Original Article

The Italian coronavirus disease 2019 outbreak: recommendations from clinical practice

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Summary

Novel coronavirus 2019 is a single-stranded, ribonucleic acid virus that has led to an international pandemic of coronavirus disease 2019. Clinical data from the Chinese outbreak have been reported, but experiences and recommendations from clinical practice during the Italian outbreak have not. We report the impact of the coronavirus disease 2019 outbreak on regional and national healthcare infrastructure. We also report on recommendations based on clinical experiences of managing patients throughout Italy. In particular, we describe key elements of clinical management, including: safe oxygen therapy; airway management; personal protective equipment; and non-technical aspects of caring for patients diagnosed with coronavirus disease 2019. Only through planning, training and team working will clinicians and healthcare systems be best placed to deal with the many complex implications of this new pandemic.

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Introduction

Novel coronavirus 2019, also named 2019-nCoV, is a single-stranded, enveloped ribonucleic acid virus responsible for producing an influenza-like syndrome [1]. The virus emerged in December 2019 in the Hubei region of China and led to an exponential outbreak in the city of Wuhan [2]. Due to the nature of pulmonary symptoms, the virus was renamed severe acute respiratory syndrome-related coronavirus-2 (SARS-CoV-2) and the consequent disease named coronavirus disease 2019 (COVID-19) [3, 4]. The clinical presentation following human infection ranges from a mild upper respiratory tract infection, commonly accompanied by fever (82%) and cough (81%), to severe acute respiratory distress syndrome and sepsis. The consequences can be lethal, particularly in the elderly or those with comorbidities such as hypertension, cardiac failure and diabetes [5]. The reproduction number (R_0) of COVID-19 is currently thought to be 2.68 (95%CI 2.47–2.86), which is more than double that of seasonal flu [6], suggesting it is highly contagious. This is, in part, affected by transmission of the virus from asymptomatic patients [7]. It is estimated there are more than 245,484 confirmed cases globally, and the case fatality rate is estimated to be in the region of 4.68% [8].

Beyond the impact on individual patients, the potential consequences of COVID-19 on local, national and international healthcare systems are significant. Data from the SARS outbreak suggest that 21% of cases were healthcare providers [9]. Similar patterns have emerged for those managing patients with COVID-19 with provisional estimates from the Italian outbreak of 9.1% [10]. The ramifications of losing significant proportions of frontline healthcare workers remain uncertain, but this may contribute to the collapse of healthcare systems affected by COVID-19 [11]. Other contributing factors include: difficulty containing spread of the disease; difficulties triaging emergency department patients; a shortage of appropriate care environments (e.g. isolation areas) and personal protective equipment (PPE); difficulties determining the level of care required or appropriate; and insufficient critical care beds to meet surging demands [12, 13]. All measures must therefore be taken to minimise risks to healthcare delivery, particularly in maintaining the pool of healthcare workers that are able to manage the significant population of critically ill patients expected, as has recently been seen in many areas of Italy.

Airway management represents one of the most critical aspects of supportive therapy for patients with COVID-19, and there are suggestions that early invasive intervention is advisable to minimise further transmission. However, some airway management techniques pose a significant risk of disease transmission to healthcare workers. During the COVID-19 outbreak in Italy, clinical experiences led to the development a national framework to optimise airway management strategies for patients with, or suspected to have, the disease. We report the current impact on healthcare infrastructure as well as the fundamentals of critical care management of patients during the COVID-19 outbreak in Italy.

The Italian COVID-19 outbreak

Italy has the highest number of cases (41,035) and deaths (3405) due to COVID-19 in Europe and is second globally as of 20 March 2020 (Table 1) [14, 15]. The Italian healthcare system is one of the most well-developed systems globally. Despite this, the recent COVID-19 outbreak found the country unprepared to cope with the impact of the COVID-19 pandemic. Despite: early responses from institutions; declaring a state of national emergency on 31 January 2020; implementing limits on public gatherings affecting schools, conferences and sport events; and healthcare restrictions in public places [16], the number of new cases continues to increase. Each region of the country faces similar and significant direct and indirect healthcare system challenges.

Although the World Health Organization (WHO) issues regular updates about disease transmission and the proper use of PPE, the reality, as noted from the same WHO report, is that such a large-scale outbreak has resulted in a shortage of PPE for healthcare providers [17]. Consequently, frontline healthcare staff, including physicians and nurses, have become infected or exposed and thus quarantined. This shortage of PPE and experienced clinicians has meant that less experienced doctors and residents have been recruited for clinical care. The biggest challenge remains the risk of a collapse of the healthcare system due to difficulty in triaging, allocation, and a shortage of high-level care beds. Italy is ranked in the top 10 in Europe for the number of critical beds per 100,000 capita of population (12.5), which is higher than the European average of 11.5 beds per 100,000 and the UK with just 6.6 beds per 100,000 [18]. The burden on critical care capacity in Italy must be considered in this context.

Extreme measures have already been undertaken, including: closure of hospital wards; restricting visitor access to hospital; identification of external triage areas; dedicated patient transport and isolation pathways; and cessation of elective surgery, with only emergency, trauma and selected oncological surgery proceeding. Notably,

Table 1 COVID-19 mortality rates for different patient baseline characteristics groups. Data on 25,058 diagnoses with 1697 associated total deaths. Median age 63 y, 59.7% male patients. Current as of 16/03/2020 [58]. Values are number (proportion).

Age; years	Cases	Case mortality
≥80	4636 (18.5%)	892 (52.5%)
70–79	5123 (20.4%)	602 (35.5%)
60–69	4438 (17.7%)	144 (8.5%)
50–59	4734 (18.9%)	46 (2.7%)
40–49	2995 (12%)	9 (0.5%)
30–39	1676 (6.7%)	4 (0.2%)
20–29	970 (3.9%)	0 (0%)
10–19	186 (0.7%)	0 (0%)
0–9	121 (0.5%)	0 (0%)
Unknown	179 (0.7%)	0 (0%)

COVID-19, coronavirus disease 2019.

operating rooms are allocated as emergency critical care beds and anaesthetists have been re-allocated to critical care management and rapid response emergency care, including dedicated COVID-19 emergency teams to assist patients in non-critical care settings. In terms of public health, several measures have been implemented, including: the use of telemedicine consultations; domestic isolation of COVID-19 patients who are not severely unwell; production and distribution of educational videos and television segments; and firm restrictions against public gatherings. Most recently, much of northern Italy had a quarantine imposed, affecting up to 16 million residents [19], and on 11 March 2020, all Italian territories were identified as 'red zones' by the Government, with firm restrictions on any public activity [20].

The acuity of the epidemic burden on healthcare infrastructure has also led to the identification of certain hospitals as 'COVID-19 sanatoriums,' and we forecast a possible future of 'COVID-19 positive' and 'COVID-19 negative' hospitals. Finally, there has been activation of military forces to construct field hospitals with bio-containment level resources. The role of anaesthetists and intensivists has been critical, complex and dynamic. They have been directly responsible for the early clinical management of critically ill patients, and have faced the hardest task of undertaking critical, ethically and psychologically disrupting triage, unavoidable though it may be. To support clinicians with these ethical decisions, The Società Italiana di Anestesia Analgesia Rianimazione e Terapia Intensiva (SIAARTI) produced guidance on clinical management and triage during the crisis [21].

Clinical management

Specific aspects of COVID-19 patient care distinguish it from routine clinical practice (Table 2). In these settings, there are factors that must be considered for: oxygen administration and non-invasive ventilation of the spontaneously ventilating patient; airway management of the patient requiring tracheal intubation; clinical management with PPE; and human factors.

Oxygen administration

Given the aggressive pulmonary involvement associated with COVID-19, the requirement for non-invasive or invasive oxygen therapy is likely. All oxygen administration strategies in the spontaneously ventilating patient carry risks of aerosolisation and disease transmission. Hudson and Venturi masks, nasal cannulae and helmets, carry a lower-risk of transmission when compared with high-flow nasal oxygen and non-invasive ventilation with facemasks or hoods [22]. Data from the SARS [23] and MERS [24] outbreaks cautioned against the use of high-flow nasal oxygen or non-invasive ventilation, although this has recently been countered by data demonstrating no increased dissemination of bacteria with high-flow nasal oxygen, yet viral spread remains unexplored [25]. As well as the potential risk of viral aerosolisation and the need for careful isolation precautions, non-invasive ventilation may also be insufficient to manage COVID-19-induced respiratory failure, and preliminary observations from the current Italian outbreak suggest there may be a poor response to non-invasive ventilation [3, 23, 25–27].

Delaying avoidable tracheal intubation may be beneficial [28], but delaying unavoidable tracheal intubation is a significant concern [27]. Invasive ventilation is associated with reduced aerosolisation and is thus safer for staff and other patients. That said, it might also be associated with hypoxia, haemodynamic failure and cardiac arrest [29, 30] during tracheal intubation, and a risk of staff exposure to high viral load secretions, given that the very act of tracheal intubation is associated with the greatest risk of exposure to healthcare professionals [31]. Patient triage based on expected prognostic outcomes has become increasingly important. Thus, early tracheal intubation is encouraged, as late or emergency tracheal intubation in rapidly deteriorating patients may be associated with greater risks, both to patients and healthcare professionals.

Ethical burden and moral distress have been emerging factors in the Italian outbreak, like that already seen in Wuhan. Invasive ventilation must account for available personnel and critical care beds, which have become rapidly saturated as our daily experience is showing, with

Table 2 Clinical aspects of COVID-19 patients during the Italian outbreak. Preliminary observations based on data from Gruppo Italiano per la Valutazione degli Interventi in Terapia Intensiva; http://giviti.marionegri.it).

Typical patient characteristics	
Age	60–70 years
Sex	Male
Most common comorbidity	Obesity
Typical investigation findings	
Procalcitonin	< 0.15 ng.ml^{-1} (normal)
Brain natriuretic peptide	< 100 pg.ml^{-1} (normal)
Creatine phosphokinase	Elevated, particularly in younger patients
Albumin	Reduced
Lymphocytes	Reduced
Chest X-ray features	Bilateral interstitial pneumonitis
CT chest features	Parenchymal and interstitial involvement
Lung ultrasound	Diffuse B-lines may indicate those who respond to high PEEP. Anterior lung regions aerated or posterior atelectasis may indicate those who respond to prone positioning
Possible treatments and therapies	
Antiretrovirals	Lopinavir or ritonavir
Other agents	Choroquine or hydroxychloroquine
Antibiotic prophylaxis	Piperacillin/tazobactam or ceftriazone or trimethoprim/sulfamethoxazole
Secretion management	N-acetylecysteine
Other pharmacological agents	Corticosteroids or immune suppression, for example, tocilizumab
Sedation	Deep
Ventilation	Lung-protective ventilation with high PEEP. Compliance is usually good.
Neuromuscular blockade	Deep, particularly during prone positioning
Fluid balance	Negative
Positioning	Consider up to seven cycles of prone positioning
Extracorporeal membrane oxygenation	Rarely used, but might be considered for those unresponsive to conventional ventilation
Renal replacement therapy	Challenging

COVID-19, coronavirus disease 2019.

650 COVID-19 patients in critical care settings in Italy on 8 March 2020 [32]. Alternatives to tracheal intubation might reduce the demand on critical care beds. Multidisciplinary evaluation, co-operation and decision-making are strongly advised during this evolving and highly dynamic crisis.

Airway management

Protocols and experiences in airway management for this and other coronavirus outbreaks [3, 23, 33–35], as confirmed by our ongoing experience in Italy, is a necessity to rigorously prepare for airway management. This includes utilisation of cognitive aids such as checklists, cross-checking and pre-planned and explicitly defined airway management strategies [36]. Any airway management procedure should be managed electively rather than as an emergency, and any means to maximise first-pass success should be adopted. Procedures should be performed in a negative pressure chamber (if available) or isolation area that is equipped with a replenished, complete and checked emergency airway trolley. Entry and departure of staff from the immediate clinical area must be strictly monitored and restricted to those who are required. Thorough airway assessment should guide clinicians to determine the safety of asleep tracheal intubation, rather than awake tracheal intubation (ATI) [37, 38]. Clinicians must note that ATI is potentially a highly aerosol-generating procedure, thus the decision to undertake ATI must be carefully considered.

Tracheal intubation

Patients with COVID-19 are at risk of rapid arterial oxygen desaturation, and therefore effective pre-oxygenation is mandatory. After pre-emptive optimisation and correction of haemodynamic disturbances, pre-oxygenation with a fraction of inspired oxygen of 1.0 for at least 3 min at tidal volume breathing or eight vital capacity breaths should be carried out [39]. Rapid sequence intubation is indicated for all cases to minimise the apnoea time during which significant aerosolisation can occur with facemask ventilation. Therefore, facemask ventilation should only be performed gently in the event of critical arterial oxygen desaturation [40]. In order to maximise first-pass success and not compromise optimal ventilation (if needed), cricoid force should not be performed, unless there are other indications [41, 42]. Apnoeic oxygenation is recommended to prevent desaturation [43], ideally with low-flow nasal oxygenation during tracheal intubation attempts. Despite the benefits of high-flow nasal oxygen [44], it is an aerosol-generating technique, particularly when the airway operator is in close proximity to the patient, and should be avoided.

Cautious administration of general anaesthetic agents is recommended to minimise haemodynamic instability, and rocuronium 1.2 $mg.kg^{-1}$ or suxamethonium 1 $mg.kg^{-1}$ should be given to ensure rapid onset of neuromuscular blockade, maximise first-pass success [45] and prevent coughing and associated aerosolisation. Neuromuscular monitoring is advisable. The most skilled and experienced airway operator should perform airway instrumentation, and all conditions should be optimised to ensure the highest chance of first-pass tracheal intubation success. We strongly recommend the use of a videolaryngoscope, which would ideally be disposable but with a separate screen to minimise patient contact. Pre-loading an appropriately-sized tracheal tube on an introducer is also advised, as this may also improve the first-pass success rate [46].

In the event of a failed tracheal intubation, gentle manual ventilation may be used, followed by a maximum of two attempts at tracheal intubation (with consideration of change in position, device and technique between attempts). After two failures, or any time if a rescue airway is needed, a second generation supraglottic device is strongly advised. Supraglottic airway devices that allow flexible bronchoscopic intubation are preferable [47]. An early emergency front-of-neck airway (surgical or percutaneous cricothyroidotomy) should be considered before a 'cannot intubate, cannot oxygenate' scenario independently of critical arterial oxygen desaturation [36].

If ATI is indicated, [37, 38], an experienced operator should perform it [48, 49] and administration of intravenous sedation may minimise coughing [50]. Aerosol or vaporised delivery of local anaesthesia should be minimised, and consideration given to the use of mucosal atomisers, swabs and tampons, and if clinical expertise permits, nerve blocks. Ultrasound-guided techniques could be adopted, though they might be time-consuming and carry challenges in terms of decontamination. Single-use flexible bronchoscopes should be used as they are associated with a reduced risk of cross-contamination [51], and a separate screen is strongly advised. The diameter of the tracheal tube should be the smallest appropriate to reduce the risk of tube impingement on the arytenoids with consequent coughing. Awake tracheal intubation with videolaryngoscopy is faster than with flexible bronchoscopy and could be considered [52]. In the event of failed ATI, tracheostomy with local anaesthesia is a viable alternative and must be considered, despite the potential for aerosolisation [31]. Should a 'cannot intubate, cannot oxygenate' scenario occur, an emergency front-of-neck airway should be performed with the aforementioned principles.

Emergency tracheal intubation may be required for COVID-19 patients. This setting increases risks to patients and healthcare workers and is often performed outside of the operating theatre or intensive care environment. However, the acuity of airway management should not compromise the safety of clinicians, and thus team members must have PPE donned before commencing airway management. This could require the delivery of gentle facemask ventilation in a hypoxic patient to buy time for the patient and treating clinicians. Principles of airway management in emergencies are like those in more controlled settings.

After successful tracheal intubation, careful management of the tracheal tube is crucial. Auscultation is not advisable due to the challenges with PPE and the risk of cross-contamination [23], but confirmation of tracheal tube placement should ideally rely on viewing the tracheal tube pass through the vocal cords, with an appropriate and repeated capnographic trace and chest wall movement. All of the aforementioned considerations need to be adopted for tracheal tube exchange manoeuvres, and strategies for protected extubation should be addressed, especially after prolonged tracheal intubation or documented difficult airway management [53]. High-efficiency particulate air filters should be placed between the primary airway device and the breathing circuit, including the expiratory limb of the circuit once the patient is connected to the ventilator [54]. To prevent viral dispersion, unnecessary respiratory circuit disconnections are discouraged. If disconnection is required, patient sedation should be optimised to prevent coughing, the ventilator should be turned to stand-by mode and the tracheal tube clamped (Fig. 1).

Non-technical skills

The management of patients with COVID-19 places additional physical and psychological burdens on healthcare workers. Physical burdens include repeated donning and doffing of PPE and physical restrictions to routine practice due to PPE. Psychological burdens include: management in unfamiliar environments; communication challenges with PPE; and changes to standard practice. Identification of suitable environments for airway management, team briefing and co-ordination, task assignment and briefings, team training and the use of checklists and cognitive aids are all crucial to reduce physical and cognitive work-loads (Fig. 1).

To reduce physical risks, consideration of predefined roles and ergonomics is imperative. There should be an independent practitioner observing the donning and doffing of PPE [23, 55]. Only the most experienced healthcare workers with full PPE should be present inside the isolation chamber. Suggested team assignments, utilised in our clinical practice during this current crisis, include an inner isolated chamber and an outer chamber (Fig. 2). In the isolated chamber, all staff should have full PPE donned. Outside of the chamber, additional PPE and other members of staff are available.

Personal protective equipment

Coronaviruses are typically found in the lower respiratory tract linked with angiotensin converting enzyme receptors, with the primary mechanism of transmission through contact and droplet spread of respiratory secretions, which

Figure 1 Società Italiana di Anestesia Analgesia Rianimazione e Terapia Intensiva guidance on airway management of the patient with coronavirus disease 2019.

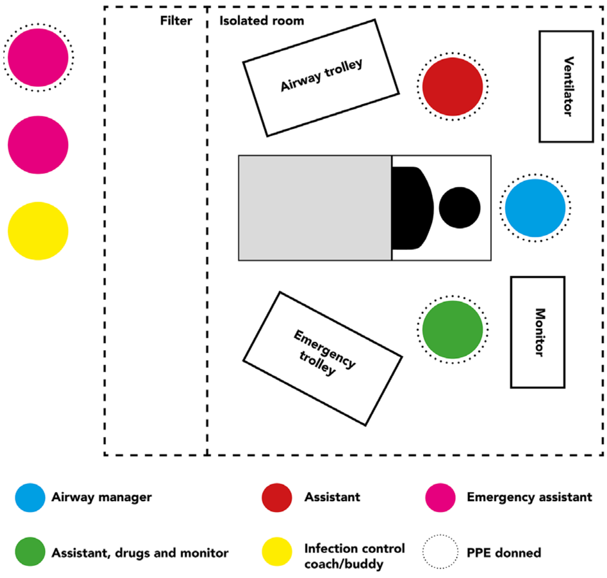

Figure 2 Suggested team roles and ergonomics for elective tracheal intubation.

Table 3 Filtering face piece (FFP) protection levels. FFP2, N95 and FFP3 masks are recommended for the management of COVID-19 patients.

Filter standard	Filter capacity (removal percentage of all particles ≥ 0.3 µm
FFP1	80%
FFP2	94%
N95	95%
FFP3	99%
N100	99.97%

COVID-19, coronavirus disease 2019.

travel up to 2 m [10]. The importance of PPE cannot be overstated, but clinicians must also be aware that effectiveness is rarely 100% [3]. Moreover, experiences in Italy have demonstrated that supplies of PPE are unlikely to meet demand, thus the use of centralised storage and distribution of PPE is recommended as well as considering the preparation of dedicated PPE kits in keeping with WHO recommendations [17].

One of the key supply restrictions is that of appropriate filtering face piece (FFP) masks. These are different to conventional masks such as surgical masks as they create a facial seal, filtering the air with different filter capacities (Table 3). Although 2019-nCoV has a size of 0.06–0.14 µm, the virus is carried with droplets that are larger than 0.3 µm, and therefore facial respirator masks with a filter against particles sized > 0.3 µm are appropriate.

The levels of protection for airway management in COVID-19 patients adopted in most of hospitals in Italy are either second- or third-level PPE, preferring the use of airborne-level PPEs for critical care aeorsol-generating procedures, including tracheal intubation, bronchoscopy and ATI. So far, the outbreak-related global PPE shortage has forced the use of lower-protection PPEs for aeorsol-generating procedures. Airborne-level protection should include: helmets, covers or hoods; FFP3 or FFP2/N95 masks, goggles or face shields (if no helmets); hazmat suits or long sleeved fluid-resistant gowns; double gloves (possibly different colours); and overshoes. Whenever possible, the maximum available protection level should be used, especially for aeorsol-generating procedures.

Donning and doffing of PPE should be practiced and when performed clinically, an external observer should supervise its meticulous performance in accordance with checklists [23]. In our experience, PPE donning and doffing presents the greatest challenge to daily working. In particular, doffing of PPE, especially when clinicians are tired and cognitively overloaded, is associated with the greatest risk of contamination. Team members should doff PPE individually and one at a time. Cycles of thorough hand disinfection must be undertaken and supervised, and meticulous waste disposal must be completed.

Transport

Local protocols should be designed for post-procedural transport of patients with PPE and biocontainment procedures strictly adhered to [55]. This must factor staff and public safety during transport.

Briefing, debriefing and training

Pre-procedural briefing and post-procedural debriefing are mandatory to review errors and determine improvements for future practice. Team-based simulation and training remains critical throughout the evolution of this pandemic, involving any level of healthcare professionals [56]. The development of local protocols and checklists, development and adoption of dedicated early warning scores [57], and accounting for regional variation in practice, is strongly recommended given the number of clinicians involved, as well as the risks to healthcare professionals.

Conclusion

We have faced many challenges with the onset of the COVID-19 outbreak throughout Italy and it is likely that other countries will face similar challenges in the coming weeks and months. We have shared systemic and clinical knowledge and experiences gained during the course of the Italian outbreak, with the aims of educating and supporting clinicians elsewhere in the global healthcare community who may face similar scenarios. Only with appropriate informed planning, training and team working will healthcare systems be best placed to face this new pandemic.

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