Use of Helmet with Invasive and noninvasive Ventilator for Patients with Acute Hypoxemic Respiratory Failure (AHRF)

I. Introduction:

A. Background:
Coronavirus disease 2019 (COVID-19) is a novel strain of the coronavirus family since the first appearance in China in December 2019. The virus has proven to be highly infectious, affecting more than 13 million cases worldwide. COVID 19 patients might develop acute hypoxic and/or hypercapnic respiratory failure. In patients with refractory hypoxemic respiratory failure, a trial of NIV for 60 min may be considered. Mechanical ventilation via helmet with good seal around the nick minimize the spread of infection at the neck interface that could reach a maximum radial distance of 270 mm, this can reduce the chance of healthcare providers exposure compared to other noninvasive interfaces however dose not completely prevent the risk of transmission of the virus. NIV via helmet minimize the distance of spread to about 15 to 23 cm with inspiratory pressure of 12 to 20 cm H2O and expiratory pressure of 10 cm H2O, whereas NIV via total face mask the distance of spread was about 62 to 81 cm with inspiratory pressure of 10 to 18 cm H2O and expiratory pressure of 5 cm H2O. It provides alternatives for cases that cannot tolerate mask / full face NIV, decreases the need for early ICU admission in selected cases and rate of early Intubation.

B. Aim & Methodology:
The aim of this guideline is to provide Health Care Workers (HCWs) with a well-organized approach to optimize the use of Helmet with ventilator machines for patients with acute hypoxemic respiratory failure (AHRF). Doing a literature review by 4 contributors and coming up with the written document developed the guideline. Meetings were held with 20 ICU consultants and 20 Respiratory Specialists and critical care nurses where protocol is reviewed for final version. Conflicts were solved by discussion and voting.

C. Targeted Population:
All adult COVID 19 patients with Mild to Moderate Acute Hypoxemic Respiratory Failure (AHRF) who are requiring high oxygen therapy in the ED, ICUs, and hospital wards. This guideline will be reviewed and updated regularly according to evidence base publication.

D. Targeted End User:
- Adult Emergency Medicine physicians
- Adult Critical Care Medicine physicians
- Respiratory Specialist
E. Conflict of interest:
• No conflict of interest.

II. Indication for Helmet NIV:
Patients with AHRF requiring more then 6L/min oxygen to maintain SpO2 >90% or RR > 30/min with any of the following:
• Mild to Moderate AHRF in (ARDS, community-acquired pneumonia, postoperative and immunocompromised patients)
• Acute cardiogenic pulmonary edema
• Blunt chest trauma

III. Contraindications of Helmet NIV:
A. Absolute Contraindications:
• Post-cardiopulmonary Arrest
• Hemodynamic Instability
• PH < 7.25
• Unconscious patients
• Absence or impaired Gag Reflex
• Elevated Intracranial Pressure
• Tracheostomy
• Upper Airway Obstruction
• Incapacity to manage respiratory secretions (excessive secretions)
• Immediate need for intubation
• Pregnancy
• Lack of clinical experience with use of Helmet NIV
• Eye Disorders

B. Relative Contraindications:
• Uncooperative patient.
• Claustrophobia.
• Chronic obstructive pulmonary disease (COPD), given the chance of CO2 retention due to increase in dead space.
• Patients’ ventilator asynchrony.
IV. **General Helmet NIV Rules of Use:**

- Medical staff should use Airborne protection (*maximum PPEs with N-95 masks and eye protection*)
- Patient should be treated in a negative pressure room, if available. A closed room (with HEPA Filter) if no negative pressure room available.
- During surge Positive COVID 19 Patients can be cohort in one large room with HEPA Filter
- It can be used in Critical Care Units, ED, and General wards.
- Critical care ventilator should have noninvasive ventilation modality (leak compensation) option to be used for the delivery of Helmet NIV.
- Blood gas should be done after initiation by maximum of 60 minutes. Then for the first 24 hours, to be done every 4-6 hours if patient hemodynamically and respiratory is stable, and then blood gas frequency should be adjusted based on patient status.
- The minimum inspiratory flow for Helmet NIV is 50 to 60 LPM to reduce exhaled CO2 accumulation inside the helmet and CO2 rebreathing.
- Apply padding under the straps in both axilla and watch for Pressure injuries

V. **Helmet NIV Application and Setting:**

A. **Helmet Setup:**

1. Size selection and helmet assembling:
   1.1. Select the appropriate helmet size (S, M, L & XL) for your patient as per manufacturer recommendations. (See appendix A for Subsalve Helmet Size & Seal Information)
   1.2. Measure patient’s neck circumference.
   1.3. Cut collar two sizes smaller than indicated by sizing the patient’s neck circumference, you can always size up if needed. Avoid cutting a jagged edge. (See appendix B figure 1)
   1.4. Fit the plastic ring into the transparent hood, must be pressed very tight. (See appendix B figure 2)

2. Interface for the mechanical ventilator and BiPAP
   2.1. For BiPAP:
      2.1.1. Connect the BiPAP circuit to one of the 22 mm connector on the helmet with a viral filter (HEPA) attached to the circuit expiratory port if present.
      2.1.2. On the other 22 mm helmet connector attach a viral filter (HEPA). (See appendix B figure 3)
   2.2. For an ICU ventilator with double limb circuit:
      2.2.1. Connect two flex tubes to both 22 mm connectors on the helmet.
      2.2.2. Then attach the other ends of the flex tubes to a Y-connector.
      2.2.3. Attach the Y-connector to a viral filter (HEPA).
      2.2.4. Connect the Y-connector of the ventilator circuit to the other end of the viral filter. Attach another viral filter (HEPA) to the expiratory port on the ventilator.
3. Perform helmet pressurization test to check for leak and placement as following:

3.1. Perform helmet pressurization test to check for leak

3.1.1. Connect the helmet to the ventilator or BiPAP.

3.1.2. Set PS/IPAP to 15 cm H2O and PEEP/EPAP to 8 cm H2O.

3.1.3. Seal the neck collar by gripping it into your handgrip. (See appendix B figure 5)

3.1.4. If helmet inflate then no leak is present.

3.2. Helmet Placement

3.2.1. Before Placement of the Helmet:

3.2.1.1. Perform oral care/suctioning as able.

3.2.1.2. Place earplugs for the patient to minimize noise & ear pressure, if needed.

3.2.1.3. Tie hair back as needed.

3.2.1.4. Place foam dressing surrounding neck over helmet neck site.

3.2.2. Stretch the rubbers collar of the helmet and place it over the patient’s head, two healthcare providers. (See appendix B figure 6)

3.2.3. Once the Helmet is fully inflated, place the arm-straps through the armpit and adjust them to secure the helmet position on the patient’s head.

3.2.4. After Helmet Placement consider the following if needed:

3.2.4.1. Adjust underarm straps to have two fingers loose fit.

3.2.4.2. If underarm breaking down, place wash cloth or place foam dressing pad under armpits.

3.2.4.3. Can place two restraints clipped together over top of helmet to help with upward movement of helmet with breathing and take pressure off armpit straps.

3.2.4.4. Assure seal is sitting on foam dressing pad.

3.2.4.5. Assure pillow is placed behind neck for support to reduce the chance of patient’s neck pain.

B. Other Considerations

1. If patient can be fed or drink liquid follow the next steps:

1.1. Remove rubber stopper from the helmet straw port then insert the straw. (See appendix B figure 7)

1.2. Have the patient seal lips on the straw first.

1.3. Add water/liquid food in a glass to the other end of the straw.

1.4. Once patient is done, Re-apply the rubber stopper to the helmet straw port.
2. If Suctioning is indicated (it should be minimized at the first 1 to 2 hours of application):
   2.1. Pre-oxygenate the patient by increasing the FiO2 top 100 for 120 to 180 seconds.
   2.2. Remove rubber stopper from the helmet straw port then insert yankuer.
   2.3. Have the patient seal his/her lips around the yankure tip then perform suctioning.
   2.4. Re-apply the rubber stopper to the helmet straw port.
   2.5. If unable, can have two staff members on opposite side of bed simultaneously lift rubberneck collar and patient can suction themselves with a yankuer.

3. Nasogastric tubes:
   3.1. Nasogastric feeding tube insertion is recommended to maintain the patient’s nutritional requirement during prolonged helmet use.
   3.2. Residuals should be regularly checked as gastric distention could develop due to airway pressurization.

4. Neck catheters and lines:
   4.1. Can be threaded between neck and rubber collar.
   4.2. Extra length of the tubing can be wrapped around the ear to prevent catheter kinks.

5. Patient can sleep with the helmet in semi-recumbent position.

6. For patient anxiety, light sedation can be utilized. Titration by physician is required to avoid over sedation.

C. Initial Ventilator/BiPAP Setup:
When initiating helmet NIV, you should consider that two ventilated compartments, the helmet and lungs.

<table>
<thead>
<tr>
<th>NIV-ICU Ventilator</th>
<th>NIV-BiPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Set up the ventilator on PSV</td>
<td>1. Set up the BiPAP on Spont/Timed (S/T)</td>
</tr>
<tr>
<td>2. Set initial PS of 10 cm H2O</td>
<td>2. Set initial IPAP of 16-20 cm H2O</td>
</tr>
<tr>
<td>3. Set PEEP at 8 cm H2O</td>
<td>3. Set EPAP at 8 cm H2O</td>
</tr>
<tr>
<td>4. Set Oxygen 100% and titrate for targeted SpO2</td>
<td>4. Set Oxygen 100% and titrate for targeted SpO2</td>
</tr>
<tr>
<td>5. Set TI max to 1.5 sec to avoid late cycling</td>
<td>5. Set TI max to 1.5 sec to avoid late cycling</td>
</tr>
<tr>
<td>6. If inspiratory flow can be set on your ventilator set at 60</td>
<td>6. Assess the inspiratory flow and ensure is higher</td>
</tr>
<tr>
<td>to 80 L/S or higher or Assess the inspiratory flow and</td>
<td>than 60 to 80 L/S</td>
</tr>
<tr>
<td>ensure is 60 to 80 L/S</td>
<td></td>
</tr>
<tr>
<td>7. Set inspiratory trigger at 2 L/min or equivalent</td>
<td>7. Set inspiratory trigger at 2 L/min or equivalent</td>
</tr>
</tbody>
</table>
8. Flow/Cycling off 50% of maximal inspiratory flow

8. Set inspiratory time at 1 second

9. Inspiratory rise time 50 ms or equivalent based on the ventilator you are using

9. Set rise to equivalent of 50 ms

D. Humidifier Setup:
- Warm humidification at 30°C causes patient discomfort and helmet fogging.
- Most comfortable setting is humidification at room temperature (or temperature of 28 °C) – Cold humidification.
- Appropriate level of humidification can be achieved via bubble humidifier with external oxygen flow of 5 L/Min entrained into the ventilator circuit proximal to the patient helmet.

E. Titration:
With noninvasive PSV via critical care ventilator or BiPAP V60 on Spontaneous/Timed (S/T):
- Increase PEEP/EPAP by 2 cm H2O every 3 to 5 minutes to achieve the following:
  i. SpO2 ≥ 92%.
  ii. Patient comfort & tolerance.
  iii. PEEP/EPAP level should not exceed 15 cm H2O
  iv. IPAP should be increased by the same increments as EPAP to maintain Δ P (IPAP – EPAP).
  v. Peak inspiratory pressure/IPAP should not exceed 25 cm H2O.
- Increase PS/IPAP level by 2 cm H2O every 3 to 5 minutes to achieve the following:
  i. Peak inspiratory flow of 60 to 80 L/S to improve carbon dioxide (CO2) washing and minimize CO2 rebreathing.
  ii. Tidal volume of 1000 to 1500 ml and patient respiratory rate of < 25 to 30 BPM. Note that about 50%-75% of the tidal volume delivered is distributed to the helmet.
  iii. Minute Ventilation (MV) of 20 to 25 L/Min.
  iv. Patient comfort & tolerance.
  v. Peak inspiratory pressure/IPAP should not exceed 25 cm H2O.
- Titrate FiO2 to less than 60% as soon as possible maintaining SpO2 92 to 96%.

F. Monitoring:
- ABG within the first hour of helmet application after appropriate ventilation setting, patient’s comfort and tolerance being achieved.
- Patient’s Hemodynamic Status
• Patient’s Vital Signs
• Patient’s Breathing Pattern, work of breathing and degree of respiratory distress if present.
• Patient’s Comfort & Tolerance.

G. Weaning & Discontinuation:
• Lower PS/IPAP by 2 cm H2O every 1-3 hours if RR < 30/min
• Wean FiO2 to less than 50% to 60%, then PEEP/EPAP can be titrated by 2 cm H2O every 1-3 hours maintaining SpO2 of more than 92%
• If RR < 30/min on PS < 10 cm H2O and SpO2 > 92% on FiO2 < 50% and PEEP < 8 cm H2O, Helmet can be discontinued, and patient switched to FM 6L/min or HFNC.

H. Helmet NIV Failure Criteria:
• After 10-15 minutes of Helmet application the patient remains with:
  a. O2 Sat < 90% despite maximum PEEP and FiO2
  b. Respiratory Rate > 35 despite high PS/IPAP levels.
  c. Ongoing acidosis with pH < 7.25
• Worsening patient condition and/or patient developing severe respiratory distress.
• If patient comfort & tolerance cannot be achieved.

VI. Declaration:
• The recommended initial ventilation settings & titration are practice & rational based due to lack of well standing clinical evidence.
• Those settings, if adopted, be applied and modified by experienced teams of intensivists & respiratory care practitioners.

VII. Decisions for intubation: (See appendix B figure 8)
Intubation should be done if no response to Helmet NIV (as per MOH Protocol Airway Management in COVID 19)

VIII. Acknowledgment:
We thank Dar Al Uloom University for their help and sponsoring writing this document.
IX. References:
Appendix A

SubSalve Helmet compared to other helmets

1. One-piece helmet: no concerns about base disconnection
2. No hard piece:
   a. More comfortable for the patient as no pieces pressing on neck & shoulders
   b. Proning position could be achieved more easily
   c. Can be used for extended periods
3. Comes in four sizes S M L XL
4. Doesn’t require cutting to adjust for neck size at the neck seal portion (but still can be done in extremes:
   a. Saves time
   b. Less troublesome
5. Has a patient access, minimize therapy interruption.
Appendix A, Cont.,

SubSalve Oxygen Treatment Hood Neck Seal Information

Neck seals are offered in either latex or silicone. Measure the individual’s neck circumference and then reference the below sizing guide.

TABLE: 1

<table>
<thead>
<tr>
<th>Material</th>
<th>Size</th>
<th>Neck circumference (Inches)</th>
<th>Neck circumference (cm)</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latex</td>
<td>S</td>
<td>8.5” - 11”</td>
<td>21.5cm - 28cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Latex</td>
<td>M</td>
<td>9” - 13”</td>
<td>23cm - 33cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Latex</td>
<td>L</td>
<td>11” - 13”</td>
<td>28cm - 33cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Latex</td>
<td>XL</td>
<td>13” - 17” +</td>
<td>33cm - 43CM+</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Latex</td>
<td>Universal</td>
<td>11” to 16.5”</td>
<td>28cm - 42CM</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Silicone</td>
<td>S</td>
<td>11”</td>
<td>28cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Silicone</td>
<td>M</td>
<td>13”</td>
<td>33cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Silicone</td>
<td>L</td>
<td>15”</td>
<td>38cm</td>
<td>Trim for comfort</td>
</tr>
<tr>
<td>Silicone</td>
<td>XL</td>
<td>17”</td>
<td>43cm</td>
<td>Trim for comfort</td>
</tr>
</tbody>
</table>

Neck Seal Care Guidance:
Both latex and silicone neck seals are durable though must be handled with care. Overstretching, sharp objects, and/or poor trimming can cause the seal to tear.

- Do not stretch the seal more than is required to place it on an individual.
- Use two hands to stretch the seal from inside the opening. Two individuals (4 hands) is even better.
- Once in place, run a finger along the inside of the seal to ensure it lays flat against the individual’s neck for comfort avoid folds over or under, or rolling the seal.
- Avoid sharp objects such as fingernails and rings.
- Use a product such as talcum powder to minimize frictional stain on the seal and for personal comfort. Talcum can be used under the seal if it will be worn for a long period of time to minimize sweat or irritation.

Neck Seal Trimming:
All seals can be trimmed for added comfort. When trimming seals, use sharp scissors. Cut edges should be as smooth and straight as possible. Do not trim lines. Avoid sharp edges and nicks.
Appendix B

Figure 1

PERFECT  OK  NOT OK
Figure 4

Figure 5
Figure 6

Figure 7
Clinical pathway for COVID 19 suspected patients with respiratory failure:

Critically ill Suspected COVID 19

- Unconscious or Hemodynamically Unstable
- or Multiorgan Failure

Intubation
- Put patient on a monitored bed
- Start HFNC
- IV Bolus
- And start RSI

Admit to ICU

YES

Self Prone
- HFNC or NIV
- In-ve pressure room with Full PPE precaution
- Assess in 2 hours

Admit to the ward

NO

Conscious
- Stable

ED management

Admission

Glossary:
- HFNC: High Flow Nasal Cannula
- NIV: Non Invasive ventilation
- RSI: Rapid sequence intubation
- PPE: Personal protective equipment

Figure 8