Tracheotomy in COVID-19 Positive Patients - "New Normal" Workflow of Tracheotomy in the Era of SARS/COVID-19 Pandemic A Systematic Review

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March 30, 2022

Abstract

Introduction With the COVID-19 pandemic, a "new normal" on how surgeons and intensivists perform tracheotomy in COVID-19 patients is essential. We aim to summarize the recommendations and present the supporting evidence of these recommendations. Methods A search of published works on tracheotomy, tracheostomy, COVID-19, novel coronavirus, SARS-CoV-2 was performed on PubMed/MEDLINE/Cochrane Library. Articles relevant to the practice of tracheotomy on patients with COVID-19 were selected. The articles were then reviewed and divided into 4 key categories: 1) Personal protective equipment (PPE) in COVID-19 positive patients, 2) Adjunctive measures of airway management before definitive intervention in COVID-19 positive patients; 3) Timing of tracheotomy in COVID-19 positive patients; and 4) Perioperative considerations in performing tracheotomy in COVID-19 positive patients. Results and key points Firstly, enhanced PPE is recommended during tracheotomy of COVID-19 positive patients. Secondly, adjunctive airway management before definitive intervention includes the use of high flow nasal cannulas (HFNC). Thirdly, non-invasive ventilation via continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines are not recommended. Fourth, the general consensus suggests that timing of tracheotomy should be at least 10 days after intubation. Finally, percutaneous dilatational tracheotomy (PDT) is likely to be associated with a lower risk of transmission of the virus to healthcare workers (HCW) than a surgical tracheotomy (ST). Other key precautions would include minimizing the use of diathermy. Conclusions The "new normal" workflow summarizes the ideal recommendations across published societal guidelines. Enhanced PPE should be recommended whenever possible. Adjunctive measures before definitive intervention of COVID-19 patients should be limited to the use of HFNC, and CPAP/BiPAP should be avoided. Tracheotomy should be performed after 10 days, although the long term sequelae of tracheal stenosis and pulmonary fibrosis should be ascertained with this approach.

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A Systematic Review

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Word count: 2969

No funding was obtained for this study.

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Title

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A Systematic Review

Key points

Question

What is the ideal workflow and practice for tracheotomy in COVID-19 positive patients to reduce healthcare worker exposure?

Findings

Different tracheotomy workflows and practices across various guidelines and publications were systematically reviewed. Enhanced PPE and percutaneous dilatational tracheotomy were recommended, with timing of tracheotomy after 10 days being preferred.

Meaning

Current tracheotomy workflows and practices are summarized in the management of COVID-19 patients. A consolidated tracheotomy workflow is presented.

Abstract

Importance/Background

With the COVID-19 pandemic, a "new normal" on how surgeons and intensivists perform tracheotomy in COVID-19 patients is essential.

Objective

We aim to summarize the recommendations and present its supporting evidence.

Evidence Review/Data sources/ Study appraisal and synthesis methods

A search of published works on tracheotomy, tracheostomy, COVID-19, novel coronavirus, SARS-CoV-2 was performed on PubMed/MEDLINE/Cochrane Library. Articles relevant to the practice of tracheotomy on patients with COVID-19 were selected, then reviewed and divided into 4 key categories: 1) Personal protective equipment (PPE) in COVID-19 positive patients, 2) Adjunctive airway management measures before definitive intervention in COVID-19 positive patients; 3) Timing of tracheotomy in COVID-19 positive patients; and 4) Perioperative considerations in performing tracheotomy in COVID-19 positive patients.

Findings/Results

Enhanced PPE is recommended during tracheotomy of COVID-19 positive patients. Adjunctive airway management before definitive intervention includes use of high flow nasal cannulas (HFNC). Non-invasive ventilation via continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines are not recommended. Timing of tracheotomy should be at least 10 days after intubation. Percutaneous dilatational tracheotomy (PDT) is likely associated with lower transmission risks to healthcare workers (HCW) than surgical tracheotomy (ST). Other key precautions include minimizing diathermy use.

Limitations/Conclusions and Relevance

The "new normal" workflow summarizes ideal recommendations across published societal guidelines. Enhanced PPE should be recommended whenever possible. Adjunctive measures before definitive intervention of COVID-19 patients should be limited to the use of HFNC, and CPAP/BiPAP should be avoided. Tracheotomy should be performed after 10 days, although the long term sequelae of tracheal stenosis and pulmonary fibrosis should be ascertained with this approach.

(250 words excluding headings)

Text

Introduction

The emergence of the SARS-CoV-2 virus has led to a worldwide pandemic with close to 100 million confirmed cases of COVID-19 reported, and over 2 million deaths in approximately 200 countries. Increasing evidence shows sustained human-to-human transmission, with high numbers of exported cases internationally given the highly globalized world. Based on the initial experience of COVID-19 outbreak in China, the estimated infection rate of HCWs is around 4%. (1) This is despite strict adherence to full PPE measures among HCWs. Our prior knowledge of the SARS outbreak in China showed a mortality rate of 1.4% among the 966 HCWs afflicted with SARS. (2). However, in European countries such as Italy, 20% of responding HCWs were infected, making up 3% of cases.

While the mortality rate of COVID-19 lies between 2-4% (1, 3), which is lower than the case fatality rate of SARS at 11%, a significant percentage of patients may still require tracheotomy. This is because COVID-19 positive patients can potentially develop severe pneumonia and acute respiratory distress syndrome (ARDS).

Faced with uncertain prospects of airway management in confirmed or suspected COVID-19 patients, we reviewed the literature regarding tracheotomy in COVID-19 positive patients on several aspects. COVID-19 is likely to co-exist with us for many years to come, and hence we also propose a new normal workflow for tracheotomy in COVID-19 positive patients, with a summary of the existing literature.

Methods

This systematic review was conducted according to PRISMA guidelines. The literature search was performed on PubMed, MEDLINE and Cochrane Library including keywords: tracheotomy, tracheostomy, COVID-19, novel coronavirus, and SARS-CoV-2. Studies included were published between January 1, 2020 and May 24, 2020. Our inclusion criteria also encompassed societal guidelines, expert consensuses, recommended protocols, surgical checklists and papers sharing surgical experiences in tracheotomy in COVID-19. All other papers, such as those discussing perceptions and medical training, were excluded. An English language

restriction was applied as well. Abstracts were independently reviewed, and for those studies fitting the inclusion criteria on the basis of the title and abstract, the full-text was retrieved and reviewed. Reference lists were also examined for any additional relevant studies not identified through the former search. A flow chart diagram of the search strategy and study selection is provided in Figure 1.

Results

The database search yielded 71 citations published between January 1, 2020 and May 24, 2020 (with duplicates removed). 4 articles were excluded based on our exclusion criteria, 1 of which was due to not having an available full text in English. The full text of potentially relevant articles was retrieved for further evaluation. The final number of papers taken into account was 67. After analysing the selected articles, a systematic review of literature was done.

17 articles were society guidelines, recommendations, expert consensuses, surgical considerations or experience regarding tracheotomy in COVID-19 positive patients. 18 papers discussed the surgical considerations of tracheotomy during the COVID-19 pandemic.

11 papers were case series or case reports while 7 papers were comment articles. 3 papers presented frameworks for tracheotomy in COVID-19. 8 papers discussed novel approaches to tracheotomy. 3 papers were literature reviews of airway management procedures in patients with COVID-19.

The contents covered by the included articles were then divided into 4 key categories for analyses (with the findings summarised in Tables 1-5): 1) PPE in COVID-19 positive patients, 2) Adjunctive measures of airway management before definitive intervention in COVID-19 positive patients; 3) Timing of tracheotomy in COVID-19 positive patients; and 4) Perioperative considerations in performing tracheotomy in SARS-COV-2 positive patients. Where necessary, the grade of recommendation was reviewed by the level of evidence.

PPE recommendations (Table 1)

Appropriate use of standard PPE was sufficient in preventing infection spread to HCWs during SARS, and is also likely to be sufficient during the era of COVID-19. (4, 5) However, enhanced PPE is recommended to minimise the risk of transmission to HCWs. Beyond that, medical personnel should be familiar with procedure guidelines, with all PPE available for immediate usage, hence minimising risk of acquiring the infection during airway management.

P100/N100 masks are not recommended in standard PPE due to their cumbersome nature, and can be substituted by N95 masks in enhanced PPE when used simultaneously with powered air purifying respirators (PAPR). Whole-body barrier suits may be used in enhanced PPE due to additional neck and lower leg coverage, but difficulty in removal leading to improper doffing increases risk of cross-contamination of surroundings and infection of HCWs. All HCWs should be trained to don and doff PPE carefully without contaminating hands or clothes, with careful hand washing before and after.

In enhanced PPE, the risk of leakage with PAPRs is negligible. Unlike reusable elastomeric respirators and N95 masks, there is no need for a fit test or additional eye protection as the head is completely enclosed.

Adjunctive measures before definitive intervention of COVID-19 patients (Table 2)

Non-invasive ventilation such as HFNC has been utilized widely in COVID-19. Initial high flow oxygen should be given immediately for patients with obvious respiratory distress or weak cough ability. In the University of Chicago, HFNC combined with prone positioning have shown remarkable results in the treatment of COVID-19 patients in respiratory distress. In patients who are clinically stable, a lower oxygen flow can be started, gradually increasing the oxygen flow if necessary. The use of HFNC could pre-emptively prevent patient deterioration, hence avoiding intubation and mechanical ventilation. A surgical mask should also be worn by the patient to reduce the risk of virus transmission through droplets or aerosols. However, it should still be noted that elderly patients are vulnerable for failed HFNC, requiring other intervention such as intubation in order to maintain respiratory requirements.

Although CPAP/BiPAP machines units with an exhalation filter could theoretically support SARS/COVID-19 patients with respiratory failure, there is a high incidence of CPAP/BiPAP mask leak which may result in inadvertent leak of aerosolized virus. If used out of appropriate airborne/droplet isolation, there are increased transmission risks. CPAP/BiPAP machines may also lead to delayed deterioration in patients, resulting in a greater incidence of emergent intubations. Hence, CPAP/BiPAP machines should be avoided in patients with COVID-19 and should only be considered in appropriate airborne/droplet isolation settings on a case by case basis.

Timing of tracheotomy in patients with COVID-19 (Table 3)

Currently, most guidelines for tracheotomy in the era of the COVID-19 pandemic recommend that tracheotomy be delayed until at least 10 days after intubation, citing reasons such as high transmission risks to HCWs and increased mortality. (6) (Table 3) However, the decision for tracheotomy should be based on the clinical indications of the patient. This is because appropriate PPE is adequate in reducing the risks of transmission to HCWs. Clinical indications for tracheotomy among COVID-19 patients should hence remain largely similar to previous guidelines for patients needing prolonged intubation. A tracheotomy should be done when patients cannot be intubated or ventilated, or when prolonged (longer than 14 days) mechanical ventilation is required.

Tracheotomy may also be delayed depending on the patient's condition. Current guidelines from the French Intensive Care Society and the French Society of Anaesthesia and Intensive Care Medicine do not recommend tracheotomy being done when there is severe hypoxemia (PaO2/FiO2 less than 100mmHg or positive end expiratory pressure (PEEP)>10cmH2O). (7) Instead, the patient should be intubated until their condition stabilises. The need for tracheotomy can then be reassessed. Furthermore, if the patient meets weaning targets (FiO2 less than 40%, PEEP < 8, PaO2/FiO2 > 200, pressure support < 8 cmH_2O), extubation could be reached between 7 and 14 days and tracheotomy should be postponed. (8)

Surgical tracheotomy vs percutaneous dilatation tracheotomy in COVID-19 patients (Table 4)

PDT is preferred over surgical ST for COVID-19 patients due to lower transmission risks from a shorter procedure, reduced number of HCW being exposed during the procedure, decreased spillage of patient fluids, and reduced risk of aerosol generation.

In the era of SARS/COVID-19, the operating theatre (OT) is the ideal setting for ST. However, transfer to OT may increase transmission to HCWs. Exposure of an infectious patient throughout the hospital would also place transport staff at risk of infection. While ST can also be performed in the intensive care unit (ICU), the smaller ICU rooms may restrict movement of surgeons. Patient positioning on a pneumatic ICU bed is difficult because patient anatomy sinks away from surgeon with any manipulation. Beyond that, ICU beds are usually wider than usual OT tables, making it ergonomically difficult for the surgeon to reach the patient. Hence, performing ST in an ICU room is technically more challenging than in the OT. On the other hand, PDT can be performed conveniently at the patient bedside. This reduces the number of HCWs exposed to the infectious patient, as there is no contact with any transport or additional OT staff.

ST is also a longer procedure than PDT, resulting in a longer period of time HCWs are in close contact with the patient. ST will also lead to greater spillage of blood and secretions than PDT, hence resulting in a higher transmission risk. (9) However, it should be noted that PDT typically requires real time bronchoscopy followed by bronchoscopic confirmation of puncture into trachea, as well as ETT withdrawal prior to puncture. These may result in an aerosol leak and possible mode of transmission of the virus to HCWs.

Therefore, PDT has been recommended over ST if there are no contraindications (such as goiter, poorly palpable laryngeal landmarks), or if an emergency tracheotomy needs to be done. (10)

Perioperative considerations during tracheotomy of COVID-19 patients (Table 5)

Tracheotomy is a procedure which generates aerosols and should be performed in negative-pressure isolation environments. Additionally, closed airway circuits can prevent aerosol leakage, and should be used except

during controlled suctioning of the trachea. Antiviral/high efficiency particulate air filters (HEPA) (e.g. Medtronic ventilator filters) should be used at all times on ventilators during the clinical care of COVID-19 patients. There should be two filters per ventilatory circuit, one between the ventilator and its expiratory port as well as another on the exhalation outlet of ventilator.

Diathermy should be avoided in tracheotomy as much as possible. There is currently limited literature with regard to diathermy during tracheotomy but coagulation with diathermy can produce small particles that may act as a vehicle for the virus. While there are currently no reports of virus incubating in muscles, the risk of increased viral aerosolization cannot be completely ruled out. Surgical ties should considered instead, especially when ligating the thyroid isthmus to expose the trachea. Tracheotomy tube change should be delayed post-tracheotomy, with the cuff kept inflated, in-line suction used, and avoidance of circuit disconnection. This should be performed preferably when the patient is no longer positive for COVID-19.

Discussion

Despite the best medical care, tracheotomy may be inevitable among a small cohort of patients (6-13%) with severe COVID-19 associated pneumonia and/or ARDS. (11) A tracheotomy confers less work of breathing when compared to breathing through an endotracheal tube (ETT), offering less resistance than the thermoliable ETT which can deform the upper airway, increasing ventilatory requirements. The lower resistance and improved secretion clearance via a tracheotomy may also facilitate weaning off the ventilator. Successful weaning of patients off ventilators is likely to be beneficial in preventing complication such as ventilator associated pneumonia. This would facilitate earlier transfer out of ICU, and potentially freeing up precious bed space for another patient who requires it. This is important in the era of SARS/COVID-19, where judicious use of ICU resources is paramount in managing a viral pandemic.

Looking at the overview of PPE recommendations, the consensus among various articles has been fairly uniform in their recommendations of at least standard PPE when dealing with COVID-19 positive patients, with enhanced PPE being preferred whenever available. Recommendations regarding adjunctive measures prior to definitive intervention have also been congruent. Non-invasive ventilation devices such as CPAP/BiPAP are discouraged, whereas HFNC use has been shown to potentially circumvent rapid respiratory deterioration in COVID-19 patients.

There is limited literature on the optimal timing for tracheotomy among patients with severe viral associated pneumonia with ARDS. Additionally, existing studies and guidelines do not distinguish between the various indications of tracheotomy in an ICU setting, and formalizing a specific guideline on timing of tracheotomy will be based on anecdotal evidence in the context of COVID-19 patients and ARDS patients.

Growing evidence has shown that the need for tracheotomy should be assessed daily. Proponents of an early tracheotomy argue that unnecessary delays in tracheotomy among patients with prolonged endotracheal intubation risk the development of post-intubation tracheal stenosis of between 10-22%. Additionally, around 1 to 2% of these patients develop symptomatic tracheal stenosis. (12) In one study among ARDS patients who had open-lung biopsy performed after 5 days of ventilation, around half (53%) demonstrated significant pulmonary fibrosis on histopathology. (13) These observations suggest that a decision for tracheotomy in COVID-19 positive patients with ARDS should be considered as early as within 4 to 7 days after intubation, so as to prevent excessive prolonged intubation when the chance of weaning off the ventilator is low. Hence, while the general consensus remains that tracheotomy among COVID-19 positive patients should be delayed beyond 10 days (table 3), a reasonable approach is to consider a tracheotomy within 10 days when these patients show no signs of improvement such as decrease in oxygen requirement or PEEP. We are also cognizant of the fact that despite clinical indications guiding us, other overarching considerations such as the variability of ICU bed availability between different countries and institutions may play a greater role in influencing a clinician's decision to do an early tracheotomy if there is a shortage of these beds during a surge of COVID-19 cases.

New recommendations have also been made to potentially help reduce the risk of aerosol generation in tracheotomy. One paper suggested pushing the endotracheal tube beyond the site chosen for the tracheal

stoma at the beginning of the procedure during ST. (14) Three papers proposed the use of a transparent surgical shield. (15) One new PDT technique was to place the bronchoscope alongside the endotracheal tube and not inside it, while another study offered sealing the bronchoscope with an in-line suction sheath. (16) Another modified PDT technique described the use of a smaller ETT cuffed at the carina. A fibre-optic bronchoscope was also inserted between the tube and the inner surface of the trachea. With this method, the authors reported improved airway management, respiratory function, patient comfort, and reduced risk of transmission to staff. (17) Another paper also presented the use of a novel negative-pressure aerosol reduction cover. (18) However, these new techniques presented have only been performed on a small number of patients, and more evidence needs to be presented before adopting these techniques into our "new normal" workflow. It is also important to note that despite the advantages of PDT, complications such as post-procedural hemorrhage may still have to be emergently sent to the OT for hemostasis. This may not give adequate time to optimise infection control considerations enroute to OT, such as ensuring a transport route clear of hospital staff and patients, leading to higher virus transmission risks as compared to an elective ST.

Currently, testing for COVID-19 positivity is performed using a Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) based pharyngeal swab for SARS-CoV-2 virus. Based on reports, this RT-PCR based test has a high specificity and sensitivity in SARS-CoV-2 detection, making it the gold standard. Additionally, performing this RT-PCR based test using bronchoalveolar lavage fluid (BALF) samples has the highest sensitivity when compared to sputum (88.9% in severe cases and 82.2% in mild cases), nasopharyngeal (73.3% in severe cases and 72.1% in mild cases) and oropharyngeal samples (60.0% in severe cases and 61.3% in mild cases). (19) Despite this added sensitivity, obtaining BALF samples is invasive and is associated with higher transmission risks. (19) Preoperative negative swabs have the advantage of allaying fears of the airway team during airway procedures such as tracheotomy; although a full PPE with PAPR donning are still required as per contact with any suspect COVID-19 patients. As there remains a small chance of a false negative result from a pharyngeal swab (17-28%) test, healthcare personnel should not be complacent when performing tracheotomy in a previously COVID-19 positive patient as the risk of exposure to any remaining virus in the lower airway is still possible.

As COVID-19 is highly infectious and likely to persist globally for an extended period of time, modifications to the existing tracheotomy workflow are necessary. Combining the assimilated findings from our review, we propose a new workflow incorporating a series of recommendations aimed at minimising the risk of transmission to HCWs. (Figure 2)

Limitations of this review include the lack of high quality articles investigating our study parameters, with most of the available articles included in our systematic review being level 4 to 5 evidence studies. This is likely due to the novel nature of COVID-19, and more prospective studies validating the "new normal" workflow are warranted. Furthermore, many of the included studies primarily look at the immediate management of COVID-19 positive patients requiring tracheotomy, and longer term outcomes of these patients are required in order to refine this "new normal" workflow.

Conclusion

The "new normal" workflow summarizes the ideal recommendations across published societal and institutional guidelines. This systematic analysis shows that enhanced PPE should be recommended where available. Adjunctive measures before definitive intervention of COVID-19 patients should be limited to the use of HFNCs. Tracheotomy is recommended to be performed after 10 days; although the long term sequelae of tracheal stenosis and pulmonary fibrosis with this approach need to be followed up.

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Table 1: PPE for HCWs during tracheotomy

Standard PPE	Enhanced PPE
Waterproof cap	Waterproof cap
Goggles with an anti-mist screen	Goggles with an anti-mist screen
N95 masks - effective in filtering 99.5% of the particles larger than 0.75 μm	N95/P100/N100 masks
Transparent plastic full facial shield (worn outside the goggles and N95 mask)	Powered air-purifying respirators (worn out
Impermeable operating room surgeon's gloves – double layers	Impermeable operating room surgeon's glov
Impermeable operating room surgeon's gown	Impermeable operating room surgeon's gow
Plastic shoe covers	Plastic shoe covers

Table 2: Adjunctive measures before definitive intervention of COVID-19 patients

Type of adjunctive measure	China experience	Chicago experience	California experience	Canada experience (20)
High flow nasal cannulas	Recommended	Recommended	Not discussed	Not discussed
CPAP/BiPAP	Not recommended	Not recommended	Not recommended	Not recommended

Table 3: Timing of tracheotomy in COVID-19 positive patients

Timing of tracheotomy	Global and multidisciplinary guidance (21)	China experience
Society	Experts from renowned medical centers globally	Tongji Medical College, Beijing To
Quality of evidence	4	5
Early tracheotomy (before 10 days)	?	??
Late tracheotomy (after 10 days)	?	??
Late tracheotomy (after 14 days)	?	??
Late tracheotomy (after 21 days)	?	??
No recommended timing		Performed as last resort
Negative COVID-19 testing	?	
Not to perform tracheotomy[1]		

[1] Not to perform tracheotomy in infectious patients unless intubation does not provide adequate airway

? Recommended

? Not recommended

??No recommendation

NIL/Not discussed

Table 4: Surgical tracheotomy vs Percutaneous dilatational tracheotomy

Aspect	Aspect	Open surgical tracheotomy	Percutaneous dilatational tracheotomy (minimally invasive tracheotomy)
General outcomes in all patients	Wound infection	+++ (Pooled odds ratio (OR) for wound infection was 0.28 (95% confidence interval, 0.16 to 0.49, $p < 0.0005$), indicating a significant reduction with PDT compared to ST (10).)	+
	Bleeding, mortality	++	+
Ideal setting	Ideal setting	OT	Easy execution at patient's bedside
Length of procedure	Length of procedure	++	+ (9)
Spillage of blood and secretions	Spillage of blood and secretions	+++ (9)	+
Incomplete paralysis of patient leading to aerosol generation	Incomplete paralysis of patient leading to aerosol generation	+++	+
Aerosol generation during procedure	Aerosol generation during procedure	++	+
Safety during difficult anatomy (short neck, morbid obesity, limited neck extension, local malignancy, tracheal deviation)	Safety during difficult anatomy (short neck, morbid obesity, limited neck extension, local malignancy, tracheal deviation)	+++	+

+ low risk

++ moderate risk

+++ high risk

Table 5: Perioperative considerations during tracheotomy in COVID-19 positive patients

Precautions	Global and multidisciplinary guidance (21)
Society	Experts from renowned medical centers globally
Level of evidence	4
PPE	Enhanced
Swab before tracheotomy	
Negative pressure room	?

Limit medical personnel to only those necessary	?
Minimise transport through hospital	?
Closed circuit systems[1]	?
Use of antiviral filters	?
Avoid electric, ultrasonic or any potential aerosol generating system	?
Preferential use of cold materials and conventional haemostatic systems	?
Experienced tracheotomy team	?
PDT over ST	
Performance of awake tracheotomy and cricothyroidotomy	

[1] Suction catheter introduced into ventilatory circuit

? Recommended

? Not recommended

??No recommendation

NIL/Not discussed

Figure 2: Recommended tracheotomy workflow in SARS/COVID-19 patients

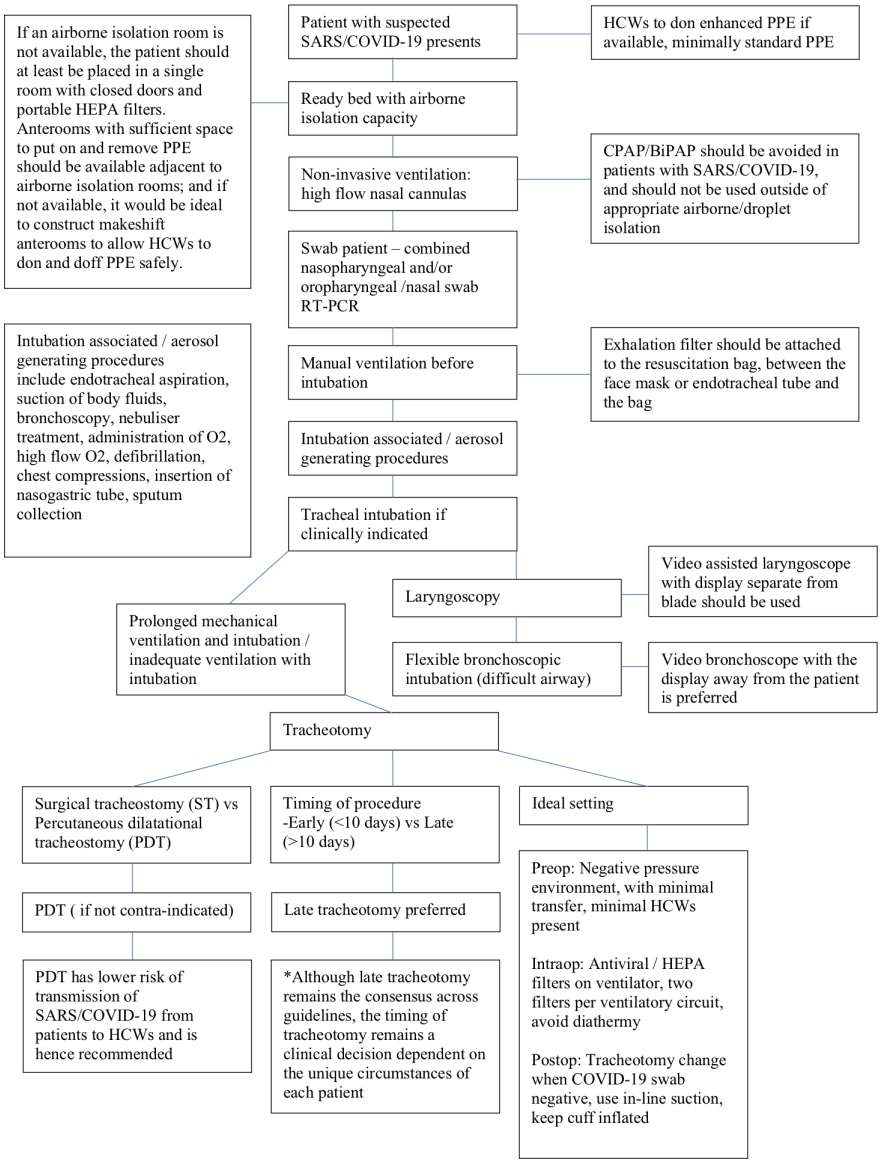
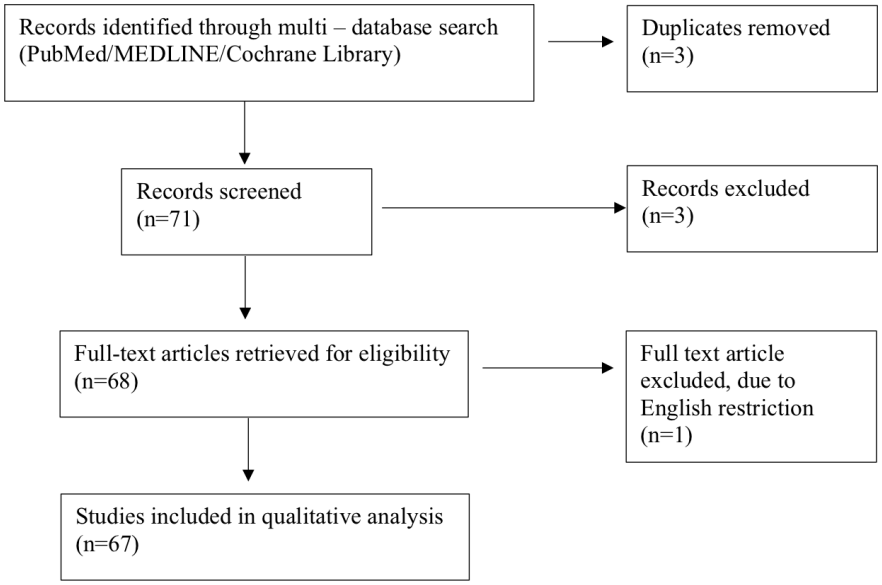


Figure 1: Flow diagram of search process



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TABLES_Clinical_oto_.docx available at https://authorea.com/users/470688/articles/562665-tracheotomy-in-covid-19-positive-patients-new-normal-workflow-of-tracheotomy-in-the-era-of-sars-covid-19-pandemic-a-systematic-review