Use of a Safe Nasal/Oral Sampling Aid in the COVID-19 Pandemic Era

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ABSTRACT

Background: Coronavirus disease-2019 (COVID-19) was first detected in Wuhan, China, after which it quickly spread throughout the world despite several precautions. It has been noted that the healthcare workforce is most susceptible to it. Maximum exposure to them was observed at the time of collection of the mucous sample. Similar activities such as nasal/oral endoscopy or biopsies also put the healthcare workers in harm's way.

Aims and objectives: A simple device was developed which would allow nasal or oral mucous sampling to be done without the patient having to take off the face mask. This would then be tested in field settings to ensure acceptability, efficacy, and safety to healthcare workers.

Materials and methods: A prototype device consisting of four parts was designed. The device can clip onto the surgical mask using the disks. Once the trocar has punctured the mask, the valve can be opened to allow a swab-stick or endoscope of up to 5 mm to be passed through it. This valve creates a tight seal when released and decreases aerosol spread in the instance that the patient coughs or sneezes.

Results: One hundred and fifty patients who reported for COVID testing at our hospital and 89 patients who reported for nasal or oral endoscopy were sampled or examined using this device. Minor difficulties of the loose fit of the device on the mask, tight valve, and inability to find nasal opening were noted.

Discussion: Our team was able to successfully develop an affordable and effective device—nasal/oral sampling aid (NOSA). Our preliminary trials found it to be dramatically effective for patient and doctor safety. It reduced instances of aerosol dispersion and gave security to the entire sampling process.

Keywords: Communicable diseases, Coronavirus disease-2019, Medical device, Sampling.

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BACKGROUND

In early December 2019, the first coronavirus disease-2019 (COVID-19) pneumonia cases were identified in Wuhan, China,¹ and thereafter this virus spread throughout the world. Several safeguards were purported by experts, such as wearing masks by all, social distancing, and washing hands.² Despite this, 83,910,386 confirmed cases of COVID-19, including 1,839,660 deaths have been documented to date.³ The people most easily infected are those working near COVID-19 patients; such as doctors, nurses, and paramedics.⁴ It has been observed at our hospital, that, from the time a suspected patient walked inside, to the time he walked out, the staff was most vulnerable at the time of collecting the sample. It is at that time when the risk of exposure to a heavy viral load is the most. Contributing factors were—removal of face mask during sampling, coughing or sneezing while sampling, and carrying of an infected sample through the atmosphere from the time of its collection till the time it was sealed inside the viral transport media (VTM) vial. Similar problems were faced during endoscopy or biopsies in suspected patients.

AIMS AND OBJECTIVES

Since, with the ongoing pandemic, any patient with flu-like illness is to be considered a suspect till proven otherwise, it is but natural for countries to test their entire populations even.⁵ Hence, a simple device was developed which would allow nasal or oral mucous sampling to be done without the patient having to take off the face mask. This was designed to save the healthcare workers from exposure to high viral load during the procedure as well as

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to protect other patients or staff in the vicinity. In the outdoor or community setting, this would be useful in crowded halls and classrooms where mass sampling is being done. In countries with high population density such as India, this would be huge assistance in preventing outbreaks and super-spreader events.

MATERIALS AND METHODS

Design

Taking help from a team of mechanical engineers and professional 3D designers (Pjumble, Ahmedabad, India) a prototype device was developed. It consists of two plastic discs, a trocar, and a valve

Figs 1A to F: (A) Inner disk (outside view); (B) Inner disk (inside view); (C) Outer disk; (D) Valve (outer view); (E) Valve (inner view); (F) Trocar

Fig. 2: Pressure on the sides of the valve opens it

(Fig. 1). The device has been developed so that it can clip onto the surgical mask using the disks. The valve is then seated into the hollow outer portion of the device and the cloth of the mask is punctured using the trocar. The valve can be opened by applying pressure to its sides thus allowing a swab-stick or endoscope of up to 5 mm to be passed through it (Fig. 2). After an adequate length of the swab-stick or endoscope has been passed through the device, the valve may be allowed to close (Fig. 3). This creates a tight seal and decreases aerosol spread in the instance that the patient coughs or sneezes. It is to be noted that after the sample has been collected, the valve must be opened again while withdrawing the instrument. This will ensure that the sample is not lost along the walls of the device.

Implementation and Evaluation

The device was then tested in real-time settings. Patients presenting to the hospital's Flu Clinic and ENT Clinic were sampled or examined using this device, incidences of complications, and patient or doctor-related discomfort were noted.

RESULTS

One hundred and fifty patients who reported for COVID testing at our hospital were sampled using this device. In all of them, NOSA performed exceedingly well. The patients did not have to take off their masks and aerosol generation from coughing or sneezing was also minimized. Complications noted were—loose fit of the device on mask ($n = 2$), tight valve ($n = 3$), and inability to find nasal opening due to narrow valve aperture ($n = 5$).

Fig. 3: The pressure on the valve can be released once the swab stick has passed to the inner surface of the mask

Eighty-nine patients reported to the hospital for nasal or oral diseases were examined or biopsied in a similar manner using Olympus Endoscopy Systems. Similar complications were noted—loose fit of the device on mask ($n = 3$), tight valve ($n = 4$), and inability to find nasal opening due to narrow valve aperture ($n = 3$).

DISCUSSION

Our team was able to successfully develop an affordable and effective device—nasal/oral sampling aid (NOSA). Our preliminary trials found it to be dramatically effective for patient and doctor safety. It reduced instances of aerosol dispersion and gave security to the entire sampling process. It was used similarly for biopsies and office endoscopy procedures too. The 3D printing of one NOSA kit takes 2 hours and costs about 50 Rupees (0.5£). Mass production using molds would reduce both these factors considerably. A somewhat comparable device has been developed by George et al., the safe nasendoscopy assisted procedure (SNAP).⁶ It has a valve system, which makes it acceptable for endoscopies, but ineligible for mucous sampling.

CONCLUSION

Since our device is in the early stages of development, it requires many modifications. At times the fit of the device is loose, the valve too tight to open properly, and the nasal opening difficult to locate. These areas need more refinement and tweaking.

Our observations demonstrate the NOSA device is a practical and safe tool to aid reduction in droplet dispersion whilst nasal or

oral sampling, endoscopy, and biopsy. We hope to see the inclusion of such a device in healthcare settings worldwide to facilitate the safety of our frontline workers in the COVID-19 pandemic era.

Summary Box

What are the features?

- Protects from airborne diseases, e.g., COVID-19, other respiratory illnesses
- A one-way manually operable valve that can be fitted to any surgical mask
- Designed to keep clinicians safe and so allow them to deliver high-quality care to their patients
- Facilitates the passage of swab sticks or an endoscope up to 5 mm in diameter

How might it impact healthcare in the future?

- Ensures safe collection of the mucous sample through a surgical mask without any sample loss along the walls of the valve due to its unique structure
- Reduces the risks associated with the patient sneezing or coughing
- Considerably reduces the prevalence of AGP (aerosol-generating particles) during sampling or examination and lowers the viral load

Provides better safety and care for both the patient and clinician

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