Evidence check

10 April 2020

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

Continuous Positive Airway Pressure (CPAP) machines

Rapid review question

Q1. What is the evidence that continuous positive airway pressure (CPAP) and/or Bilevel Positive Airway Pressure (BiPAP) are aerosol generating?

Q2. What is the current advice regarding for use of CPAP as a substitute for ventilators during the COVID-19 pandemic?

In brief

- There is limited evidence on the topic of CPAP and/or BiPAP as aerosol generating procedures. Some publications describe CPAP and BiPAP as potential aerosol-generating procedures involved in nosocomial virus transmission. A systematic review found non-significant results for transmission for CPAP
- Healthcare authorities in Australia (TGA) and the US (FDA) believe that modifications to these modes of therapy would not create undue risks to treat patients with COVID-19 with respiratory insufficiency, provided that appropriate mitigations are in place to minimise aerosolisation
- The use of CPAP may forestall the need for or provide a bridge to intubation, and some guidance states that CPAP is the preferred form of non-invasive ventilatory support
- Regulators and medical device companies recommend healthcare professionals utilise PPE when using CPAP on COVID-19 patients due to the potential risk of transmission
- There is limited advice on the use of CPAP in community settings during COVID-19; and no studies on bubble CPAP.

Limitations

- Evidence on this topic is emerging rapidly
- Guidance included in this document is based on low levels and weak evidence

Background

CPAP and BiPAP are both modes of non-invasive ventilation. CPAP provides a constant steady pressure to keep the lungs expanded, generally used for obstructive sleep apnoea.BiPAP delivers two distinct pressures, one for inhalation and the second for exhalation, which leads to air flow in and out of the lungs. (1) There have been some suggestions that non-invasive ventilation therapy, such as CPAP or BiPAP, could be used for patients with COVID-19 to prevent the need for intubation and reduce days on a ventilator. Patients with the most severe disease require ventilators, however for some patients

non-invasive ventilation therapy may be able to assist, provided that appropriate mitigations are in place to minimise aerosoliaation. (2)

Methods (Appendix 1)

Databases and grey literature sources were searched on 1st April 2020 (Q2) and the 6th April 2020 (Q1)

Results (Tables 1 and 2)

Three clinical trials are currently underway relevant to question 2;

- Early CPAP in COVID Patients with Respiratory Failure. (EC-COVID-RCT).
- Early CPAP in COVID Patients with Respiratory Failure. A Prospective Cohort Study
- Acute Respiratory Failure and Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection in Real Life.

Table 1: CPAP as an aerosol generating procedure

Publication	Title	Findings
Peer reviewed literature		
Judson 2019 (3)	Nosocomial Transmission of Emerging Viruses via Aerosol-Generating Medical Procedures	Potential aerosol-generating medical procedures involved in nosocomial virus transmission includes non-invasive ventilation, such as CPAP, BiPAP, and HFOV. The mechanism is via possible mechanical dispersal of aerosols, and via the respiratory tract.
Hui 2019 (4)	Exhaled Air Dispersion During High-Flow Nasal Cannula Therapy versus CPAP via Different Masks.	Exhaled air dispersion during high flow nasal cannula (HFNC) and CPAP via different interfaces is limited provided there is good mask interface fitting. Gas flow rates and mask interface fitting seem to dictate how much air and aerosol escape upon exhalation.
Hui 2015 (5)	Exhaled Air Dispersion During Noninvasive Ventilation via Helmets and a Total Facemask	Examined exhaled air dispersion by two different helmets via a ventilator and a total facemask via a bi-level positive airway pressure device. During NIV via a total facemask for mild lung injury, air leaked through the exhalation port to 618 and 812 mm when inspiratory pressure was increased from 10 to 18 cm H2O, respectively, with the expiratory pressure at 5 cm H2O.
Tran 2012 (6)	Aerosol Generating Procedures and Risk of Transmission of Acute Respiratory Infections to Healthcare Workers: A Systematic Review.	Procedures that are believed to generate aerosols and droplets as a source of respiratory pathogens include positive pressure ventilation (BiPAP and CPAP), but when pooled the procedures were not significant.
Lim 2004 (7)	Hospital management of adults with severe acute respiratory syndrome (SARS) if SARS re-emerges	Procedures that might promote the generation of aerosols should be avoided where possible to reduce the risk to healthcare workers, this list includes non-invasive ventilation and CPAP.
Hui 2009 (8)	Exhaled air dispersion distances during noninvasive ventilation via different respironics face masks. Hui et al, 2009, Oct 9, Chest, 136(4). DOI: 10.1378/chest.09-0434	Substantial exposure to exhaled air occurs within a 1m region, from patients receiving non-invasive positive pressure ventilation (NPPV) via the ComfortFull 2 mask and the Image 3 mask, with more diffuse leakage and room contamination from the latter, especially at higher Inspiratory positive airway pressure (IPAP). Healthcare workers should take adequate precautions when providing NPPV support to patients with pneumonia of unknown aetiology complicated by respiratory failure.
Grey literature		

Publication	Title	Findings
ResMed 2020	Ventilators and COVID-19. Information on applications in the treatment of patients with COVID-19.	Evidence suggests that non-invasive ventilation procedures are more likely to produce large droplets (>10μm) rather than aerosols, and that these are largely confined to within one meter due to their large mass. This suggests that the risk of droplet dispersion as a result of use of non-invasive ventilation or bi-level devices may not be that different to that of any COVID-19 patient in the hospital who is coughing or sneezing.
Australian sleep association 2020	Consensus statement on the safe use of respiratory therapy and sleep studies to minimise aerosolisation of CoVID-1. 26 March 2020. Australasian Sleep Association	The use of nebulisers, high flow oxygen and non-invasive ventilation all pose a risk of transmission of viral infection to staff and patients. Healthcare workers should use PAP in isolation /single rooms and wear PPE.
FDA 2020	Fact sheet for healthcare providers. Emergency use of ventillators during the COVID-19 pandemic.	A positive pressure breathing device may expose others to aerosols that could be contagious.

Table 2: CPAP in COVID-19

Organisation	Guideline title	Recommendations
Community		
Health Protection Scotland	Novel coronavirus (COVID-19) Guidance for Primary Care Management of patients presenting to primary care. Version 10.5. 2nd April 2020.	Primary care staff should avoid visiting patients at home who are on CPAP/BiPAP and to consider phone consultations in the first instance. If a home visit must be carried out, staff are advised to wear PPE and ensure they visit at least 1 hour after the CPAP/Bi PAP was switched off which will provide adequate time for the aerosols to dissipate.
Acute care		
USA Food and Drug Administration	Enforcement policy for ventilators and accessories and other respiratory devices during the Coronavirus Disease 2019 (COVID-19) public health emergency. Guidance for Industry	FDA does not intend to object to modifications to FDA-cleared indications of the use of devices indicated for sleep apnoea (including non-continuous ventilators delivering continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP)) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimise aerosolisation.

Organisation	Guideline title	Recommendations
	and Food and Drug Administration Staff.	
USA Food and Drug Administration	Ventilator Supply Mitigation Strategies: Letter to Health Care Providers. 22nd March 2020. USA Food and Drug Administration	If the number of ventilators in your facility is running low, consider alternative devices capable of delivering breaths or pressure support to satisfy medically necessary treatment practices for patients requiring such ventilatory support. One options include: Continuous Positive Airway Pressure (CPAP), auto-CPAP, and bilevel positive airway pressure (BiPAP or BPAP) machines typically used for treatment of sleep apnea (either in the home or facility setting) may be used to support patients with respiratory insufficiency provided appropriate monitoring (as available) and patient condition. Take appropriate precautions with environmental control (for example, negative pressure) or additional filtration where feasible.
Australian Government Therapeutic Goods Administration	COVID-19 information for clinicians on ventilators and alternative strategies when in short supply. 26th March 2020.	Off-label use and modifications may be applied to ventilators, anaesthesia gas machines and other devices intended for respiratory support, in response to the COVID-19 pandemic. The TGA believes that modifications would not create undue risks, including for devices indicated for sleep apnoea (including non-continuous ventilators delivering continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP)) to treat patients with respiratory insufficiency, provided that appropriate mitigations are in place to minimise aerosolization.
UK Medicines and Healthcare Products Regulatory Agency	Guidance: Specification for rapidly manufactured CPAP system to be used during the coronavirus (COVID-19) outbreak. 29th March 2020.	This is a specification of the minimally (and some preferred options) clinically acceptable CPAP system to be used in UK hospitals during the current COVID-19 pandemic caused by SARS-CoV-2 virus. It sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators given the emergency situation. It is for devices, which are most likely to confer therapeutic benefit on a patient requiring CPAP because of respiratory failure caused by SARS-CoV-2, used in the initial care of patients requiring urgent support. A CPAP system with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians.
American Society of Anaesthesiologists	COVID-19 Recommendations. 3rd March 2020.	In patients with acute respiratory failure, it may be prudent to proceed directly to endotracheal intubation, because non-invasive ventilation (e.g. CPAP or biPAP) may increase the risk of infectious transmission.

Organisation	Guideline title	Recommendations
USA National Academy of Medicine	Duty to Plan: Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2. 5th March 2020.	Use of BiPAP or Continuous Positive Airway Pressure (CPAP) may forestall the need for intubation and has been broadly used in early case series and anecdotal reports. Additional CPAP machines might be available from home users for use in hospital settings, and adjusted criteria for intubation and weaning may reduce days on a ventilator.
UK NHS	Guidance for the role and use of non-invasive respiratory support in adult patients with coronavirus (confirmed or suspected). 6th April 2020. UK NHS.	CPAP is the preferred form of non-invasive ventilatory support in the management of the hypoxaemic COVID-19 patient. Its use does not replace invasive mechanical ventilation (IMV), but early application may provide a bridge to IMV. Assess the response to CPAP in a monitored environment within 30 to 60 minutes, with regular review as clinically indicated thereafter. Where there is no adequate response, where clinical decline continues, or where patient tolerance limits use, early intubation and mechanical ventilation should be sought where appropriate.
World Health Organisation	Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected Interim guidance. 13th March 2020.	Because of uncertainty around the potential for aerosolisation, high flow oxygen (HFO), non-invasive ventilation (NIV), including bubble CPAP, should be used with airborne precautions until further evaluation of safety can be completed. In situations where mechanical ventilation might not be available, bubble nasal CPAP may be used for newborns and children with severe hypoxemia, and may be a more readily available alternative in resource-limited settings.
The Faculty of Intensive Care Medicine, The Intensive Care Society, The Association of Anaesthetists and The Royal College of Anaesthetists, UK	COVID-19 airway management principles. 19th March 2020.	Anaesthetic and airway technique for emergency tracheal intubation: If there is a good seal on the face mask, gentle continuous positive airway pressure (CPAP) may be applied only after reliable loss of consciousness (to avoid coughing) to minimise the need for mask ventilation. Bag-mask ventilation may be used to assist ventilation and prevent hypoxia if indicated. Use a Guedel airway to maintain airway patency. Use the 2-handed, 2-person technique with a VE-grip to improve seal. When bag-mask ventilation is applied, minimal oxygen flows and airway pressures consistent with achieving this goal should be used.
Anaesthesia journal	Consensus guidelines for managing the airway in patients with COVID-19. 27th March 2020.	For anaesthetic and airway technique for emergency tracheal intubation: Only after reliable loss of consciousness – to avoid coughing - gentle continuous positive airway pressure (CPAP) may be applied, if the seal is good, to minimise the need for mask ventilation.

Organisation	Guideline title	Recommendations
Australian sleep association 2020	Consensus statement on the safe use of respiratory therapy and sleep studies to minimise aerosolisation of CoVID-1. 26th March 2020. Australasian Sleep Association	The use of nebulisers, high flow oxygen and non-invasive ventilation all pose a risk of transmission of viral infection to staff and patients. Healthcare workers should use PAP in isolation /single rooms and wear PPE. When using PAP, humidification should be avoided due to the risk of aerosolisation. For oxygen therapy the lowest flow rate of oxygen should be used to maintain oxygen saturations to minimize risk of viral aerosolisation. For sleep apnoea treatment, some sleep physicians suggested that oxygen flow rates higher than 6L/min led to more aerosol dispersion and humidified high flow nasal canula (HFNC) with well-fitted nasal prongs may be a better option.

References

1. ResMed Ventilators and COVID-19. Information on applications in the treatment of patients with COVID-19. Accessed on 10 April 2020 Available from: https://wwwresmedcom/us/dam/documents/anz/covid-19/COVID19-ResMed-Device-Clinical-White-Paper_30Mar2020_Revision-23pdf. 2020.
2. Therapeutic Goods Administration. COVID-19 information for clinicians on ventilators and alternative strategies when in short supply. Accessed on 10 April 2020 Available from: https://wwwtgagovau/covid-19-information-clinicians-ventilators-and-alternative-strategies-when-short-supply. 2020.
3. Judson SD, Munster VJ. Nosocomial Transmission of Emerging Viruses via Aerosol-Generating Medical Procedures. Viruses. 2019;11(10).
4. Hui DS, Chow BK, Lo T, Tsang OTY, Ko FW, Ng SS, et al. Exhaled air dispersion during high-flow nasal cannula therapy versus CPAP via different masks. Eur Respir J. 2019;53(4).
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6. Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. PLoS One. 2012;7(4):e35797.
7. Lim WS, Anderson SR, Read RC. Hospital management of adults with severe acute respiratory syndrome (SARS) if SARS re-emerges--updated 10 February 2004. J Infect. 2004;49(1):1-7.
8. Hui DS, Chow BK, Ng SS, Chu LCY, Hall SD, Gin T, et al. Exhaled air dispersion distances during noninvasive ventilation via different Respironics face masks. Chest. 2009;136(4):998-1005.

Appendix 1

Search strategy and strings:

- PubMed: (CPAP OR “continuous positive airway pressure”) AND restrict to year 2020.
  PubMed: (CPAP OR “continuous positive airway pressure”) AND (aerosol* OR exhale*)
  PubMed: ((aerosol* OR exhale* OR transmission)) AND ((BIPAP) OR (Bilevel Positive Airway Pressure))
- LitCovid: CPAP OR “continuous positive airway pressure”
- Google: (CPAP OR “continuous positive airway pressure”) AND (covid19 OR covid 19 OR 2019-nCoV OR nCoV OR covid-19 OR coronavirus)
  Google: : (CPAP OR “continuous positive airway pressure”) AND (aerosol* OR exhale*) AND (covid19 OR covid 19 OR 2019-nCoV OR nCoV OR covid-19 OR coronavirus OR SARS)
- TRIP Database: (CPAP OR “continuous positive airway pressure”) AND restrict to year 2020.
- Cochrane Library: (CPAP OR “continuous positive airway pressure”) AND restrict to year 2020.
  Australian Government Sources:
- Australian Therapeutic Goods Administration
- Australian Government Medical Services Advisory Committee

Other Sources (e.g. medical technology regulators and medical technology peak bodies):

- USA:
  - Center for Disease Control
  - Food and Drug Administration
  - AdvaMed
  - USA National Academy of Medicine
- Europe:
  - European Medicines Agency
  - UK Medicines and Healthcare Products Regulatory Agency
  - MedTech Europe
  - EuroScan International Network
  - UK NICE
  - UK NHS
- Australia:
  - MTAA
  - ResMed
  - Australian Sleep Association
- Canada
  - CADTH