Diagnostic and surgical innovations in otolaryngology for adult and paediatric patients during the COVID-19 era

Innovazioni diagnostiche e chirurgiche in otorinolaringoiatria per i pazienti adulti e pediatrici durante l’era COVID-19

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SUMMARY

During the Coronavirus Disease 2019 (COVID-19) pandemic, otolaryngology has been shown to be a high-risk specialty due to the exposure to aerosol-generating physical examinations, procedures and surgical interventions on the head and neck area, both in adult and paediatric patients. This has prompted the issue of updating the guidelines by International Health Authorities in the Ear Nose and Throat (ENT) field and, at the same time, has stimulated engineers and healthcare professionals to develop new devices and technologies with the aim of reducing the risk of contamination for physicians, nurses and patients.

Methods. A review of the literature published on PubMed, Ovid/Medline and Scopus databases was performed from January 01, 2020 to December 31, 2021.

Results. 73 articles were eligible to be included, which were subdivided into 4 categories: (“Artificial Intelligence (AI)”; “Personal Protective Equipment (PPE)”; “Diagnostic tools”; “Surgical tools”).

Conclusions. All of the innovations that have been developed during the COVID-19 pandemic have laid the foundation for a radical technological change of society, not only in medicine but also from a social, political and economical points of view that will leave its mark in the coming decades.

KEY WORDS: COVID-19, SARS-CoV-2, otolaryngology, adult, pediatric, technology

RIASSUNTO

Durante la pandemia da COVID-19, l’otorinolaringoiatria ha dimostrato di essere una delle specialità a più alto rischio di contatto con le malattie virali a trasmissione aerea, a causa dell’esposizione a procedure generanti aerosol sul distretto testa-collo, sia sul paziente adulto che pediatrico. Questo ha rappresentato il punto di partenza per un’emanazione di nuove linee guida da parte delle Società scientifiche internazionali, ma ha anche stimolato l’inventiva di tecnici e operatori sanitari nello sviluppare nuovi dispositivi e tecnologie per ridurre il rischio di contaminazione per gli operatori sanitari e per il paziente.

Metodi. È stata eseguita una revisione della letteratura dal giorno 1 gennaio 2020 al 31 dicembre 2021 utilizzando i database di PubMed, Ovid/Medline e Scopus. I risultati sono stati selezionati 73 articoli e raccolti in 4 categorie differenti (“Intelligenza Artificiale”; “Dispositivi di Protezione Individuale”; “Strumenti diagnosticci”; “Strumenti chirurgici”).

Conclusioni. Le innovazioni sviluppate durante la pandemia da COVID-19 hanno posto le basi per una trasformazione in ambito tecnologico di tutta la società, non solo da un punto di vista medico ma anche da un punto di vista sociale, politico, ed economico, riflettendosi in una trasformazione che segnerà la mentalità dell’intera popolazione mondiale per i prossimi decenni.

PAROLE CHIAVE: COVID-19, SARS-CoV-2, otorinolaringoiatria, adulto, pediatrica, tecnologia
Introduction

Amongst all healthcare specialists, otorhinolaryngologists are especially increased risk of COVID-19 infection due to their exposure to aerosol-generating physical examinations, procedures and surgical interventions on the head and neck area, in both adult and paediatric patients. In addition, while the adult patient is more manageable because of his vaccinated status and general compliance, paediatric patients are even more hazardous to the healthcare worker because they are less compliant and more inclined to cry and cough, and because they may not be wearing face masks.

Therefore, in order to minimise the spread of SARS-CoV-2 spread during everyday practice, several protective measures have recently been developed. We conducted a review of the literature with the aim of describing the strategies – especially technological innovations – that have been adopted to mitigate viral transmission during the COVID-19 pandemic in ENT clinical practice.

Methods

We reviewed the literature to identify innovations that have been developed for the management of the ENT patient during the COVID-19 pandemic era. English-language papers and abstracts published on PubMed, Ovid/Medline and Scopus databases were examined from January 01, 2020 to December 31, 2021, according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Fig. 1). Our search was based on the following key-words: “innovations, COVID-19, otolaryngology”; “innovations, COVID-19, ENT”; “COVID-19; otolaryngology”; “COVID-19, ENT”; “COVID-19 pediatric ENT surgery”; “COVID-19, masks”; “otolaryngology, masks”. The latest interventions, techniques, diagnostic and surgical solutions were evaluated according to the Oxford Center for Evidence Based Medicine (EBM) criteria.

Results

The search performed on PubMed, Ovid/Medline and Scopus databases has yielded 1483 English-language abstracts and papers. Based on the titles and abstracts, we selected innovations about: upper airways’ Personal Protective Equipment (PPE); diagnostic and surgical devices in laryngology and head and neck surgery, rhinology and skull base surgery, audiology and ear surgery; Artificial Intelligence (AI) related devices employed during the COVID-19 pandemic in the ENT specialty. Therefore, we excluded papers whose title and abstract were unrelated to these topics. After narrowing the search according to our topic of interest, 73 articles were eligible to be included in our review. These articles were subsequently divided into 4 categories: 4 papers were included in “Artificial Intelligence (AI)”; 26 papers were included in “Personal Protective Equipment (PPE)”; 11 papers were included in “Diagnostic tools”; 33 papers were included in “Surgical tools”. One article was cited twice because it contained some innovations that we selected to be included both in “Personal Protective Equipment (PPE)” plus “Diagnostic tools”.

Discussion

Artificial Intelligence (AI)

During the COVID-19 pandemic, we have witnessed significant development and diffusion of innovative tools – already available to the general population – which have played a positive role in health communication by raising awareness of health status and safety of the healthcare provider and patient. They substantially contributed to behavioural changes, i.e. increasing cognition of seriousness, susceptibility, action clue and self-efficacy. All of this was achieved through the use of social media and videogame platforms.

Jiang conducted a study on college students using “Plague Inc.”, an infectious disease-themed, simulation game developed in 2012 by Ndemic Creations® for Iphone Operating Systems and Android Systems, based on Centers for Disease Control and Prevention algorithms. He successfully demonstrated how a videogame can help gain deeper understanding of factors influencing infectious disease out-
breaks, improve knowledge and educate both healthcare personnels and the general population.
Murri et al. 5 have shown that, as the COVID-19 pandemic unfolded, health professionals turned to rapid communication media (i.e. Facebook groups, Whatsapp and Telegram chats, Twitter feeds) more than to official academic sources in an attempt to seek information and update their scientific knowledge. This has the potential to spread misinformation and distrust towards public health authorities.

At the same time, during the pandemic, machine learning and deep learning-based AI technology have improved medical equipment and workflow to minimise contacts with patients 6, enabling healthcare workers to make more efficient and safer clinical decisions. This was implemented thanks to: wearable devices with patients’ GPS data on Wi-Fi, 5G and Bluetooth technologies (cardiac and respiratory wearable sensors); Internet of Things systems-based remote screening (color-coded patient severity identification, facial recognition, smartphone applications for screening); intelligent diagnostic systems for neural networks and digital image processing technology (chest X-rays and CT images); remote intensive care to reduce unnecessary patient-doctor contacts.

Furthermore, Wang has proposed the use of a remotely-controlled, low-cost microrobot for nasopharyngeal swab sample collection 7, replacing medical staff and therefore limiting aerosol and droplet contamination for healthcare workers.

All of these technologies can help solve not only staff shortage, but also limit healthcare-related rising costs and waste, reaching a safety level that may go beyond Personal Protective Equipment (PPE), since they are able to minimize contact with the infected patient (Tab. I).

**Personal Protective Equipment (PPE)**

This is the richest chapter of innovations that has been proposed during lockdown and, more extensively, during these two years of the COVID-19 pandemic; it also plays a fundamental role against future airborne infectious disease outbreaks in the field of otolaryngology.

A survey on performing in-office otolaryngology procedures during COVID-19 pandemic 8 showed gloves and masks are the most commonly used types of PPE by ENT specialists. Another international survey noted a significantly higher use of powered air-purifying respirators (PAPRs) in high-risk aerosol-generating medical paediatric procedures 9. In fact, health authorities recommend that every diagnostic procedure needs to be performed on patients who are possibly or certainly infected with COVID-19 should take place in Negative Pressure Rooms (NPRs) wearing full PPE. However, PAPRs and NPRs may not always readily available in healthcare facilities.

To overcome this limitation, Sayin et al. 10 presented a closed chamber unit for ENT examination during aerosol-generating endoscopic examinations, allowing for communication between the examiner and patient to take place thanks to a Bluetooth speaker in the room, with the negative pressure blocking aerosol dissemination. Other authors 11 have modified a liftable, protective methacrylate shield to enclose the whole ENT examination chair, with holes placed in the front, allowing the ENT specialist to introduce his hands and equipment.

A smaller airway-isolating system, called COVID-19 Airway Management Isolation Chamber (CAMIC) 12 covering the patient’s head and chest area, aims at creating an internal negative pressure generated by an aspiration mechanism. This device consists of a polyvinyl chloride hollow frame with fenestrations, with a suction vacuum line and a contralateral air supply line (Fig. 2). Its strong barrier allows the creation of a safer environment for noninvasive upper airway management. A negative-pressure plastic cover with a smoke evacuator and high-efficiency particulate air (HEPA) filtration unit 13 was tested for patients needing tracheostomy. For the same purpose, other authors have developed an external fixator equipment made up of a metal frame wrapped with a sterile plastic cover 14.

For the paediatric patient, protective acrylic boxes have been developed to perform microlaryngoscopy and bronchoscopy, containing aerosolised respiratory secretions

**Table I. Artificial Intelligence's core elements.**

| Artificial Intelligence (AI) | Key point |
|-----------------------------|-----------|
| Innovations                 | Platforms and technological devices are able to promote a rapid – often real-time – spread of relevant information and minimize interhuman contacts, thus reducing the contamination risk related to airborne infections during the present and future public-health crises |
| Simulation games            |           |
| Social media                |           |
| Wearable devices            |           |
| Internet of Things          |           |
| Intelligent diagnostic systems |           |
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HEPA filters, PAPRs, N95s and other PPEs used to protect team members during aerosol-generating medical procedures can negatively affect communication, increasing noise levels and listening effort in ENT operative rooms. Therefore, either repurposing operative room team members’ headsets and cellphones towards a conference call or using an in-ear communication device has been shown to be an effective strategy to facilitate communication.16,17

For in-office examinations, given the potential for airborne conjunctival transmission, wearing enhanced PPE plays a pivotal role in ensuring physicians’ individual safety during the COVID-19 pandemic. Notwithstanding, eye protection may often be neglected by ENT specialists. It has been demonstrated that the addition of either safety goggles or glasses to an upward-facing face shield are able to decrease the risk of eye contamination during cough.18

More importantly, enhanced PPE devices can successfully be integrated to everyday ENT practice tools, such as headlights. Namely, standard headlights were modified so as to provide better protection for the healthcare provider. Some authors have succeeded in doing so by using a 3D-printed adaptor that is able to generate a protective barrier through a transparent sheet. Another headlight-related innovation is represented by a custom-made clear laminated shield that should be directly fixed to the headlight, functioning as a barrier between the examining ENT specialist and the patient.11

Despite being less comfortable to wear, face masks remain the first-line defense device for every airborne infection, as

Figure 2. CAMIC polystyrene hollow frame: (A) CAMIC architecture; (B) CAMIC assembled frame; (C) CAMIC on the surgical bed, viewed from above; (D) CAMIC on the surgical bed, viewed from below (from Blood et al., 2021).
they are able to guarantee safety of healthcare personnel and the general population even when facing potential COVID-19 future variants of concern. Convissar et al. 20 assembled a reusable makeshift filter mask, called Modified Airway from VentilatoR Circuit (MAVerIC), starting from an adult anaesthesia breathing circuit with HEPA filters, a facemask and a rubber head strap, with or without an eye protection. MAVerIC is able to filter 99.7% of particles ≥ 0.3 microns.

3D-printed adaptors have represented another great innovation for PPEs, whose potential has been exploited both on their own, as an interface between elastomeric respirators and anaesthesia circuit filters 21 or together with masks. One of the most affordable examples is represented by the use of snorkeling masks (Fig. 3). Thierry et al. tested the EasyBreath snorkeling mask with an upper adaptor connected to a filter, which greatly increased surgeons’ visual comfort and safety 22.

Different models of modified full-face snorkeling masks were tested by Vicini et al. during ENT surgical procedures 23.

On the other hand, a cheaper, cost-effective innovation, is represented by a reusable half-face respirator, the Sundstrom SR 100 respirator, routinely used in industrial settings to filter gas and vapour particulates 24.

The COVID-19 pandemic has marked the rise of 3D-printing technology, especially for endoscopy masks, thus allowing ENT specialists to use rigid and flexible endoscopes during in-office evaluations. Davies et al. 25 studied a stereolithographic 3D-printed nasal endoscopy mask with a side port for connection to supplemental oxygen or inline ventilation filter. Two types of endoscopy masks have been tested, both reusable and disposable, which were effective in preventing diffusion of large droplets after a simulated cough.

Another 3D-printed mask was tested – first on mannequins and then on human volunteers – by Ference et al. 26,27 (Fig. 4). It is an Aerosol Containment Mask with an

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**Figure 3.** A modified snorkeling mask: (A) EasyBreath® mask with an adaptor and a filter; (B) EasyBreath® mask with dive lights and lower adaptor (from Thierry et al., 2020 22).
N-95 respirator filter and two frontal ports to support the passage of a rigid or flexible endoscope or suction. Other authors have developed a modified ENVO® mask by SleepNet, which uses suction to create a negative-pressure environment in the nasal and oral cavity of the patient during laryngoscopy 28.

Hoffman et al. 29 proposed a new model for a negative-pressure face shield with controlled access to the nose and mouth. Alternatively, a standard endoscopy face mask has been altered to allow the passage of a flexible laryngoscope by fashioning a 3-mm slit with a scalpel 30. For flexible endoscopy, other authors 31 developed patient-worn enhanced protection face shields. The fibreoptic endoscope was inserted into stellate openings, obtaining a barrier against aerosolised particles. To limit airborne contamination, Curran et al. 32 proposed the use of a low-cost device made up of an anaesthetic closed facemask, anaesthetic filter, and DAR (Covidien) connector with a reusable harness attachment for CPAP.

Lastly, the idea of making a hole in a surgical mask worn by the patient must be limited to children, since according to some authors the use of a pre-prepared modified mask for the paediatric patient with a hole for the scope should also be considered to cover the nose and the mouth during the endoscopy depending on the age and compliance of the patient 33 (Tab. II).

**Diagnostic tools**

During lockdowns, some healthcare workers asked parents to monitor their children’s throat using smartphone cameras 34. These digital tools have also been successfully used on adults and were deemed to be convenient by patients and reliable by doctors 35. However, to avoid difficulties in evaluation and diagnostic errors, digital photo shooting must follow strict rules, i.e: the patient needs to position himself in front of the mirror with optimal room lighting and setting flash to forced mode; 16:9 image ratio and highest resolution; horizontal format to cut all unnecessary facial features (nose, eyes, forehead, etc.); use of the back camera without digital zoom and audible indicator when shooting 36.

It may be something of an understatement, but whenever in-office fibrolaryngoscopic examination is required, it should be performed not by using the endoscope lens, but with a camera and monitor so as to maximise the distance between the patient and examining physician 33. This holds

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**Table II.** Personal Protective Equipment’s core elements.

| Personal Protective Equipment (PPE) | Innovations                                                                 | Key point                                                                 |
|------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------------------------------------|
| **Innovations**                    | Environmental isolation (powered-air purifying respirators, negative pressure rooms, closed chamber examination unit, chair shields) | Isolation methods play a fundamental role in the reduction of contamination related to airborne infections |
| **Patient isolation**              | Patient isolation (head and chest shields, face shields, plastic covers and protective boxes with HEPA filters, endoscopy masks) |                                                                           |
| **Healthcare personnel isolation** | Healthcare personnel isolation (N95 masks, eye protection, headlight shields, filter masks, snorkeling masks) |                                                                           |

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**Figure 4.** An aerosol containment mask for endoscopy: (A) mask architecture; (B) mask on patient; (C) patient undergoing endoscopy (from Ference et al., 2021 27).
especially true for paediatric patients, given their higher propensity to cough and cry along with less compliance. As an alternative to the traditional approach, the so-called “back approach to the patient” 37, where during the endoscopic examination the specialist positions himself behind the patient facing the monitor, may represent a simple yet effective solution to decrease healthcare professionals’ exposure to viral particles.

Sciancalepore et al. 38 have tested the accuracy of transcutaneous laryngeal ultrasonography (TLUSG) for vocal fold mobility assessment, which was a noninvasive alternative to fibrolaryngoscopy during COVID-19 pandemic given its ability to screen for vocal fold paralysis without aerosol-generating procedures, especially in patients undergoing thyroidectomy. A further step to this approach may be telerobotic ultrasound examination 39 which, despite being more time-consuming, is safer for healthcare professionals and a valid alternative to diagnose patients who cannot go to the hospital.

Lockdowns have marked the rise of digital USB-otoscopes (DUO), of which different models – even unexpensive ones – have been developed by companies all over the world. They can be connected to smartphones to visualise the auditory canal and tympanic membrane, thus allowing self-monitoring 40, even on children 41. Even though more professional otoscopes have been developed, such as Smartphone-Enabled Wireless Otoscope (SEWO) 42 to be employed during telehealth consultations, and many patients have found these devices ready and easy-to-use, physicians reported that they would not feel comfortable using the images for diagnosis or to defer an in-person examination 43 (Tab. III).

**Surgical tools**

During the COVID-19 pandemic, rather than tool-related surgical innovations, we witnessed a rethinking of surgical approaches and choices of techniques and instruments, with the purpose of minimising the risk of contamination. Indeed, health authorities in the ENT field have tried to face the evolving viral outbreak by rapidly developing specific guidelines to ensure the safety of both patients and healthcare professionals. The common ground to all guidelines, both for adult and paediatric patients 44, is to defer to a later date every procedure, except those that are deemed to be emergent and/or whose management and prognosis is time-sensitive, i.e: urgent/emergent cases that could require surgery; surgery for acute airway obstruction; prompt diagnosis of suspected cancer; surgical intervention for sepsis following initial first-line medical management. Other recommendations include the suggestion of letting procedures to be done by the most skilled surgeons and the use of open approaches rather than endoscopic ones, with the aim of reducing time of exposure both for patients and clinicians 45.

As far as pre-surgical anaesthesia is concerned, general anaesthetic procedures should preferably be switched to local ones. However, when intubation is necessary, shortening peri-procedural aerosolisation and pausing to allow for aerosol dispersion may be useful 45. In addition, as just the act of intubating COVID-19 positive patients is considered to be at high risk of viral transmission; we witnessed the development of innovative devices to protect healthcare professionals from particle aerosolisation.

A tracheostomy should be performed on a careful case-by-case indication, and key technical modifications become necessary. In particular, the use of myorelaxants helps to reduce the risk of cough-generated particle diffusion 46. Due to the high viral aerosolisation risk, other devices have been developed and can be adapted to the neck and chest of the patient through a plastic envelopment, with holes allowing the specialist to manoeuvre surgical tools 47-49. Other authors 50 have tested a negative airway pressure respirator (NAPR) system to protect health care workers. When suction was applied to the NAPR, no particle escape was noted. Another study tested a specific protocol to avoid droplet contamination during unsecured airway procedures independently from COVID-19 test results, consisting in the use of a surgical tent surrounding the patient. An ultrafiltration smoke evacuator is secured to the drape on the patient’s chest 51. Continuous suction should be placed near the operating field 52.

To reduce the risk of viral transmission, it is advisable to

| Table III. Diagnostic tools’ core elements. |
|-------------------------------------------|
| **Diagnostic tools**                      |
| **Innovations**                           |
| Smartphone cameras                        |
| USB otoscopes                             |
| New endoscopic approaches to the patient  |
| Transcutaneous laryngeal ultrasonography  |
| **Key point**                             |
| The use of modern video tools with diagnostic purposes and the adaptation of alternative approaches and diagnostic tools significantly contributes to reduce contact between the healthcare worker and the patient, proving to be effective in minimizing airborne contamination risk |
employ viricidal substances perioperatively; in particular, pre-operative hypertonic solution (< 5% NaCl) irrigations have been shown to improve mucociliary clearance. Alternatively, 0.23-7% povidone iodine – whose efficacy had already been reported for Severe Acute Respiratory Syndrome Coronavirus 1 (SARS-CoV-1) and Middle East Respiratory Syndrome Coronavirus Infection (MERS-CoV) – was confirmed to be an optimal choice during SARS-CoV-2, even in paediatric patients. The use of these substances as nasal and oropharyngeal washings both for the patient and for healthcare professionals has been suggested before and after surgical interventions performed on subjects on patients who are possibly or certainly infected with COVID-19. Povidone iodine irrigations have also been suggested for every procedure where drilling is involved, such as mastoidectomies.

During surgery, the employment of adhesive dressings on nasal and oral cavities is recommended to reduce particle diffusion. The same has also been demonstrated for ear surgery: the use of a barrier drape (so-called OtoTent) significantly reduced particulate dispersion. International guidelines also recommend to minimise – whenever possible – the use of surgical electrical instruments, such as drills, electrical and diathermic devices, in order to avoid biological particle aerosolisation. The risk of viral spread following drilling or CO₂ laser ablation-derived smoke is well established in every ENT surgical subspecialty, i.e. head and neck surgery, nose and skull base surgery and ear surgery. Therefore, during the COVID-19 pandemic, the use of coarse or cutting burs, irrigation, handheld suction, or additional suction becomes of crucial importance.

Among the few truly innovative devices that were conceived during the lockdown, Hoffman et al. tested laser plume containment for diagnostic and operative transnasal potassium-titanyl-phosphate laryngoscopy for biopsy in local anaesthesia. The device – developed by the University of Iowa – consists of a negative-pressure face shield installed on a camera stand with two frontal access ports and a lateral suction port. The suction system was a standard wall suction for all the diagnostic laryngoscopies and a portable one for laser and biopsy procedures.

As far as nasal and skull base surgery is concerned, other authors have created a modified Vent Mask, using a surgical mask with the finger of a non-latex glove, to allow passage of an endoscope, with significant reduction of aerosolisation. This solution was only tested on a cadaver model. In another cadaver model, the authors tested a suction mitigation system of airborne particulate generated during sinonasal drilling and cautery, with a rigid suction placed in the contralateral nostril. Another study tested the efficacy of SPIWay® Endonasal sheaths to reduce particle dispersion caused by nasal drilling. When a flexible suction was inserted together with the SPIWays, no aerosols were spread during drilling. Others have introduced the Negative-pressure Otolaryngology Viral Isolation Drape (NOVID) system to reduce the risk of aerosolisation; it consists of a plastic drape suspended above the patient’s head and surgical field with a smoke evacuator suction (Fig. 5). In another study, a low-cost, modifiable and easily producible negative pressure face-mounted antechamber was developed utilising 3D printing and silicone moulding to effectively reduce aerosolisation from endoscopic drilling without disturbing the flow of the operation.

Lastly, in ear surgery, a COVID-19 Airway Management Isolation Chamber (CAMIC) Ear system was tested by using a schedule of Poly-Vinyl Chloride pipes with holes in order to create a hollow frame with fenestrations to facilitate vacuum suction (Fig. 6, Tab. IV).

**Conclusions**

In conclusion, the COVID-19 era has significantly strengthened the application of many innovations that were considered routine in our everyday life, even in the non-medical field. Moreover, it has contributed to empower
both patients and healthcare workers on the relevance and correct use of PPEs to such an extent that it represents the most important chapter of the innovations that were developed during these past two years. Rethinking customary diagnostic and surgical approaches can minimise the risks related to airborne viral transmission. However, these novelties in the diagnosis of upper airway diseases – by reducing interhuman contact – may affect the human dimension of care in the doctor-patient relationship. All these innovations developed during the COVID-19 pandemic represent a true revolution, triggered by the fast-paced evolution of biomedical technology, in an attempt to create something that is able to face the multifaceted challenges in every field of medicine. Consequently, a radical mindset and changes in approach has affected every specialty, and especially in otolaryngology. The pandemic has influenced the development of artificial intelligence-based tools available to the general population, becoming a powerful surge of social, political and administrative change. These are able to influence medicine behind the scenes, while supporting its growth in the coming decades.

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The authors declare no conflict of interest.

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**Authors’ contributions**
PP, EB, CM and MLF: design of the work, data collection, data analysis and interpretation; drafting the article; critical revision of the article, final approval of the version to be published; RA, PIS, ADM, PD, CR, VDC and MM: acquisition of data, analysis and interpretation of data, critical revision of the article.

**Ethical consideration**
Ethical review and approval was not required for the study. All review procedures have been performed in accordance with the requirements of the World Medical Association’s Declaration of Helsinki.

**Availability of data and materials**
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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