Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Original Article

Performing sleep studies after the COVID-19 outbreak: practical suggestions from Bologna's sleep unit

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ABSTRACT

The Coronavirus Disease 2019 (COVID-19) pandemic required a thorough re-organization of every sector of the healthcare system. Sleep laboratories need to renew protocols in order to guarantee the safety of patients and healthcare staff while providing exams. Polysomnography (PSG) examinations are essential for the diagnosis and treatment management of several sleep disorders, which may constitute a public or personal safety issue such as obstructive sleep apnea syndrome. Here we provide some practical advice on how to perform sleep studies after the COVID-19 outbreak based on our experience, the review of the existing literature and current national and international recommendations by Health Authorities. We believe that with appropriate precautions it is possible to guarantee a safe restart of PSG and other sleep studies.

1. Introduction

The novel coronavirus (SARS-CoV-2) is responsible for a highly infectious respiratory syndrome that carries a considerable morbidity and mortality. Individuals may maintain high viral load in the upper airways with significant potential for viral transmission even in asymptomatic subjects [1,2]. Mainly transmitted by droplets, airborne transmission through aerosolization in the setting of certain procedures such as intubation, endoscopy, or non-invasive positive pressure ventilation is also possible [3].

The Coronavirus disease (COVID-19) pandemic started in Wuhan, China, in late 2019 and rapidly spread all over the world, requiring a thorough re-organization of every sector of the healthcare system. In areas with a high case load, like ours (northern Italy), many medical care procedures not considered immediately life-saving were postponed to avoid overcrowding of hospitals, the depletion of stocks of personal protective equipment (PPE) and the risk of further infections. This affected also sleep lab activities.

Nowadays, many countries are close to a gradual "reopening" and to resume regular hospital activity. In this phase, after a careful risk-benefit assessment, it is necessary to reschedule sleep studies giving maximal priority to patients and healthcare workers' safety [4].

Polysomnography (PSG) is the gold standard for the diagnosis of several sleep disorders, including sleep-related breathing disorders (SRBD), sleep-related seizures and parasomnias [5,6]. These conditions need prompt diagnosis and appropriate treatment as they may have serious consequences in the short and/or long term. For example, REM sleep behaviour disorder (RBD) or sleep-related hypermotor epilepsy (SHE) may be associated with violent, potentially injurious behaviours for the patient or the bed partner [7,8]; obstructive sleep apnoea syndrome (OSAS) might cause excessive daytime sleepiness that could jeopardize motor vehicle drivers and those working in the public transportation sector; moreover, it is associated with increased morbidity especially in the presence of concomitant cardiovascular risk factors such as obesity, diabetes, and dyslipidemia [9]. Furthermore, PSG is necessary for

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initiation and monitoring of continuous positive airway pressure (CPAP) treatment in patients with SRBD.

Apart from PSG, sleep laboratories perform various polygraphic assessments such as the Multiple Sleep Latency Test (MSLT) and the Maintenance of Wakefulness Test (MWT) for the evaluation of pathological sleepiness and the ability to stay awake for a defined time respectively. These studies are particularly important for diagnosis and treatment of excessive daytime sleepiness in narcolepsy, idiopathic hypersomnia, and sleep deprivation which may constitute a public or personal safety issue [10].

PSG can be performed either in the sleep lab with an attending technician, or, in selected patients, unattended by means of a portable monitoring (PM) system or home sleep apnea test (HSAT) at patients' home [11,12]. In both cases, the PSG set-up requires close and prolonged patient-technician contact. Both in attended and unattended studies in some phases of the PSG, it is not possible for the patient to wear the medical mask and the sleep technician is in close contact with the patient and potentially exposed to droplets and aerosol particles. In particular non-invasive ventilation (NIV), including CPAP, is currently listed by the WHO as a high-risk aerosol generating procedure [13].

In this article we provide some suggestions to reorganize sleep laboratory activities to ensure continuity of care while guaranteeing safety for staff and patients. There are no randomized trial data addressing these issues, thus the thoughts here reflect the review of literature, the main recommendations from International health regulatory authorities and the experience of one of the main sleep centers in Italy.

Considering the different impact of the COVID-19 pandemic between different nations and also regions within the same country, as well as the different physical locations of sleep laboratories (in hospitals versus free-standing facilities), our advice may be tailored according to national and regional legislations and local occupational health procedures/routines.

2. Methods

For the review of the literature, we searched all published English language articles on PUBMED using the following keywords or MeSH terms as appropriate: *"covid-19"* and *"polygraphy", "polysomnography", "sleep-laboratory", "CPAP", "sleep-disorders"*. We selected articles published from February 1st to June 1st 2020, finding 42 articles, of which only seven were relevant to our study.

We searched the Institutional recommendations on the websites of the World Health Organization (WHO), the European Centre for Disease Prevention and Control (ECDC), the Italian Istituto Superiore di Sanità (ISS), and the American Academy of Sleep Medicine (AASM). In addition, we checked our institutional guidelines to reduce disease transmission.

From the WHO website, we selected 8 reports in the section *Country & Technical Guidance - Coronavirus disease (COVID-19)*: 1. Critical preparedness, readiness and response actions for COVID-19; 2. Surveillance, rapid response teams, and case investigation, 3. Clinical care, 4. Infection prevention and control/WASH, 5. Guidance for health workers, 6. Maintaining Essential Health Services and Systems.

From the website of the ECDC, after filtering for the keyword *"covid-19"*, we found a total of 84 publications, including 22 data (infographic, video and poster) and 62 articles, 25 of which were technical reports dealing with public health issues in general. Only 5 of these reports were selected because relevant to our study.

From the website of the Italian ISS in the section PUBBLICAZIONI-Rapporti ISS COVID-19b we found 37 reports (seven available in English), four of which dedicated to clinical care and disinfection.

We consulted the report COVID-19 Mitigation Strategies for Sleep Clinics and Sleep Centers – REOPENING (April 27) of the AASM, the Considerations for the practice of sleep medicine during COVID-19 (Aug. 27, 2020) and Summary of CDC recommendations relevant for sleep practices during COVID-19 (Updated August 27, 2020) [14] which are based on current guidance available from the CDC in its "Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic" (updated July 15, 2020).

3. Results

3.1. Organization

3.1.1. Patient

When organizing sleep studies, medical providers should consider the balance between the potential risk of infection while performing the exam and the potential harm for patients if care is deferred on a case-by-case basis, also taking patient preferences into consideration. The potential risk of infection may differ according to the location of the Sleep Center (in hospital compared to free-standing facility). Nevertheless, precautions should be adopted in both settings.

The patient should remain in the hospital for the strictly necessary time so as to reduce the risk of infection. In order to do so, the patient is previously contacted by phone to collect general clinical information and medical documents such as previous exams reports [15,16]. Moreover, the patient must be specifically interviewed about the presence of symptoms suggestive of COVID-19 (fever, cough, shortness of breath, myalgias, acute olfactory and/or gustatory dysfunction) [17] and possible contacts with COVID-19 patients. If the patient reports symptoms suggestive of COVID-19 or has recently come in close contact with a COVID-19 patient, the exam should be postponed and the patient referred to the primary physician for proper counseling. Otherwise, the patient is informed about the current hospital policy, which, in agreement with the WHO and the ECDC recommendations, requires that the patient comes to the hospital wearing a surgical mask, performing hand sanitization and temperature check at the hospital entrance [18,19]. Patients must be provided with detailed information on how to reach the laboratory. Facilities must predispose signs, tape marks, or other visual cues such as decals or colored tape on the floor to indicate the route to follow.

Only one caregiver is admitted for non self-sufficient patients. In order to avoid overcrowding, patients will be admitted only at the time of the assessment and are not allowed to stay for long in waiting rooms [20]. Importantly, visitors are required to distance themselves of at least 1 m all the time [13].

Some hospitals require COVID-19 testing for all patients undergoing polysomnography in-house. The utility and practicalities of this procedure is still debated. Under conditions of high background prevalence, the likelihood of false negative (unrecognized cases) is expected to be higher. Therefore, even patients whose COVID-19 testing is negative should be treated with caution. In our Institute nasal swab for COVID-19 testing is required only for inpatients.

Fig. 1 summarizes the steps to perform sleep recording.

3.1.2. Healthcare staff

The staff is provided with all the necessary PPE including surgical gown, apron, gloves and face mask, in order to manage all patients as potentially infected with SARS-CoV-2 [21].

Since PSG is a potentially aerosol generating procedure, face mask FFP2 or higher (according to the European standards) or N95

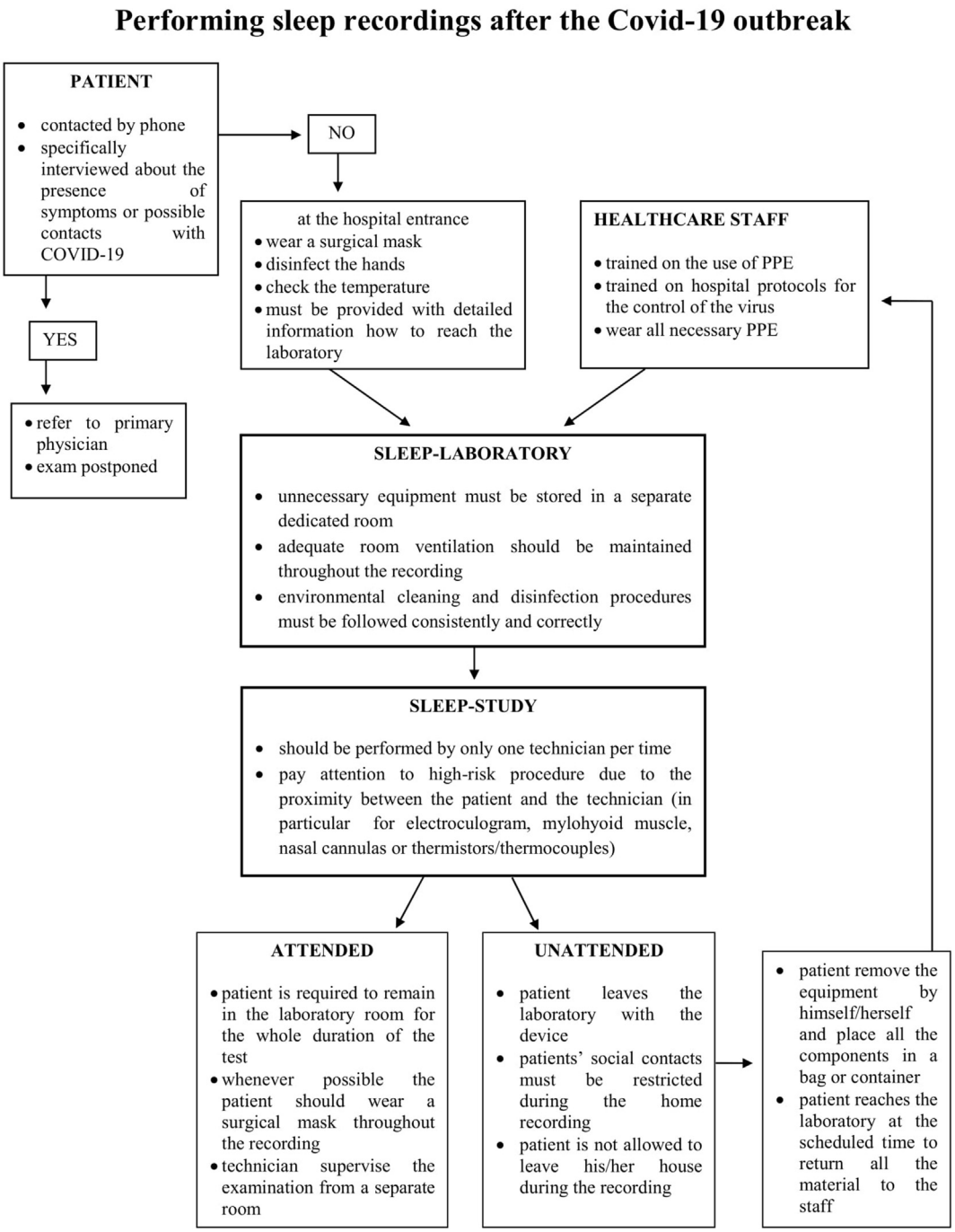

Fig. 1. Performing sleep recordings after the COVID-19 outbreak.

mask (according to the American classification) and face shield or goggles are recommended [21].

Wearing and removing PPE need to be performed following specific procedures, with the help of an assistant to avoid contamination as indicated in the ECDC Technical Report: Guidance for wearing and removing PPE [22].

All healthcare staff must be adequately trained on the use of PPE and on hospital protocols for disease control and prevention, including ambient and medical devices sanitization [23].

3.1.3. Sleep laboratory

In order to avoid overcrowding and reduce potential exposure, the laboratory room should be kept as clear as possible and unnecessary equipment should be removed. All items that cannot be removed from the room must be covered with disposable sheets.

All the equipment for PSG set-up should be stored in a separate dedicated room.

Whenever possible, adequate room ventilation should be maintained throughout the recording.

ECDC recommends that rooms where aerosol generating procedures have been performed (bag-valve ventilation, intubation, administration of nebulised medications, bronchoscopy, etc.) need to be ventilated with fresh air for 1–3 h, if they are not functioning under negative pressure, before cleaning and admitting new patient(s).

In buildings where windows do not open and the ventilation system functions in a closed circuit, high-efficiency particulate air (HEPA) filtration should be used for the recycled air. Other options may include, after expert engineering advice, placing temporary HEPA filters over the vents and exhausts in the rooms housing COVID-19 patients or using a portable HEPA air filtration system placed in close proximity to where the patient was located [24].

At the end of each recording, an adequate downtime should be allowed to ensure active or passive air change according to room specifics. During this timeframe, all the elements that have been in contact with the patient and technician are cleaned and sanitized. These include: trolleys, armchairs, bed, furniture, handles, desk, chairs and telephone [25].

Although scientific evidence has shown that coronaviruses can persist on inanimate surfaces such as metals, glass or plastic for more than 9 days, the same viruses can be effectively inactivated through surface disinfection procedures by means of 62–71% ethyl alcohol, 0.5% hydrogen peroxide or sodium hypochlorite with 0.1% active chlorine for at least 1 min. Other biocidal agents, such as 0.05%–0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate have less efficacy [26].

It is recommended checking the technical sheet of each disinfection product to use it properly and always verifying that it complies with the indications of equipment and accessories' manufacturers [27].

Particular attention must be paid to the disinfection of the reusable sensors for oronasal flow and the thermistors. The cleaning of nasal cannula entry space ("luarlock") remains an open issue as it is not accessible, but the degree of possible contamination is still questioned. For precaution, the AASM report recommends avoiding the use of non-disposable devices for at least 72 h after each use and proper sanitization [3,28].

It is important to ensure that environmental cleaning and disinfection procedures are followed consistently and correctly [29].

All the laboratories/clinics must be equipped with proper containers for PPE and disinfection products disposal. The container must be emptied after each exam and disposed of according to current regulations [30].

3.2. Sleep study set-up

PSG can be used for different diagnostic suspicions, which imply a different set-up and duration of the examination.

PSG should be performed by only one technician per time, with the exception of patients with special needs (children or non-cooperating patients) in order to minimize the number of health-care workers in the room to essential team members [31].

Patient preparation should be now performed in the examination room to avoid any unnecessary transfer through hospital facilities. In this regard, we now use EC2 EEG conductive adhesive paste for reusable EEG electrodes, because it has an optimal cost-benefit ratio in terms of recording performance and time consumption compared to collodion and does not require to move the patient to a dedicated room with gas extractor hood to apply the EEG electrodes.

The sleep technician should prepare all required materials in advance in order to minimize the time spent with the patient. Materials, if possible, must be for single use only.

Patient preparation is a high-risk procedure due to the proximity between the patient and the technician, especially for non self-sufficient patients, since it is not possible to maintain the recommended distance of >1 m [32] or >2 m [33] for a prolonged time (>15 min).

Furthermore, the application of some sensors/electrodes such as those for the electrooculogram and mylohyoid muscle requires that the patient removes the facemask. The same applies to the application of nasal cannulas or thermistors/thermocouples.

For PM, a protective film is placed around the device to avoid contact with the patient.

3.3. Sleep study recording

3.3.1. Attended studies

Nocturnal and diurnal PSG, MSLT and MWT are highly complex procedures that require a prolonged stay in the recording rooms with close contact between technician and patient. The patient is required to remain in the laboratory room for the whole duration of the test.

We advise performing the recordings with video-monitoring in order to allow the technician to supervise the examination from a separate room and intervene only when strictly necessary.

Whenever possible the patient should wear a surgical mask throughout the recording. During night sleep recording, patients could find it difficult to wear the facemask, however it is advisable as the attending technician might need to enter the recording room and interact with the patient on several occasions.

Regarding CPAP titration, if possible the patient should be placed in isolation rooms with negative pressure (at least 12 air changes per hour), a dedicated bathroom and an anteroom. If negative pressure rooms are not available, choose rooms with natural ventilation with airflow of at least 160 $L \cdot s^{-1}$ per patient [34].

Different studies investigated the infection control measures when managing patients with respiratory infectious diseases. *Hui* et al. showed that coughing without wearing a mask produces an exhaled air jet on a median sagittal plane of 68 cm; wearing a surgical mask reduces this distance to 30 cm, while wearing a N95 mask the distance was reduced to 15 cm [35]. Using different masks probably produce different exhaled air dispersion [36].

In order to protect patients that in the diagnostic phase use the hospital reusable devices (CPAP, APAP etc.) disposable masks, connection tubing, filters, and water chambers are used once per patient. To reduce the possibility of aerosolization viral filters should be installed on the exhaust tubing of the in-lab PAP devices [37]. These filters, which work with a mechanical and electrostatic mechanism of action, must have a viral filtration efficiency of 99.999% for each particle of 0.027 microns and should have a cumulative 24 h duration of use during ventilation in the same patient. They must be changed between one patient and another. The use of humidifiers shall be suspended.

Furthermore it is necessary to put particular attention to the maintenance of the devices (respiratory circuits, masks).

Each laboratory is invited to contact the manufacturer of the CPAP and APAP for the procedures of disinfection and consider a period of "quarantine" for the devices as the AASM suggests for HSAT devices.

Specific precautions employed for aerosol generating procedures are not necessary for MSLT and MWT, whereas the rest all apply.

3.3.2. Unattended studies

In the current medical emergency, unattended studies are preferable whenever it is possible to perform them instead of attended studies. In any case, the same precautions adopted for the in-hospital assessments regarding patient and instrumental management should be applied.

In unattended studies, after the set-up, the patient leaves the laboratory with the device and is instructed to go straight home

avoiding intermediate stops. We recommend that patients' social contacts be restricted during the home recording and relatives avoid coming in contact with the equipment. In addition, the patient is not allowed to leave his/her house until the end of the recording, usually the day after, when the patient reaches the laboratory at the scheduled time to return all the material without delays.

We advise the patient to remove the equipment by himself/herself, placing all the components in a sealed bag or container provided by the laboratory.

The same procedures can be applied also for actigraphy for the assessment of adult patients with sleep-wake circadian rhythm disorder or suspected insufficient sleep syndrome.

4. Discussion

PSG is indispensable for diagnosis and treatment management of several sleep disorders, which constitutes a public or personal safety issue. The COVID-19 pandemic created great difficulties and halted the activities of many sleep laboratories around the world. We are facing now the need to reschedule sleep laboratory activity considering the past months missed appointments and future needs.

At the beginning of the pandemic outbreak, some authors suggested stopping CPAP unless medically necessary to support life [38,39] whereas others underlined that interrupting CPAP treatment for the entire epidemic duration should not be recommended [40]. In this controversial scenario it is possible to imagine an increased need for re-titration after months of CPAP non-use, even though some authors reported improvement in CPAP adherence during the COVID-19 lockdown [41].

With the appropriate precautions, it is necessary to guarantee a safe restart of all PSG examinations for both the patient and the staff.

Here we identify the potential risk of exposure of healthcare staff to patients in this environment and provide some useful practical suggestions based on literature review and our experience to conduct sleep studies safely.

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Conflict of interest

Dr. Provini reports personal fees from Vanda Pharmaceutical, Sanofi, Zambon, Fidia, Bial, Eisai Japan, Italfarmaco, all not relevant to the submitted work. The other Authors have no disclosures.

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