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Case report

Use of aerosol protective barrier in a patient with impending cholangitis and unknown COVID-19 status undergoing emergency ERCP during COVID-19 pandemic

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SUMMARY

WHO declared worldwide outbreak of COVID-19 a pandemic on 11 March 2020. Healthcare authorities have temporarily stopped all elective surgical and endoscopy procedures. Nevertheless, there is a subset of patients who require emergency treatment such as aerosol-generating procedures. Herein, we would like to discuss the management of a patient diagnosed with impending biliary sepsis during COVID-19 outbreak. The highlight of the discussion is mainly concerning the advantages of concurrent use of aerosol protective barrier in addition to personal protective equipment practice, necessary precautions to be taken during endoscopy retrograde cholangiopancreatography and handling of the patient preprocedure and postprocedure.

BACKGROUND

At present, the pandemic of COVID-19 has infected approximately 3 million people with more than 200 000 deaths globally and it is still counting. Healthcare experts and scientists are constantly finding measures to combat this viral pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).¹ In Malaysia, the first reported case of COVID-19 was on 23 January 2020. Since then, the number of positive COVID-19 cases has exponentially increased to approximately 5800 cases in a matter of 3 months.²

With the current consensus to cease or defer all the elective surgical and endoscopy procedures to concentrate on the COVID-19 outbreak,^{3,4} healthcare systems throughout the world are constantly facing shortage of personal protective equipment (PPE),⁵ lack of capacity and efficiency of real-time reverse-transcriptase-PCR testing⁶ as well as shortage of medical resources, especially, ventilators and dialysis machines. To add to the severity of problem, emerging cases of influenza-like illness and severe acute respiratory infections (SARI), which could be infected with SARS-CoV-2, have also burdened the healthcare system due to the lack of confirmatory testing facilities.⁶

As a result, the risk of contracting the infection is not only faced by the front-line healthcare providers but also to surgeons and endoscopists who perform emergency aerosol-generating procedures⁷ such as endoscopy retrograde cholangiopancreatography

(ERCP) and oesophagogastrroduodenoscopy (OGDS). Recent studies also reported asymptomatic individual can be infected with SARS-CoV-2^{8,9} and the person infected with this virus is capable of transmitting the infection to others.⁹ World-wide healthcare experts are recommending the use of full PPE to safeguard the team members from contracting SARS-CoV-2 infection via airborne transmission while performing procedures.⁴ Indications for emergency endoscopy are mainly based on sound clinical judgement, institutional resources and efficient communication between healthcare experts. Cholangitis and choledocholithiasis are among the indications considered for emergency ERCP.¹⁰

Therefore, in addition to the use of PPE, we have come out with an idea which could potentially suppress or reduce the risk of direct and airborne transmission of COVID-19 to the endoscopist and team by applying a disposable waterproof barrier on the patient during the aerosol-generating procedure. In addition, we also discussed in length the whole process of handling this patient prior to, during and following ERCP as well as the importance of taking certain necessary precaution when performing emergency ERCP in a patient with suspected cholangitis.

CASE PRESENTATION

A 28-year-old woman presented to a district hospital with 5-week history of right hypochondriac pain, which radiated to the back. Two weeks later, she experienced jaundice and passing tea-coloured urine. There were no known medical illness and no history of surgery before. She was seen in the emergency room. Clinically, she was stable with blood pressure of 145/94 mm Hg, pulse rate of 80 bpm and afebrile.

INVESTIGATIONS

Blood test revealed mild hyperbilirubinaemia with alanine aminotransferase (ALT), aspartate aminotransferase (AST) and alkaline phosphatase (ALP) within the normal range. Her total white cell count was $8.6 \times 10^9/L$. Other laboratory parameters such as full blood count, renal profile, coagulation profile and serum amylase were normal. Abdominal ultrasonography reported gallstone with no dilated

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Figure 1 Arrow shows a well-circumscribed elongated lesion likely to a soft distal bile duct stone.

biliary ducts. However, in a matter of 2 days, her total bilirubin has climbed from 57.6 $\mu\text{mol/L}$ (direct 40.2 $\mu\text{mol/L}$ and indirect 17.4 $\mu\text{mol/L}$) to 126.4 $\mu\text{mol/L}$ (direct 82.4 $\mu\text{mol/L}$ and indirect 44 $\mu\text{mol/L}$). Other parameters such as ALP, ALT and AST were also elevated from 237 units/L to 357 units/L, 251 units/L to 523 units/L and 266 units/L to 288 units/L, respectively. In spite of that, she has no recorded fever. An urgent CT of the hepatobiliary system demonstrated dilated intrahepatic and extrahepatic biliary dilatation secondary to a lesion in the distal bile duct (figure 1). Given her age and short history of presentation coupled with gallstones, a diagnosis of impacted soft stone in the common bile duct was more favourable. Subsequently, the patient was referred to a hepato-pancreato-biliary centre for emergency ERCP. The patient was explained regarding the procedure, risk and benefit followed by informed consent.

TREATMENT

Pre-ERCP process

She was screened for COVID-19 symptoms and signs prior to transfer. She denied having travelled abroad, locally or involved in any recent mass activity in last 2 weeks, no contact with any person who has been tested positive for COVID-19 or anyone who has symptoms of COVID-19 and also not having any fever, sore throat, cough, difficulty in breathing and diarrhoea. She was also required to sign the health declaration document with regards to COVID-19, which was made compulsory by the Malaysian Ministry of Health (MOH). In view of shortage of COVID-19 testing facilities, she was not tested. The healthcare staffs who will be accompanying the patient were screened in the same manner and ensured to perform the health declaration online on the MOH website.

In our institution, we have created a protocol, where each step of the emergency endoscopy workflow during this COVID-19 crisis has a checklist to ensure patient's and healthcare workers' safety, smooth flow of procedure, use of full PPE, correct technique of donning and doffing of PPE, proper handling of endoscopy and radiological equipments and accessories, proper disposal of clinical waste, handling of specimens and follow-up of patient 2 weeks after treatment to ensure patient has no symptoms of COVID-19.

On arrival to our institution, our frontline COVID-19 team was ready to check everyone in the ambulance. The patient was asked to remain in the ambulance along with the accompanying staff nurse and other healthcare personnel. They were checked for their body temperature and the same kind of verbal screening was done again to double check that everyone was not having any symptoms of COVID-19. All staffs were ensured to wear surgical mask as N95 respirators are limited and performed hand hygiene followed by gloving prior to entering the institution buildings. The patient was sent directly to the operating theatre (OT) complex using a stretcher, where ERCP will be performed in positive pressure OT room since the institution does not have negative pressure room.

At the airlock, the patient was required to wear long sleeve waterproof gown, cap and glove. The usual checklist for patient undergoing conscious sedation procedure was carried out. Prior to commencement of the procedure, the entire endoscopy team, including the radiographer, was ready in the OT room with the image intensifier (II) machine placed next to the OT table. Intravenous antibiotic was given prior to the procedure.

A total of seven staffs involved in the endoscopy procedure, which consist of an endoscopist, a doctor administering intravenous medication, two staffs assisting the procedure, a nurse recording the patient's vital signs, a staff to keep the patient head in position and communicate with the patient during procedure and a radiographer handling the II machine. Standard radiation precautions were taken by all team members.

While in the OT changing room, all personnel performed donning of PPE. First, they performed hand hygiene, then putting on OT cap followed by shoe covers (preferably knee level shoe covers). Next, they performed hand hygiene again and putting on N95 respirator/surgical mask (depending on stock) followed by a visor. Lastly, they put on the full body lead shield aprons and thyroid shields. In the OT room, everyone wore a disposable OT gown and double gloved.

During ERCP and use of aerosol protective barrier

Once the patient was positioned prone, oxygen therapy was delivered via nasal prongs and vital signs were checked before administering intravenous sedative medication. Then, the protective barrier was placed on the patient. The barrier used was a large disposable waterproof aerosol protective shield, which covered from the patient's head until the lower limbs and the corners of the barrier reaching below the OT table. There was also a transparent plastic sheet on the barrier, which allows the endoscopist constantly see and communicate with the patient throughout the procedure. A small slit-like opening is made below the transparent plastic sheet for the entry of the scope and another opening for the introduction of Yankauer sucker, if required.

The patient's vital signs and dosage of medication were recorded throughout the procedure. Adequate sedation was given to the patient so that the patient could hear the endoscopist talking. The patient was being calmed and reassured during the procedure.

The ampulla was floppy and bile was not present. Pus was seen on partial sphincterotomy following successful cannulation into the bile duct (figure 2). Limited contrast injection was done to ensure guide wire was in the bile duct and to minimise risk of cholangitis in an obstructed biliary system. A 10-French 9 cm plastic stent was deployed at the end of the procedure. The bile flow was good. Reversal medication was administered and the patient was fully awake.

Figure 2 Pus (small arrow) draining from bile duct following endoscopic sphincterotomy (big arrow).

Post-ERCP process

Post-ERCP, two endoscopy staffs were in charge of handling the endoscopy equipment. The duodenoscope and accessories were placed in the container and later sent to endoscopy room for disinfection. While still in the OT room, once endoscopy equipment was safely kept, every staff was instructed to remove the outer layer of their gloves. Doffing of PPE was performed in pair, by the assistance of a colleague who stood behind. Basically, the role of the person standing behind the other is to assist in removal of gown, visor and mask so as to minimise facial and body contamination. The steps are as follows. Step 1: the person in front stands still, and the person behind will untie the gown for the person standing in front. Step 2: once the gown has been removed carefully and disposed into the clinical waste bin, the person behind will untie the visor for the person in front. The visor will be left in the OT for disinfection and reuse for subsequent cases because of limited supply. Step 3: after removal of the visor, the mask will be untied by the person behind. Step 4: the person standing in front will wear a new mask by him or herself. Once this is done, the pair will switch the side and the same systematic doffing flow is followed. Before leaving the OT room, the same pair of endoscopy staff will remove their shoe covers using their inner gloves (outer layer was removed on completion of the procedure). Hand hygiene is performed and a new pair of glove is worn followed by a plastic apron. They left the room with the OT cap on, wearing a new mask and sending the equipment to the endoscopy suite using a trolley. PPE were used, including long sleeve waterproof gown and visor, during washing and handling of ERCP equipment to prevent splashing of contaminants.

The remaining staffs in the OT room performed the similar doffing of PPE (including lead shield aprons and thyroid shields) in pair. Once done, everyone wore a new mask and a plastic apron. They proceeded to clean the patient, removed her gown, changed her OT cap and applied new mask for her. The patient was transferred to the OT stretcher and sent to the recovery bay by the OT staff outside the room. The patient was later sent back to the referral hospital and intravenous antibiotic was continued.

Once the patient is sent out of the OT room, everyone removed their plastic apron and inner layer of gloves. Then, they put on

a new pair of gloves to handle other equipment. The endoscopy and II machines were wiped with disinfectant. This was followed by disinfection of the floor and surrounding surfaces. Finally, the team members removed their shoe covers followed by gloves and performed hand hygiene before leaving the OT room with their equipment.

OUTCOME AND FOLLOW-UP

Two days later, the patient's total bilirubin has dropped to 50 $\mu\text{mol/L}$ (direct 23 $\mu\text{mol/L}$ and indirect 27 $\mu\text{mol/L}$) and total leucocyte count was $9.98 \times 10^9/\text{L}$. Similarly, her ALP, ALT and AST have gradually reduced to 354 units/L, 359 units/L and 100 units/L, respectively. Subsequently, she was discharged after 5 days with oral antibiotics. Two weeks later, she was seen in the surgical outpatient clinic and the latest blood test has revealed significant improvement. Her total bilirubin was 21.8 $\mu\text{mol/L}$ (direct 15 $\mu\text{mol/L}$ and indirect 6.8 $\mu\text{mol/L}$), ALP 134 units/L, ALT 21 units/L and AST 20 units/L. She was scheduled for ERCP and stone clearance in 6 weeks.

DISCUSSION

Biliary obstruction with impending sepsis regardless of aetiology is an emergency situation which necessitate intervention. Delay in treatment can lead to septic shock and organ failure culminating to mortality rate of up to 100%.¹¹ Bacterial dissemination is theorised by the mechanism of cholangiovenous and cholangiolymphatic reflux due to the increased intraluminal pressure of an obstructed biliary system.^{12 13}

In a normal situation, young patient with gallstone disease and evidence of dilated biliary system by ultrasonography would call for an ERCP. However, for a few reasons, a CT was ordered. First, the initial ultrasound reported no dilated system. Second, patient was referred from another state. The ambulance journey took approximately 1 hour 30 min to 2 hours. Third, ERCP is an invasive procedure; the authors have to be cautious before a definite diagnosis has been made. Fourth, ERCP has been categorised as an aerosol-producing procedure and in addition, the authors were dealing with a patient with an unknown COVID-19 status. Therefore, the authors have to ensure that ERCP is really indicated. After considering the negative ultrasound findings, logistic issue, risk of procedure and unknown status of COVID-19 status, we have decided to obtain a CT scan and be sure of the underlying pathology. Since the CT procedure is relatively short and performed in a room separated from the radiology team, the risk of viral transmission was considerably low. Weighing the risk and benefits between the aforementioned reasons and not having the patient to undergo CT scan, the authors humbly think performing a CT is essential in that particular situation. On the other hand, should the ultrasound demonstrates a stone in the bile duct, a CT scan would not be necessary.

ERCPs are commonly performed under sedation. However, in situation where the patient requires intubation, our anaesthesia team has a custom-made transparent plastic box, which allowed for safe endotracheal intubation. Basically, the box covers the neck and head of the patient. The anaesthetist performs the intubation procedures through the side holes of the box. Once the patient is intubated, the box is removed and the protective barrier will be placed on the patient.

The whole procedure took approximately 50 min. Prior to the arrival of patient to the OT room, the duration of donning of PPE took approximately 10 min. The endoscopy system and image intensifier were ready while the patient was sent to the OT airlock bay. From the start until the end of ERCP, the procedure

Figure 3 Large aerosol protective barrier for aerosol-generating procedure. Edges of barrier reaching down to the floor (big arrow). Small arrow indicates site of scope entry. Note: not the actual patient.

took 35 min. The duration of ERCP varies from patient to patient in terms of the technical difficulty in cannulation of the ampulla. The doffing of PPE took approximately 15 min, including sending the patient out to the recovery bay. As time goes along, the time taken for the whole procedure would improve as this was the first time we have implemented this protocol.

Our patient was diagnosed with possible acute cholangitis based on the Tokyo Guidelines 2018.^{14 15} She has a history of gallstone disease and right hypochondriac pain, biochemical test demonstrated deranged liver function test and CT showed dilated biliary trees. Therefore, this patient is indicated for emergency ERCP.⁴ A plastic biliary stent was placed to drain the infected bile. Minimal contrast was injected into the biliary system to ascertain the position of the guide wire prior to stent insertion to avoid from further increase of the intraductal pressure in an already obstructed system. The procedure was uneventful. She was discharged on completion of intravenous antibiotic and given a tentative date for re-ERCP and stone clearance once the COVID-19 crisis is under control.

In this report, we would like to focus on our discussion regarding the potential benefits and indications of using aerosol protective barrier during ERCP in COVID-19 epidemic. Studies have shown that airborne particles produced by coughing, sneezing, talking and breathing are of a few mm to less than 1 μm .^{16 17} Infectious viruses and viral RNA are reportedly detected in particles of more than 5 μm and less than 5 μm .¹⁸ Following cough, air flow forms a jet-like propulsion that gradually widens and then dissipates.¹⁹ Therefore, droplet transmission can spread directly from an individual with COVID-19 to the other in close contact within 1 m of distance.¹⁶ Large droplets of more than 50 μm diameter usually land on the ground almost instantly. Intermediate-sized droplets of 10–50 μm settle in minutes and small particles of less than 10 μm can circulate in the air for hours. Lindsley *et al* reported 4 μm particles at a height of 1 m takes 33 min to settle and 8 hours for 1 μm particles.²⁰ Particles or droplet nuclei of less than 5 μm could lodge in the lungs as far as the alveoli.^{21 22}

During ERCP, constant air insufflation is generated from the endoscopic machine.⁴ Hence, the air pressure may accelerate and propel higher respiratory droplets from the patient's respiratory system causing direct and airborne transmission of viral infection to the endoscopist standing next to the patient and staffs.

Therefore, in addition to the current recommendation on the use of PPE during aerosol-generating procedures, concurrently, we propose the use of a large protective barrier to help fence off the aerosolised respiratory droplets and particles from the patient in order to provide additional protection for the endoscopy personnel. The aerosol protective barrier is a custom-made disposable waterproof polypropylene sheet measuring 271×181.5 cm (figure 3) sufficient to cover from the patient's head until below the waist. The corners of the barrier should reach down below the procedure table. An opening or window measured 32.5×23.5 cm for viewing is created on the barrier and sealed with a piece of transparent plastic sheet, which allows visualisation of patient's facial reactions and communication during the procedure. Another two small slit-like openings are made below the plastic sheet for the entry of the duodenoscope and Yankauer sucker.

The aerosol protective barrier offers several beneficial points: (1) The barrier can deflect the trajectory of expiratory droplets from the patient to the endoscopist who is standing near to the patient. Due to the air insufflation from the endoscopy system, the barrier can potentially block bigger respiratory droplets propelling directly towards the endoscopist. (2) By using this large barrier, the respiratory droplets and particles are forced towards the floor and as a result reduces the amount of circulating aerosolised particles in the air. That way, the endoscopist and staffs are less likely to expose to large amount of respiratory droplets. (3) The transparent plastic sheet on the barrier allows visualisation of scope intubation, constant monitoring of patient's facial reaction and communication throughout the procedure (figure 4). (4) The slit-like opening on the barrier enables versatile handling of the endoscope during procedures. (5) Even though the barrier is disposable, the plastic sheet can be cycled after disinfection.

We believe this method offers extra protection to the healthcare experts and team when performing upper gastrointestinal endoscopy in patients who are unknown to have COVID-19 infection in the presence of full PPE.^{4 7} The authors also believe this additional measure can be applied in patients with positive COVID-19 infection. In the event of emergency setting where patient tested positive for COVID-19 infection, the idea of pre-upper GI endoscopy intubation in order to control aerosolisation so as to reduce the airborne viral transmission is not clearly known. However, one study showed that patients who were asymptomatic with confirmed COVID-19 infection underwent elective surgeries under general anaesthesia developed COVID-19 pneumonia postoperatively. A total of 44% of this group of patients required intensive care unit admission and mortality rate was as high as 20.5%.²³

Other indication to apply this barrier is when the practice of full PPE is not possible owing to insufficient resources. This serves as an extra precaution that can be taken by the managing team. The indication could also be extended to patients with active pulmonary tuberculosis who need emergency upper GI endoscopy.

CONCLUSION

Prompt, careful and effective management of acute cholangitis is vital especially in the time of crisis like COVID-19 pandemic. In this dire situation where every healthcare institution around the world is running out of medical resources, time-consuming clinical studies, low capacity of testing facilities and surveillance, we believe that this idea of protective barrier, which has not been described in the literature, could potentially minimise

Figure 4 The transparent plastic sheet allows visualisation of the patient. A small opening is made on the barrier just adequate for the introduction of endoscope. Another small opening for entry of Yankauer sucker when needed (arrow). Note: not the patient described in this case report.

airborne viral transmission via respiratory droplets and particles during emergency upper GI endoscopy in order to provide greater protection to our healthcare experts and personnel. It is simple and yet a possible effective measure that can be implemented because of easily accessible material, simplicity of design and economical. Nevertheless, more studies are encouraged to deal with airborne transmission of viral infection during aerosol-generating procedures.

Learning points

- ▶ Suspect acute cholangitis when patient has painful obstructive jaundice evidenced by worsening of hyperbilirubinaemia, progressive elevation of transaminases (alanine aminotransferase and aspartate aminotransferase) and imaging (in this patient, CT scan) in the absence of fever and leucocytosis.
- ▶ Consider upgrade imaging (CT scan or magnetic resonance cholangiopancreatography, MRCP depending on institutional facility) whenever clinical and biochemical working diagnosis do not tally with ultrasonography findings.
- ▶ Endoscopy retrograde cholangiopancreatography with minimal biliary contrast injection followed by stenting is preferred in acute cholangitis.
- ▶ Consider using aerosol protective barrier in all situations, especially when full personal protective equipment practice is not possible during COVID-19 outbreak for potential extra safety against transmission of airborne viral infection.
- ▶ The practice of aerosol protective barrier is universal and cheap. It allows proper coverage of patient during the procedure and also permits versatile manipulation without damaging the endoscope. A tiny passage can be made on the barrier for additional procedure, such as suction.

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