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Covid-19 and ENT practice: Our experience☆,☆☆
ENT outpatient department, ward and operating room management during the SARS-CoV-2 pandemic

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ABSTRACT

Objectives: The current study aims at assessing the effectiveness of the guidelines set up by our clinic for the protection of patients and staff which enabled us to proceed with urgent and oncological surgery after the outbreak of the Covid-19 pandemic.

Material and methods: Our ENT department devised specific equipment to be worn by the staff for personal protection when dealing with Covid-19 patients both in aerosol generating and non-generating procedures. Moreover, restrictive measures were enforced both for the outpatient department and for the ward where only urgent practices were carried out and visitors were not allowed, while non-urgent elective surgery was postponed. A codified scheme was followed to perform tracheostomy procedure in Covid-19 positive testing patients on the part of 3 specific teams of 2 surgeons each, while the resident educational program was reorganized to limit the spread of the infection.

Results: In about a couple of months (from March 8th to May 3rd) a relevant amount of medical tests and surgical procedures were carried out on non COVID-19 patients and a certain number of tracheostomies were performed on COVID-19 patients. Consequently, all the ENT personnel were checked and found negative. Also, all the patients in the ward were swab tested and chest X-rayed, only one had a positive outcome and was adequately handled and treated.

Conclusion: Our ENT guidelines regarding personal protection equipment and multiple simultaneous diagnostic procedures have proved to be an essential instrument for the management of patients with both known and unknown COVID-19 status.

1. Introduction

In Italy there have been so far (June 6th, 2020) more than 234.000 cases of COVID-19 positive testing patients of which about 33,800 have deceased, most of whom were elderly people (mean age 80) with pre-existing illnesses.

Everything started on January 30th when two Chinese tourists coming from Wuhan were hospitalized at Spallanzani Hospital in Rome displaying symptoms compatible with COVID-19 disease (high temperature, cough, breathing difficulty).

The first case of secondary transmission occurred on February 18th in Codogno in Lombardy which became the district with the highest percentage of cases.

A vast surveillance and screening network was immediately set up and a panel of experts was called to define procedures.

On February 23rd some areas, where the infection was most widespread, were restricted access and in March all commercial businesses as well as all non-essential manufacturing activities were shut down. Lockdown was enforced and people were told to stay at home, save for vital necessities, and to work from home where possible and, with few exceptions (work, health problems and urgencies), they couldn't move from their hometown.

Italy was one of the first countries to be affected by the SARS-CoV-2 pandemic, and one of the worst-hit in Europe.

For this reason, the Italian health system had to handle an unexpected number of hospitalized patients in its wards and intubated patients in the Intensive Care Units.

This implied the reorganization of entire hospitals and great

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changes in the working practices [1].

There was no time to test and verify both plans and protocols as ENTs also faced the pandemic by preparing new admission/pre-operative guidelines within a short time.

COVID-19 does not affect only elderly people since, according to a European epidemiological study, the mean age of the people suffering from COVID-19 was 39.17 ± 12.09 years [2].

As this infectious disease affects all ages and every kind of patient, including ENT ones, we had to change our daily practice in order to create adequate protocols also for the ENT staff protection.

In the Veneto area the first COVID-19 case was diagnosed on February 27th, and the pandemic peak occurred around April 1st with 350 new critical patients in ICU and 1718 new non-critical patients in the wards. To June 6th in Veneto we had a total of 19,183 COVID-19 patients, of which 5558 were hospitalized and 1954 died [3].

In the whole Italian country, a considerable percentage (20%) of COVID-19 cases were healthcare workers, and some of them died [4].

There were no pre-existing protocols or guidelines, therefore we elaborated a protocol to try to keep a "COVID-19 free" clinic and ward, managing our resources in view of a possible shortage of personal protection equipment in the first stage of the pandemic in Italy.

The current study aims at assessing the effectiveness of the measures/guidelines followed in our Clinic, to continue our urgent and oncological surgical activity, while preserving a "COVID-19 free" environment and protecting our patients and staff. This was important to limit the spread of the infection.

2. Material and methods

2.1. Staff

Our protocol devised access restriction of patients and medical staff. Our ENT medical staff in Verona is composed of:

15 ENT specialists;
17 residents.

Throughout the SARS-CoV-2 pandemic, our surgical and clinical activities decreased and the resident educational program was significantly altered, in fact ENT residents had 2 weeks of internship and work alternating with 2 weeks of lockdown, for their protection.

Every day 2 medical doctors worked both in the ward and in the clinic, while 3 of them were involved in surgery.

2.2. Patients

As far as the different branches of our ENT clinic are concerned, in the outpatient department we carried out urgent medical examinations or the ones which required investigation within 10 days, in particular post-hospitalization non deferrable medications and cancer patients' evaluation. All the other non-urgent visits were postponed. In any case all the patients accessing the outpatient department were strictly required to wear a facial mask.

Restrictive measures were introduced for our ward as well. Only urgent patients (like the ones with neck abscesses and dyspnoea) were admitted to the ward, as well as cancer patients who needed to undergo surgery. No visitors were allowed, save special cases like the assistance of patients with dementia or underage ones, in which only one visitor was admitted.

Patients pending hospital admission who suffered from high temperature, dyspnoea and rhinorrhoea had to contact the on-call physician on the phone and they couldn't gain access to the ward.

For what concerns the operating room it was used for head and neck cancer surgery, for emergency procedures such as the drainage of neck abscesses, urgent tracheostomies, bleeding control and the management of post-surgical complications. Non-urgent elective surgery was postponed.

2.3. Patients with surgical indication

Every patient who needed surgery was admitted and isolated in an appropriate triage room, apart from the ward, in order to keep a "COVID-19 free" ward.

All the hospitalized patients were tested for SARS-CoV-2 infection with RT-PCR from a swab of the oropharyngeal, nasopharyngeal mucosa and of both nasal cavities in search of SARS-CoV-2 and pulse oximetry was measured. Until they got their results they were isolated in a single room and they had to wear a surgical mask. If they tested negative, they would undergo chest X-rays and walking test, to exclude SARS-CoV-2 infection.

In case of negative swab test, the patients could be moved from the triage room to the ward to undergo surgery the following day.

On the other hand, in case of a positive swab or if the swab was negative but chest X-rays were doubtful or walking test was suggestive of SARS-CoV-2 infection, surgery was postponed, and the patient was isolated at home and followed by his general practitioner, until he had 2 negative swab tests in a row. None of this was taken into account for emergency surgery.

2.4. Tracheostomy procedure in COVID patients

During the pandemic, part of the surgical activity was necessarily represented by tracheostomies in COVID-19 patients. Our protocol required the performance of these procedures in the COVID-19 dedicated area at the patient's bed.

Moreover, we set up 3 teams, made up of 2 surgeons each, to perform tracheostomy procedures for COVID-19 positive testing patients. These teams operated in both hospitals of our city 3 times a week, so that each group was involved in surgery (2 daily tracheostomies at most) just once a week. This schedule allowed minimum exposure to the virus of the team's members. This procedure followed some precise surgical steps. First of all, the trachea was exposed, then the ventilation tube was positioned in the most caudal portion of the trachea. Then, the trachea was incised and connected to the skin. Subsequently the apnoea state was reinstated and the endotracheal tube was replaced with a tracheostomy cannula, the circuit was eventually connected with a closed circuit and ventilation restarted.

2.5. Use of personal protection equipment

The reduced working time of medical staff was important for their safety and to avoid protection equipment waste.

Protection equipment was used only by the medical staff according to the risk of infection in our clinic, in the operating room and in the dressing room of the ward.

According to the below mentioned settings the protocol required the protections mentioned below.

2.5.1. Operating room

In particular, when dealing with COVID-19 negative swab testing patients, while performing procedures which did not generate aerosol, our medical staff was instructed to wear both a FFP2 and a surgical mask, a disposable gown, one pair of gloves, eye and face protection devices and shoe covers. For the procedures which generated aerosol in COVID-19 negative testing patients, the medical staff wore a FFP2 and a surgical mask, one disposable gown and a sterile disposable gown above it, two pairs of gloves plus a sterile one, eye and face protection devices, a cap, a surgical drape around the neck and two shoe covers.

Conversely, while dealing with COVID-19 positive testing patients, for both aerosol generating and non-generating procedures, the medical staff wore an FFP3 and a surgical facial mask, one disposable gown plus a sterile gown above it, two gloves plus another sterile one, eye and face

protection, two caps, a surgical drape around the neck and two shoe covers.

2.6. Clinic

Patients who accessed the clinic had to wear a surgical mask and gloves. For otological examinations, the staff wore a surgical mask, and gloves, since no aerosol production was involved. Instead, for oncological visits, pharynx and larynx evaluations, the medical staff wore an FFP2 mask, a surgical mask, face protection, a disposable gown, gloves and a cap (for risky aerosol producing procedures).

2.6.1. Ward (dressing room)

The medical staff wore an FFP2 mask, a surgical mask, a face protection device, a gown, gloves and a cap for dressings procedures, to clean and change tracheostomy tubes, inner cannula, etc. in the ward.

3. Results

All the protocols described in Section 2. *Material and methods* were enforced for all ENT activities from March 8th to May 3rd (phase 1).

3.1. Restrictive protocol

During phase 1, all ENT staff members (both residents and specialists) did not show any COVID-19 related symptoms. At the end of March, the whole staff was tested for the search of SARS-CoV-2 RNA through nasopharyngeal and oropharyngeal mucosa swab test and they all tested negative. Even though the whole wore adequate personal protection equipment the swab test was repeated for those involved in aerosol-producing procedures with COVID-19 positive patients (such as endotracheal tube cuff rupture during a tracheostomy procedure) and they all tested negative again.

3.2. Patients with surgical indication

During this time, we performed:

216 medical examinations in the Emergency Department;
1264 outpatient check-ups and hospitalized patients consulting;
80 surgical procedures in patients with negative COVID-19 tests.

We performed 13 tracheostomies, 4 lateral skull base procedures, 3 anterior skull base procedures, 43 oncologic head and neck surgeries, 17 other procedures.

All hospitalized patients were tested with a nasopharyngeal and oropharyngeal mucosa swab in search of SARS-CoV-2 RNA and subsequently chest X-rayed.

Out of 80 hospitalized patients, 1 patient without any symptoms tested positive for COVID-19 during swab testing. She was isolated in the triage room until the test results came, then she was immediately discharged wearing gloves and a surgical mask, isolated at home and followed by her general practitioner.

None of the patients who had a negative swab test, showed any sign suggestive of COVID-19 when chest X-rayed or when undergoing walking test. Patients who showed symptoms compatible with COVID-19 during hospitalization (cough, fever, rhinorrhea), repeated the swab test, and none of them tested positive.

3.3. Tracheostomy procedure in COVID-19 patients

The three above-mentioned équipes performed 22 tracheostomies on COVID-19 patients altogether, every team was involved in surgery once a week, with an average of 6 tracheostomies each team. None of the surgeons got a positive swab when tested, nor any COVID-19 related symptoms.

4. Discussion

The epidemic of COVID-19 caught the Italian Health Care Service unprepared, therefore it was necessary to set up protocols and reorganize hospitals for COVID-19 and non-COVID-19 patients.

The protocol implemented in our ENT Clinic represents one of the first ENT ones during the pandemic, after the Chinese experience.

Assessment of this protocol was made after it was confirmed that the great majority of people suffering from COVID-19 disease (50–75%) did not show any symptoms but represented “a formidable source” of infection [5] and that the performed oropharynx and nasopharynx mucosa swab tests led to a high percentage of false negatives.

Among the available tests (serological, swab) to detect SARS-CoV-2, we decided to use the swab test because it is easy and user-friendly even though, despite being widely used, it shows a high percentage of false negatives.

A Chinese study dating back to February 2020, showed that reverse transcription polymerase chain reaction (RT-PCR) test results of pharyngeal swab specimens were variable and potentially unstable. So, we realized that swab testing should not be considered as the only possible indicator of diagnosis, treatment, isolation, recovery/discharge and relocation for hospitalized patients clinically diagnosed with COVID-19 [6].

Indeed, several factors have been proposed to explain the inconsistency or the high false negative rate [7].

For example, results from RT-qPCR testing using primers in the ORF1ab gene and N genes can be influenced by the variation of viral RNA sequences. In terms of natural history of the disease and viral load in different anatomic sites of the patients, sampling procedures largely contribute to a high number of false negative results. According to estimates, false negative results from one-time testing were as high as 30–50% in real COVID-19 cases [8].

False negatives may also be caused by insufficient viral material in the specimen, laboratory errors during sampling, or inconveniences in sample transportation [9].

Another study found that the positive rate of 2019-nCoV nucleic acid test of sputum is more accurate if compared to the nasopharyngeal mucosa. It also concluded that multi-sample 2019-nCoV nucleic acid detection can improve the accuracy and reduce the false negative rate [10].

Since in patients with acute influenza, nasopharyngeal swabbing was clearly superior to oropharyngeal one in terms of diagnostic yield through real-time PCR, we preferred to test both oropharyngeal and nasopharyngeal mucosa [11].

Therefore, we decided to perform a mucosa swab RT-PCR test (both nasopharyngeal and oropharynx mucosa) on every patient pending hospitalization, combined with chest X-rays and pulse oximetry.

Through the execution of the combination of these 3 tests, diagnosis of COVID-19 became more accurate.

In our Italian experience with COVID-19 patients we noticed a clear disproportion between the degree of dyspnoeic symptoms and the pulmonary status. Some of the COVID-19 patients did not show any apparent symptoms but their chest X-rays showed interstitial pneumonia, or desaturation during the walking test, suggesting a SARS-CoV-2 infection.

Hence, the importance of combining more diagnostic tests to increase validity from experience and literature reviews. Therefore, we noticed that the combination of swab testing, chest X-rays and pulse oximetry leads to a more adequate screening by reducing the numbers of false negative results.

The major mode of human-human transmission of SARS-CoV-2 is presumed to be through respiratory droplets, even if evidence suggests that the virus may also spread via the faecal-oral route and through the conjunctiva [12].

Early reports also suggest the possibility of transmission during aerosol-generating procedures, like instrument usage in the upper

aerodigestive tract.

For this reason and because the viral load of SARS-CoV-2 is higher in the nasal cavity than in the pharynx [13], upper airway examination and procedures, as well as endoscopic or open sinus and skull base surgery should be considered extremely risky operations for the transmission of SARS-CoV-2 [14].

ENT is one of the branches with the highest risk of SARS-CoV-2 contagion, as it requires the management of the upper airways [15].

Since in case of ENT emergency surgery or in outpatient ENT examinations, the patient has an unknown COVID-19 status (testing being impossible), healthcare workers must wear protective equipment and follow the same procedures as they would, in case of COVID-19 positive patients. Conversely, when oncologic surgery is performed, there is the possibility to test the patient through lab tests, swab tests, pulse oximetry and chest X-rays. Therefore, knowing the COVID-19 state of the patient, the staff will decide the appropriate protective equipment.

Since our protocol was used during phase 1, we did not observe any infected healthcare workers. None of the members of the whole staff was infected or presented COVID-related symptoms.

Regarding tracheostomy, the timing in the critically ill COVID-19 positive patient is a controversial issue. Siempos et al. found no significant difference in the mortality outcome between early (< 48 h) and late (> 15 days) tracheostomy [16].

In literature, open tracheostomy is considered superior to the percutaneous procedure for a number of reasons. First, it shows a presumed lower risk of producing viral droplets or aerosols [17], secondly there is no need of a simultaneous bronchoscopy, last but not least it does not require a long period of exposure to an open tracheostomy site during serial dilations resulting in an increased risk of virus aerosolization [18].

In our Clinic the staff specifically devoted to performing tracheostomies in COVID-19 positive patients tested negative throughout and they did not show any symptoms. Following our protocol, the tracheostomy procedure did not involve the production of aerosol or it was minimized.

In our COVID Units, a trained observer checked personal protective equipment doffing, to minimize self-contamination after high risk procedures, which was consistent with Chinese recommendations [19,20].

5. Conclusion

To face the SARS-CoV-2 pandemic it is paramount for the ENT staff to have adequate personal protective equipment, a proper protocol to be followed for the management of known, dubious or positive COVID-19 patients and suitable guidelines for both the staff and the patients' safety.

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