



The efficacy of a protective protocol for oral and maxillofacial surgery procedures in a COVID-19 pandemic area—results from 1471 patients

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Abstract

Objective To examine the effectiveness of an empiric protection protocol during oral surgical treatments in a COVID-19 pandemic area and to evaluate the potential effect of postponed dental procedures on the frequency of facial infections during a lockdown period.

Methods We performed a retrospective analysis of a case series of a broad-spectrum of oral surgeries in a COVID-19 pandemic area. Data collection included patient age, type of procedure performed, and COVID-19 status of staff and patients. Data were analyzed using descriptive statistics.

Results Between February 21 and April 23, 2020, 1471 patients were treated in the outpatient clinic ($n=1404$) and under general anesthesia ($n=67$). All procedures were carried out under a strict empiric protective protocol that included patient screening, personal protective equipment allocation protocol, frequent staff testing, and patient testing before general anesthesia. Treatments included emergency and urgent elective procedures. Only one staff member was confirmed positive for COVID-19 during routine weekly testing, and an independent epidemiologic investigation suggested he was likely infected outside of hospital facilities.

Conclusions Our empiric protective protocol was found to be effective in preventing staff cross-infection with COVID-19 in an oral and maxillofacial surgery setting.

Clinical relevance To the best of our knowledge, this is the first report that provides data regarding oral surgical activity in a COVID-19 pandemic area. Our suggested protective protocol may assist oral surgeons in continuing dental services in a safe manner.

Keywords Coronavirus · Personal protective equipment · Patient screening process · PPE allocation protocol

Introduction

The coronavirus disease 2019 (COVID-19) pandemic, known to be caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), began in December 2019 in the city of Wuhan, Hubei province, in China [1]. Since then, the

disease spread rapidly worldwide and has become a significant global public health threat. On January 20, 2020, it was declared by the WHO as a public health emergency [1].

The proportion of asymptomatic infection is still unclear and is estimated to range between 16 and higher than 80% [2–4]. Classic signs of symptomatic patients are fever, dry cough, fatigue, and shortness of breath [5]. In some cases, the disease may progress to bilateral pneumonia, multi-organ failure, and death. Recent reports from sites worldwide have shown that anosmia and dysgeusia are also symptoms associated with COVID-19 [5]. Patients with pre-existing comorbidities (e.g., diabetes, hypertension, and cardiovascular disease) are at a much higher risk of severe illness and death by COVID-19 [6].

The typical transmission routes of this novel coronavirus include inhalation of respiratory secretions (e.g., cough,

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sneeze, exhalation during speech) or contact transmission (contact with oral, nasal, and eye mucous membranes) [7]. SARS-CoV-2 remains viable and infectious in aerosols dispersed in the air for at least 3 h and on surfaces up to several days [8]. Symptomatic patients are the main reservoir for transmission; however, evidence suggests that asymptomatic patients and even patients during the incubation period can shed and transmit SARS-CoV-2 [9]. The infective potential of asymptomatic patients may be reduced by the use of advanced personal protective equipment, including N95 (or equivalent) respirators during aerosol-generating procedures [10]. Nevertheless, this epidemiologic feature of COVID-19 has made its control extremely challenging, as it is difficult to identify and quarantine asymptomatic patients in time [11].

The first reported physician fatality related to COVID-19 in Wuhan, China, was an otolaryngology physician [12]. As SARS-CoV-2 can be found in high concentrations in saliva and the upper aerodigestive tract [13, 14], many medical professionals, particularly dentists, otolaryngologists, and oral and maxillofacial surgeons, are at high risk for COVID-19 infection, especially during aerosol-producing procedures without advanced personal protective equipment (PPE). Hence, strict and effective infection control protocols are needed for these high-risk specialties to minimize the risk of transmission.

The first case of the coronavirus pandemic in Israel was confirmed on February 21, 2020, and the first casualty announced on March 20, 2020. As of April 23, 2020, 14,592 laboratory-confirmed cases, with 5334 recoveries and 191 deaths, have been reported. In spite of the pandemic outbreak in Israel, the Department of Oral and Maxillofacial Surgery (OMS) of the Hadassah University Medical Center and the Faculty of Dental Medicine at the Hebrew University have continued to provide a broad spectrum of medical services, including both emergent and urgent elective procedures. To minimize the risk of infection for the staff, we developed an empiric protective protocol that includes a quadruple patient screening process, use of specific PPE, and routine patient and staff testing for COVID-19. The purpose of this manuscript is to share our experience during the COVID-19 pandemic and to introduce the protective protocol under which we operated during this time.

Methods

We retrospectively collected and analyzed data regarding patients and staff members of the OMS department at Hadassah University Medical Center and the Faculty of Dental Medicine of the Hebrew University between February 21 and April 23, 2020. All patients treated in our department during this period were included in the analysis. Patient age, indication for visit, type of treatment provided, treatment

setting, and patient COVID-19 testing results were collected from patient records. Patients with odontogenic fascial space infections were questioned regarding the history of their infection and specifically regarding their attempts to seek dental care during the lockdown prior to arrival in the emergency room. Results of COVID-19 testing of the medical staff were obtained from the Hadassah Medical Center data center.

The retrospective study was approved by the Institutional Review Board (HMO-0316-20), and PIs were not afforded access to personal data of the participants.

Medical team

The department of OMS includes 37 staff members: 22 physicians, 11 nurses, and 4 administrative staff.

Members of the medical team were tested daily for COVID-19 symptoms. They were instructed not to attend the department if they exhibited one of the following symptoms, fever ($>37.3^{\circ}\text{C}$), respiratory infection symptoms, and flu-like symptoms, or if they had come in close contact with a confirmed COVID-19 case.

Staff members had their temperature measured at every entrance to the hospital. During the entire duration of their stay in the hospital, medical staff members were instructed to wear surgical masks and vinyl gloves. Prior to donning gloves and after their removal, staff members were required to scrub their hands for 60 s, followed by a hand-rub with a 70% ethanol-based formulation.

The entire medical staff was divided into two separate teams: members of each group were forbidden to come in close contact with members of the other group. The rationale behind this directive was to lower the chances of transmission between medical personnel, potentially risking the department's ability to provide continuous patient care. Ward rounds were led by the on-call attending physician with outgoing and incoming on-call residents. All staff meetings and academic activities were held using a video conferencing platform.

Patient screening protocol

A “quadruple screening protocol” was implemented to screen patients and to identify suspected undiagnosed COVID-19 cases:

1. Telephone questionnaires—patients with scheduled appointments underwent a telephone screening questionnaire. Patients were asked about their body temperature and were instructed not to come to the hospital if their temperature was above 37.3°C . They were also requested to state that they are free of cough, respiratory difficulties, sore throat, rhinorrhea, and anosmia. In addition, patients were required to guarantee that they were not obligated to quarantine on the treatment day, as defined by the

Ministry of Health regulations. Patients with fever or respiratory symptoms who tested negative for COVID-19 were requested to complete a 48-h symptom-free waiting period before their appointment.

Patients with medical comorbidities that put them at higher risk for COVID-19-related morbidity were invited to the early sessions of every workday.

2. Temperature measurement—patients had their temperature measured at the entrance of the hospital. Fever-free patients were referred to the department. Patients with fever were referred to a “biological emergency room (ER),” primarily geared for COVID-19 screening.

Patients that did not mandate urgent treatment were sent home until they were symptom-free for 48 h before returning to the hospital. Patients in need of urgent care (mainly trauma and facial infections) were tested for COVID-19 using polymerase chain reaction (PCR) tests. The tests were analyzed in the Hadassah Medical Center laboratories, and the results were available 12–24 h after testing.

3. Patients, who, upon arrival, did not have protective masks or gloves, were provided with such by department personnel. Upon admission, patients underwent clinical triage to establish they did not have respiratory symptoms, flu-like symptoms, rhinorrhea, or anosmia. Subjects who successfully passed these three screening procedures were assigned to a group for treatment. We routinely used pre-procedural mouth rinse with 0.2% chlorhexidine gluconate or 0.3% hydrogen peroxide to reduce the microbial load in aerosols and splatter generated during surgical procedures.
4. Patients that did not successfully pass one of the screening procedures mentioned above were referred to the biological ER and were tested for COVID-19 and checked by an OMS physician. In the case that the COVID-19 test was negative, the patients were referred back to the department. Positive COVID-19 patients were admitted for treatment in designated negative-pressure rooms in a separate building assigned for COVID-19 patients in the following indications: maxillofacial trauma, head and neck malignancies, bleeding, pain, post-operative osteitis, dental abscess, dental trauma that requires treatment (e.g., tooth luxation/avulsion), pericoronitis, dental/surgical treatment before scheduled radiotherapy/chemotherapy/other medical treatment that requires pre-operative dental preparation, a biopsy of suspected malignancy, evaluation of patients with new numbness in the orofacial region, and other acute/new symptoms that do not allow for basic eating/drinking/speech.

Personal protective equipment (PPE) allocation protocol

In the absence of COVID-19 testing of the general population, all patients submitted to treatment in our department were

regarded as potentially COVID-19–positive patients. Hence, we saw a high necessity for the use of PPE to protect both staff members and patients from potential cross-infection with COVID-19. Nevertheless, PPE inventory was limited, and a programmed PPE allocation protocol was required. The PPE allocation protocol was based on findings by the CDC [15].

Appropriate OMS PPE was defined according to the aerosol production potential of the various surgical procedures:

1. *Aerosol-producing procedures*—procedures that require the use of rotatory, ultrasonic, or external water-cooling equipment were performed with *grade-1 PPE*:
 - a. Two sets of facial masks—N95 facial mask for multiple uses, covered by a regular surgical mask for single use
 - b. Face shield
 - c. Long-sleeve disposable waterproof gown
 - d. Disposable head covering
2. *Non-/minimal-aerosol-producing procedures*—procedures that did not require the use of rotatory, ultrasonic, or external water-cooling equipment were performed with *grade-2 PPE*:
 - a. Regular surgical mask
 - b. Face shield
 - c. Long-sleeve disposable gown
 - d. Disposable head covering

The distribution of different procedures, according to the above criteria, is presented in Table 1.

Routine COVID-19 tests

The department staff underwent routine weekly PCR testing for COVID-19. PCR tests were also performed for all patients before surgery under general anesthesia.

Odontogenic fascial space infections due to lack of dental services

Patients admitted to the department with odontogenic fascial space infections during the lockdown period were interviewed by the on-call physician, as part of their anamnesis, regarding previous attempts to seek dental treatment prior to their admission to the hospital. Patients were also asked if they were in the course of dental treatment prior to the lockdown and, if so, why it was postponed and what temporary measures were used to avoid dental deterioration. To the best of our ability, we did not use suggestive questioning, reinforcement, or delivery of approving and disapproving statements contingent on a patient’s report.

Table 1 The division and examples of the primary procedures performed together with their aerosol-producing potential

Non-/minimal-aerosol-producing procedures	Aerosol-producing procedures
Examination/follow-up	Surgical extraction
Suture removal	Dental implants
Non-surgical extraction*	Sinus lift/alveolar reconstruction/bone-regenerative procedure
Soft tissue biopsy	ORIF of facial bone fractures
Sialendoscopy	Craniofacial and orthognathic surgery
Abscess drainage	Ablative procedures
IMF of facial bone fractures	Apicoectomy
Arthroscopy/TMJ lavage	Open TMJ surgery

*non-surgical extractions that require tooth separation are aerosol-producing procedures

Results

A total of 1471 patients have been treated in our department (Table 2). A total of 1404 patients were treated in the outpatient setting. There were 664 procedures and 894 examinations/follow-ups performed. Sixty-seven surgeries (42 non-emergent and 25 emergent) were performed under general anesthesia. Non-emergent procedures were selected on the premise that a delay in surgery may cause irreversible damage to the patient.

Patients were divided into three age groups: 0–20, 20–65, and 65+ (median, 37; upper quartile, 21; lower quartile, 62.5). Most patients were 20 to 65 years old (56%) with an average age of 47. However, 249 subjects were above 65 years old.

Patients and staff members' COVID-19 status

All staff and patient tests were analyzed at the Hadassah Medical Center laboratories. Results were available between 12 and 24 h after testing. All patients pre-operatively tested for COVID-19 were found to be negative. A total of 193 tests

were performed on the staff members, with an average of 5.2 tests per staff member. One staff member was confirmed positive for COVID-19 during routine weekly testing. He was symptom-free at the time of testing. An independent epidemiologic investigation demonstrated he was likely infected with COVID-19 outside of hospital facilities while visiting relatives in a pandemic region of the country. He stayed in isolation until testing negative in two consecutive tests, followed by an additional waiting period of 48 h. He was symptom-free throughout his isolation period. Another physician who had close contact with the confirmed COVID-19 physician during a work shift was also sent to quarantine as per the same protocol. He, too, was symptom-free and remained in quarantine until testing negative in two consecutive tests.

Odontogenic fascial space infections due to lack of dental services

Forty-three patients were admitted to our emergency room during the lockdown for drainage of odontogenic fascial space infections (35 under local anesthesia; 8 under general

Table 2 Procedures that have been provided to 1471 patients in our department between 21.02 and 19.04

Outpatient clinic		General anesthesia service	
Procedure	Number of cases	Procedure	Number of cases
Follow-up meeting	549	Emergent	25
Examination	345	Trauma	15
Surgical extraction	146	Deep facial infection	8
Non-surgical extraction	76	Oncology	2
Dental implants	60		
Impacted tooth exposure	19	Non-emergent	42
Sinus lift procedure	10	Dentoalveolar	17
Minor procedure	136	Benign pathology	10
Moderate procedure	148	Salivary glands	9
Major procedure	59	Orthognathic surgery	6

Left: Outpatient clinic activity. Right: Surgeries under general anesthesia—classified into emergent and non-emergent surgeries. Other surgical procedures were divided into three sub-categories based on the scope of the procedure—minor, moderate, and major procedures

anesthesia) (Fig. 1). Twenty-three patients (53%) reported that their deep fascial infection had developed after failed attempts to receive dental care and/or a significant delay in their ongoing dental treatment.

Discussion

Since the WHO officially declared COVID-19 a public health emergency, countries and health organizations recommended delay of all elective dental procedures [16–18]. Despite lack of empirical proof reported regarding the heightened risk for COVID-19 transmission in a dental or OMS setting, the assumption was that dental and OMS procedures have a high risk for transmission of COVID-19. This risk is due to the proximity between the physician and the patient's oral cavity. Furthermore, many procedures use rotatory, ultrasonic, and water-cooled equipment that may raise aerosol dispersion risk in the clinical setting. Studies have found that aerosol may remain in the air for up to 3–5 h and claimed that this increases the chance for cross-infection with COVID-19 in undiagnosed subjects [8]. However, this assumption was never tested in a protected setting.

Despite the global recommendations to delay elective dental and OMS procedures during the COVID-19 epidemic, many of these procedures cannot be considered as non-urgent. Dental care is an essential facet in human health, and delaying dental care may lead to severe and even irreversible morbidity. Many researchers have warned that COVID-19 may continue to be prevalent for quite some time with recurring outbreaks in

the future [19, 20]. Hence, without comprehensive dental care, entire communities may suffer from an increased prevalence of severe dental morbidity. In addition, the diagnosis of many ailments, some of which are severe, may be significantly delayed, because people will avoid routine dental exams and supporting treatments.

Out of 43 cases admitted to our department due to an odontogenic fascial space infection during the period of this study, 23 cases were the result of absence of dental services. Patients reported that despite seeking treatment from their regular dentists, they were provided with telemedicine consultations or with a recommendation for medication, but not with a dental appointment. Among other reasons for odontogenic infections, patients were admitted to our department due to infections related to incomplete root canal therapies, untreated caries, and crown or filling detachment that caused root fractures. The data suggest that a lack of dental services due to the lockdown raised the incidence of fascial infections, a health complication that may lead to life-threatening situations. Although our means for detection of these patients were relatively limited and included mainly an anamnestic interview, we believe that the data collected show an important pattern.

Some patients suffering from chronic conditions may experience irreversible damage due to treatment delay. Treatment delay of patients with benign pathologies in the head and neck region may lead to increased morbidity or the need for more extensive treatment. As such, a delay in the treatment of odontogenic cysts that were allocated for simple procedures (decompression and/or enucleation) may result in the need for ablative surgery [21]. In cases of a very long delay of treatment, these may also lead to pathological fractures [22]. Some benign pathologies, such as dentigerous cyst and pleomorphic adenoma, may undergo a malignant transformation if not appropriately treated in time [23].

Patients with sialolithiasis may suffer from recurring infections in the absence of treatment, and instead of minimally invasive sialendoscopic surgery for the removal of the sialoliths, they may later require sialadenectomy [24].

For subjects scheduled for orthognathic surgery, who completed the orthodontic preparation (including decompensation), a delay in surgery has the potential to cause deterioration of the occlusion and difficulty to eat and speak as well as other dental and periodontal damage [25].

Due to the concern that the deferral of dental treatments may increase the prevalence of severe morbidity (and, potentially, mortality) and the knowledge that dental and oral surgical procedures are at high risk for COVID-19 transmission, proper implementation of strict protective protocols is of utmost importance. We used a “quadruple protocol” for patient screening.

This protocol initially required patient screening based on self-report, temperature check upon entry to the department, clinical triage, as well as PCR testing in suspected COVID-19

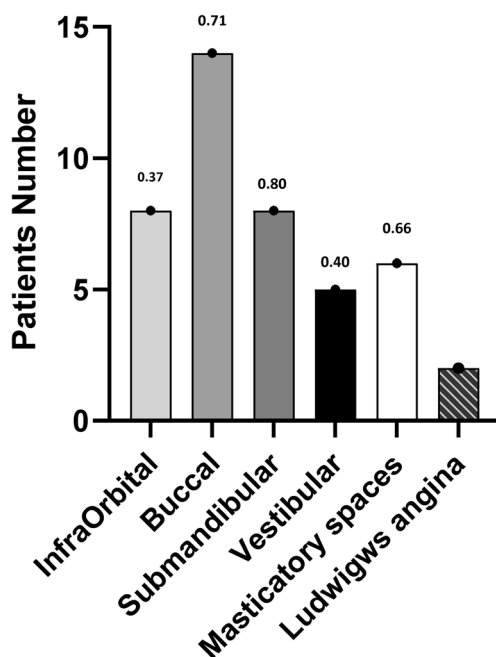


Fig. 1 Quantification of patients with odontogenic infections. The number at the top of each column represents the percentage of patients reported to have deteriorated due to delay in dental care

(subjects with a fever) and all cases prior to general anesthesia. This enabled us to treat subjects that were low risk for carrying COVID-19. However, because we are yet unable to provide PCR testing of the majority of our patients—in particular, those that are symptom-free—we must institute a safety protocol that assumes all patients may be asymptomatic carriers for COVID-19.

The decision to perform several non-emergent procedures during a lockdown period, including orthognatic surgeries and pre-prosthetic procedures, was made due to various case-specific reasons, such as the possibility of damage due to the preparatory orthodontic treatment, functional problems, and also psychological reasons and patient request. Nevertheless, it is important that the provision of such non-emergent treatments during a lockdown period is carefully evaluated and

that the benefits for the individual patient will not elevate public health risks.

Pre-procedural mouth rinse with 0.2% chlorhexidine gluconate or 0.3% hydrogen peroxide was used prior to surgical procedure to reduce potential microbial load in aerosols and splatter. This was performed in accordance with several publications and recommendations available at the time this study was active [15, 16]. These recommendations were primarily based on the general vulnerability of SARS-CoV-2 toward oxidation [26] and on data that showed coronavirus inactivation with products containing oxidizing agents on inanimate surfaces within a 1-min exposure period [27, 28]. However, in vivo studies show that hydrogen peroxide does not decrease the intraoral viral load in SARS-CoV-2–positive subjects [29], and further investigation regarding pre-procedural mouth

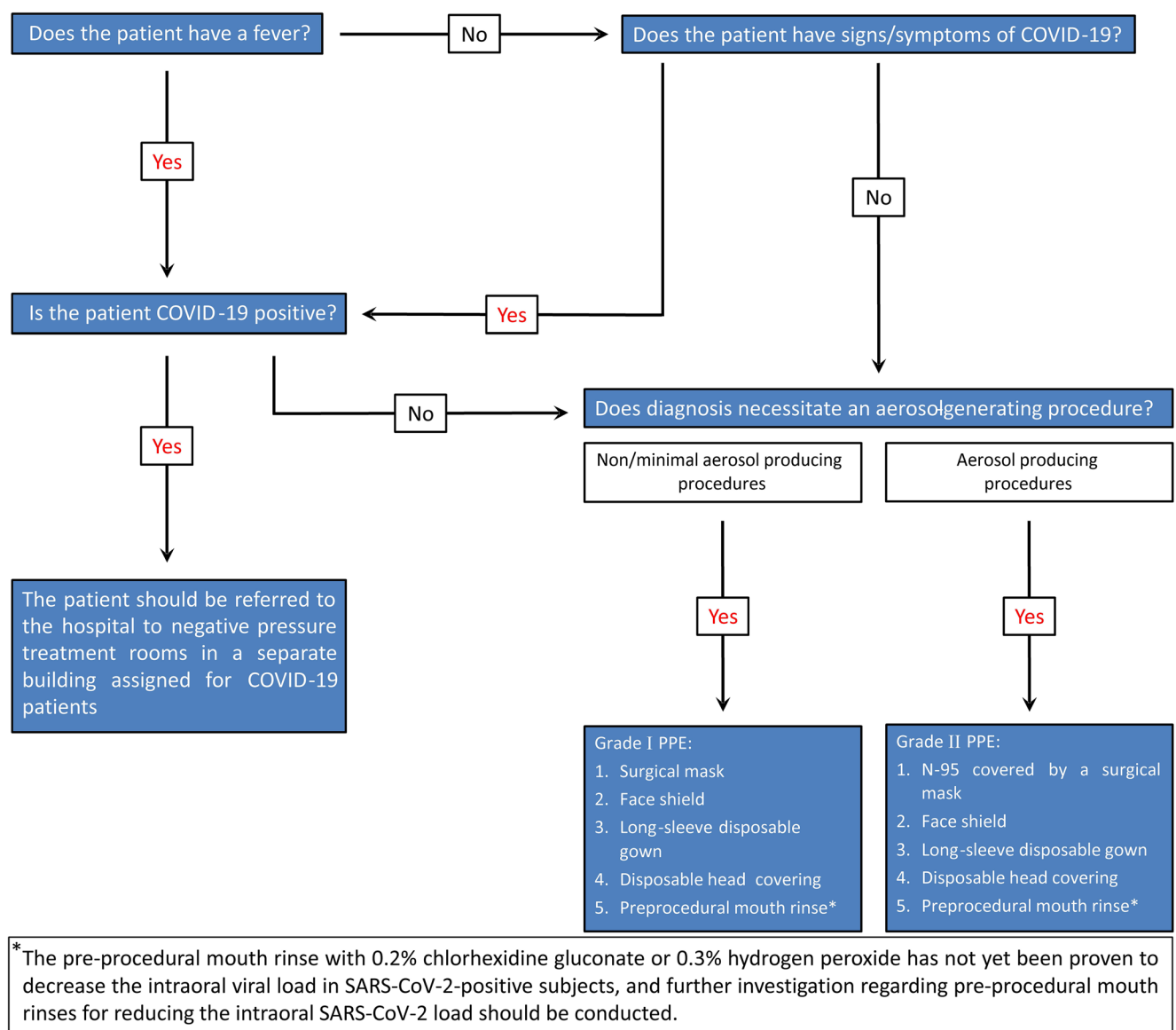


Fig. 2 Algorithm for recommended management protocol for practitioners in affected areas based on our experience and the scientific literature about COVID-19

rinses for reducing the intraoral SARS-CoV-2 load should be conducted.

Proper use of PPE is a critical layer in the protection of the medical team. Even though we are not aware of precise measures for the amount of aerosol released during our procedures, nor of this aerosol's actual transmission potential, aerosol production potential was our marker for opting for the PPE protocol.

This protection protocol enabled us to allocate our PPE inventory properly. In cases of a limited PPE supply, it is vital to implement a planning mechanism for the proper distribution of PPE. Our plan allows for maximum protection of both team and patients, and sufficient supply of PPE guarantees continued and uninterrupted medical services over time. Our screening and PPE allocation workflow is summarized in Fig. 2.

Another essential element for ongoing work in the COVID-19 era is routine testing of the medical personnel and the patients. The department staff underwent routine PCR testing for COVID-19 every week. PCR tests were also performed for all patients before surgery under general anesthesia. All patients were found negative for COVID-19. One physician was found positive for COVID-19. Our protocol mandated the confirmed COVID-19 physician to stay in isolation until two consecutive tests were negative. By frequently testing staff, we were able to distance COVID-19–confirmed personnel immediately and better protect our patients and team members from cross-infection. To ensure possible cross-infection did not jeopardize our services' durability, we divided our personnel into two separate teams. Using this method, even though a staff member from one of the teams was positive for COVID-19 and had to be sent to isolation, the second team was still able to fulfill all department tasks and obligations and to continue providing all services.

The OMS department of the Hadassah Medical Center is situated in Jerusalem. As of April 24, 2020, there have been 3061 confirmed COVID-19 cases in Jerusalem, which is currently considered a national pandemic center and ranked highest in the country in the number of confirmed cases. Nevertheless, except for one staff member who, according to an independent epidemiologic investigation, was most likely infected with COVID-19 outside of the hospital facilities, no medical personnel contracted COVID-19 during their work period in the department. This is a positive indicator that our screening process, PPE allocation protocol, routine, and frequency of testing of both staff and pre-surgical patients, likely acts as a “safe treatment envelope” during the COVID-19 era. Our strict protocol adaptation allows us to perform dental and OMS treatments, including selected elective procedures.

To the best of our knowledge, this is the first report that provides data regarding elective OMS activity during the COVID-19 crisis. The information and results presented in this manuscript may enable structuring of new treatment protocols in the dental and OMS settings. However, more data are

required, alongside a significant improvement in diagnostic test availability and reliability, to allow for routine dental and OMS activity.

Conclusions

COVID-19 may continue to be prevalent for quite some time, and there is a fear of recurring outbreaks in the future. Protective protocols are needed to allow regular oral and maxillofacial services. OMS services for the public during a health crisis such as the COVID-19 pandemic are important for the public health and should be available under safeguarded conditions. Here we proposed our protective protocol that may allow for dental and OMS services during a COVID-19 outbreak. This protocol was found to be effective in preventing staff cross-infection with COVID-19 in an oral and maxillofacial surgery setting. More data are needed in order to evaluate the effectiveness of this protocol on patient cross-infection in this setting.

Declarations

Ethics approval This article does not contain any studies with human participants or animals performed by any of the authors.

Consent to participate For this type of study, formal consent is not required.

Conflict of interest The authors declare no competing interests.

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