dissection (0.7 µm), laser coagulation (larger) or ultrasound dissection (0.35-6.5 µm).[19,22] Activated charcoal filters absorb gas and vapour and they minimize the smell from burnt tissue but are no good for containing the virus.[23]

Studies in the pre-COVID-19 period have confirmed the presence of Hepatitis B, Human Papilloma virus.[24,25] HIV virus in surgical smoke. Doremalen et al demonstrated the viability of SARS-CoV-2 in aerosols for hours and on surfaces for hours to days.[26,27] However presence of SARS-CoV-2 in surgical smoke, though plausible has not been experimentally verified.[28]

There is controversy in literature as to whether open or laparoscopic surgery is better in the context of the COVID-19 pandemic. The occurrence of COVID-19 infection in the control hospital in spite of following identical protocols suggests that the currently used protocols may be inadequate to completely protect the surgical team. With the deployment of the UVC chamber In the OR in our hospital we have been successful in not having even one infection even though our OR personnel were exposed to the OR more often and for significantly longer duration.

The device we have used in this study may be of use in other high risk situations like the ICU and Emergency Room but this needs to be prospectively studied.

Limitations

Pre-operative RT-PCR was possible in only 16 out of 35 cases in the study hospital (due to non-availability in the first month of the epidemic due to strict Government restrictions on RT-PCR testing) but in all 19 cases in the control hospital. It is possible that some of those who got infected acquired the infection outside the hospital setting. If this is true it is likely to occur equally in both study and control hospitals but this was not the case. We have not done viral cultures for SARS-CoV-2 on samples before and after they passed through the UVC chamber as the facility is not available to us. This is something that can be done by bigger institutes like the National Institute of Virology Pune.

CONCLUSION

In conclusion we presented limited evidence in a pilot study that use of UVC chamber in the OR reduces risk of SARS-Co-V2 infection in OR personnel over and above the protection afforded by proper use of PPE. Our observations need to be confirmed in a larger study. Viral cultures of aerosols and surgical smoke before and after passage through the UVC Chamber, if undertaken by level 3 Bio safety viral research laboratory will confirm the efficacy of this device in eliminating SARS-CoV-2 from the OR environment..

ACKNOWLEDGEMENTS

Author would like to thank Ragavkrishna Ranganathan, ATATRI, Coimbatore for technical input, and to Dr. J. E. Diwakar PhD (Chief Research Scientist Retd), Indian Institute of Science, Bengaluru for guiding them.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: John PH, Thanakumar JAC, Rao AM, Kapali NT, Seshadri MS. COVID-19: Ultraviolet-C device for protecting operation theatre personnel: a pilot-controlled study. Int J Community Med Public Health 2020;7:4927-33.