Scoring System for the Use of Nebulizers in the Primary Care Settings: An Expert Consensus Statement

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Abstract

Background: The use of nebulizers is an important and useful method for delivering drugs to the lungs in patients with various airway and lung parenchymal disorders. They are primarily used in patients with acute symptoms and in a selected group of patients for maintenance treatment. Its use has increased, especially during the coronavirus disease 2019 (COVID-19) pandemic. To ensure the appropriate use of nebulizers by primary care physicians and to guide them, we aimed to develop a simple nebulizer use score.

Methods: An expert working group (EWG) of pulmonologists were formed who using a semi-Delphi method, developed a list of variables and a cut-off score to decide when to use nebulizers. We started with a total of 55 variables that were developed through an exhaustive review of the literature. These were further reduced to smaller numbers that had the maximum score as well as concordance with the EWG. The scores ranged from 1 to 10 (completely disagree to completely agree), and only those above 7.5 were selected.

Results: A total of 8 variables with the highest scores were selected (Table 1), which had a total maximum score of 40. A score of <15 was suggested to indicate no use of nebulizer and >20 to suggest definite use of nebulizer. A score between 15 and 20 was suggested for physician judgment. A separate table of 12 conditions was made where the use of nebulizers was mandatory.

Conclusion: This first-of-its-kind nebulizer score can be used by primary care physicians to decide which patients should be put on nebulizer treatment.

Introduction

The inhalation route is the most natural route of drug delivery to the lungs. It is the safest, fastest, and most effective route and constitutes the cornerstone for treating patients with a variety of respiratory conditions. Various devices have been developed to deliver the drug directly to the lungs, which include pressurized metered-dose inhalers (pMDIs), dry powder inhalers (DPIs), breath-actuated metered-dose inhalers (MDI), and nebulizers. Inhalation therapy is primarily recommended for all patients with asthma and chronic obstructive pulmonary disease (COPD) (bronchodilators and corticosteroids), but is also used to treat pneumonia and cystic fibrosis (antibiotics), surfactant deficiency (surfactant) and other lung diseases.

Nebulization is an important and useful route of delivering drugs to the lungs in patients with various airway and lung parenchymal disorders. They are primarily used in the treatment of acute exacerbations of asthma and COPD because of their ease of use in patients who are breathless. However, they are also used in the maintenance treatment of obstructive airway diseases, both in the hospital setting as well as at home in a selected group of patients. Some drugs can be delivered only by the nebulization route and have no alternatives. In patients, it is important to ensure that the nebulizers are not misused (either underused or overused).

During the COVID-19 pandemic, home nebulization has gained increased popularity as it has been relatively easy to make people learn its use than the use of a MDI with a spacer, especially on teleconsultation without physically meeting the patient. Nebulization requires minimal or no direct cooperation from the patient and can be administered by a caregiver or a family member. During this COVID-19, the surge in the use of nebulizers has been somewhat worrisome because of the fear of increased transmission of infection due to the spread of the virus in the environment during nebulization. However, this perceived risk is not supported by any objective evidence. Moreover, a systematic review of 22 studies reported no conclusive evidence of viral transmission by the nebulizer.

We considered it important to clearly define the indications when nebulization can be safely employed in both non-COVID-19 and COVID-19 patients. Deciding the key conditions for the rationale use of nebulizers would prevent their overuse and thereby the ill effects. We attempted to define a method based on the assessment of a simple clinical score that could be utilized in primary-care practice to decide whether to use the nebulized drugs or to avoid them.

Nebulizers are misused in clinical practice (both overuse or underuse) largely because of a lack of guidelines as to when nebulizers can or should be used in place of pMDIs or DPIs. The aim of this exercise was to develop a list of key conditions and a scoring system that could help general practitioners assess the requirement of domiciliary nebulization and help them decide which patients are likely to benefit from the use of nebulized medications.

Methodology

This document was developed as a clinical expert consensus statement by a panel of nine experts from the field of respiratory medicine. It reflects key conditions and scoring for the use of a nebulizer both during an endemic/pandemic situation or otherwise. We first performed an extensive literature review of a total of 729 articles

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published in Pubmed, Google Scholar, and Google on the conditions that determine the use of nebulizers at domiciliary and hospital setups. Out of 729 articles whose full text we reviewed, 63 articles were found relevant to the topic that listed variables that could be used for deciding the need for nebulization.

A list of 55 “key conditions” deciding the nebulizer use and related information was extracted, which mainly covered the conditions related to: (1) the patient’s disease and its severity; (2) presence of comorbid conditions; (3) age; (4) physical and mental condition of the patient; (5) the need of aerosolized drug delivery system and their limitations to using the pMDI, DPI, and nebulizers. The 55 key conditions/criteria were further combined, and those that seemed to have the highest value (as evaluated by SKJ, SP, and SS) were further reduced to 20 key conditions. All the 20 conditions were then sent to the expert panel to score on a Likert scale from 1 to 10 using the following criteria: 1–2 strongly disagree, 3–4 mostly disagree, 5–6 agree, 7–8 mostly agree, and 9–10 completely agree. Expert members were encouraged to score them as single points.

An internal review was performed on the selection of the most appropriate “key conditions” which would help to decide the use of a nebulizer. The review resulted in the identification of 20 key conditions with the scores for respective conditions.

In the second stage, both the list of key conditions and scoring separately developed were shared with all the expert members using the Delphi process (Flowchart 1). At the end of the Delphi process, the comments from all the experts were reviewed and collated for discussion during the consensus meeting. The average score was computed and was ranked from the highest score (strongly agree—score 10) to the lowest score (strongly disagree—score 1), and the same was used to develop three tables based on consensus from all panelists. Finally, the panel agreed upon an 8-point clinical score to decide the use of nebulizers based on the total score.

After the completion of the Delphi process, the consensus meeting was held online using the Zoom platform. The outcome of the Delphi process was discussed and finalized. The panel agreed with 25 key conditions with some additions, deletions, and modifications. Scores for each condition were obtained from the individual expert members.

**Results**

The clinical scoring system consisted of 8-point criteria with different weights amounting to a total of 40 score points (Table 1). The total points given to a patient need to be added to reach a total score. It was decided by consensus to keep the cut-off score of 20. A patient with a score of 20 or more would most likely benefit from nebulization whenever inhalational treatment is required. On the other hand, one may avoid nebulization for a patient who has a total score of <15 points. A nebulizer can be used depending on the clinical judgment of the medical practitioner and the disease severity of patients if the total score is between 15 and 20. At the end of this article, we have listed five case scenarios explaining how the scoring system can be used to decide whether nebulization therapy would be appropriate or otherwise.

We also listed clinical conditions where there is no alternative to nebulization whenever inhalational treatment is required (Table 2). Similarly, we made a list of drugs that can only be given by the nebulization route (Table 3).

**Discussion and Conclusion**

Inhalational administration of drugs is an essential mode of therapy for several lung diseases, particularly for emergency use for sick patients. pMDIs, DPIs, and nebulizers have their own advantages and disadvantages. Nebulization is an effective method of drug delivery to the airways and the lungs but generally requires a larger dose of drugs than with inhalers. Nebulizers are not recommended where pMDIs and DPIs are clinically preferred, for example, for conditions like mild–moderate asthma and COPD. Nebulization is generally reserved for either severe and acute conditions or when inhalers cannot be used for various reasons.

There has been an obvious lack of clarity on the safe use of domiciliary nebulizers without increasing the risk of dissemination of infection from contagious diseases, especially during an epidemic. Unlike all aerosol-generating procedures, which are recommended not to be used or to be used...
with caution during the current COVID pandemic, nebulizers are believed to be very useful, especially in the management of acute respiratory conditions. There are algorithms that have been developed to guide medical practitioners who practice in primary care settings on when to use the nebulization of drugs as the preferred mode of inhalational therapy. A previous consensus document on practitioners who practice in primary care that have been developed to guide medical respiratory conditions. There are algorithms that have been developed to guide medical practitioners who practice in primary care settings on when to use the nebulization of drugs as the preferred mode of inhalational therapy. A previous consensus document on practitioners who practice in primary care settings on when to use the nebulization of drugs as the preferred mode of inhalational therapy. A previous consensus document on

Table 1: Scoring criteria with different assigned scores

<table>
<thead>
<tr>
<th>No.</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disease-specific</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Asthma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>COPD</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Disease severity (asthma or COPD)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Mild-to-moderate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Patient previously using inhalers with the benefit</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>pMDI, pMDI + spacer, and DPI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nebulizer</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Noncompliance with the use of pMDIs with spacer and DPIs or persistent use of nebulizers, despite best efforts to encourage the use of pMDIs or DPIs in patients.</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>Distressing or disabling breathlessness despite maximal therapy with inhalers and feels better with a nebulizer.</td>
<td>7</td>
</tr>
<tr>
<td>6</td>
<td>Severe coexisting COPD in patients with lung cancer.</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>Inability to inhale quickly and deeply using a DPI despite best efforts to train patients in DPI usage.</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>COVID-19 positive/patients with other contagious viral infections.</td>
<td>3*</td>
</tr>
<tr>
<td></td>
<td>*If the patient is already on a pMDI or DPI and uses it correctly and is happy to continue with that, we should encourage them to use that only for patients with COVID-19/other viral infections.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Only for patients with COVID-19/other viral infections.</td>
<td></td>
</tr>
</tbody>
</table>

Total maximum score: 40

Recommended cut-off scores: <15, nebulizer will not be necessary/useful; >20, nebulizer will likely be necessary/useful; 15–19, a nebulizer can be used depending on clinician judgment.

Table 2: Conditions where nebulizers must be used (no need for scoring)

<table>
<thead>
<tr>
<th>No.</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drugs whose inhalational forms can be delivered only by the nebulizer route (Table 2).</td>
</tr>
<tr>
<td>2</td>
<td>Acute exacerbations of asthma or COPD requiring hospitalization.</td>
</tr>
<tr>
<td>3</td>
<td>Altered mental state/cognitive decline/confused state requiring inhalation therapy.</td>
</tr>
<tr>
<td>4</td>
<td>Patients who are inadequately controlled on DPIs or MDIs need high doses of inhaled bronchodilators or corticosteroids.</td>
</tr>
<tr>
<td>5</td>
<td>Lack of coordination while using pMDI despite best efforts to train in the pMDI technique.</td>
</tr>
<tr>
<td>6</td>
<td>Visual factors that may limit the ability to use DPIs and pMDIs, such as macular degeneration, cataracts, or glaucoma.</td>
</tr>
<tr>
<td>7</td>
<td>Dexterity issues such as Parkinsonism or stroke.</td>
</tr>
<tr>
<td>8</td>
<td>Hand arthritis in elderly patients (the use of pMDI or DPI use should be encouraged if assisted inhalation for pMDI or DPI is possible through caregivers).</td>
</tr>
<tr>
<td>9</td>
<td>Non-CF bronchiectasis in patients requiring inhaled antibiotics.</td>
</tr>
<tr>
<td>10</td>
<td>Bronchiolitis in patients requiring inhaled epinephrine or antiviral drugs.</td>
</tr>
<tr>
<td>11</td>
<td>Cystic fibrosis (antibiotics and mucolytics).</td>
</tr>
<tr>
<td>12</td>
<td>Pulmonary arterial hypertension in patients requiring inhaled nitric oxide and prostacyclin.</td>
</tr>
</tbody>
</table>

Although nebulizers generate aerosols, they do so from the nebulization chamber containing the drug, and unless that is contaminated with the virus, it will not transmit the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection to others. Concerns were earlier raised for aerosols being generated from the patient's cough following the use of nebulizers as a potential source of viral transmission. However, a systematic review of 22 articles, including seven case series and seven simulation-based studies, reported that although case series reported concerns of transmission risk and droplet dispersion with virus recovery, there was no conclusive evidence to suggest that the use of nebulizers increases the transmission of coronavirus. The Centers for Disease Control, United States of America, recommends appropriate safety measures to be followed during the use of the nebulizer, such as the use of an N95 mask, eye protection, gloves, and a gown for the healthcare provider (HCP) in the acute emergency setting in the hospital. Visitors or relatives should not be present during the nebulization process, and the room surfaces and nebulizer equipment should be properly disinfected after use. Also, patients do not need to be transferred to a higher level of care solely for the purpose of providing nebulizer treatment. HCPs should also follow appropriate hand hygiene measures when helping patients remove nebulizers and oxygen masks.

The scoring system described in the present study is based on the review of the literature and a Delphi process with experts from across the country in the field of respiratory medicine. None of the experts had any conflicts of interest to declare. The scoring does not apply to the use of drugs, such as surfactants, inhaled antibiotics, and mucolytics, which can only be delivered by the nebulized route (Table 3).

In conclusion, the scoring system derived through a structured consensus process for deciding nebulization therapy is simple to use for general practitioners for the selection of patients with obstructive airway diseases such as asthma and COPD, both during the COVID as well as non-COVID periods.

**Case Scenarios**

- A 68-year-old male shopkeeper has known COPD for over 10 years. During the COVID-19 pandemic, he develops acute exacerbation with fever and breathlessness. He was found to be COVID-positive (SARS-CoV-2) on a throat swab real-time reverse transcription polymerase chain reaction (RT-PCR) test. He was admitted to the local health center.
He had been previously admitted twice in the last year and frequently required nebulization. His oxygen saturation was 87%. Besides standard treatment, he required bronchodilator administration with the help of nebulization, but the physician was afraid of nebulization for fear of dissemination at home. How will you decide, and what decision will you make on this issue?

Answer: The patient has an acute exacerbation of COPD, presenting with breathlessness and requiring hospitalization. According to Table 2, point No. 2, this is an indication where scoring is not required. For his hospital stay, he needs to be put on a nebulizer. No need to do the scoring here.

However, if the patient is now discharged home and the rest of the information remains the same, we could now use the scoring method as follows:

- Disease specific, COPD = 2
- Disease severity, severe = 4
- Previous use of nebulizers = 4
- Do not comply with MDIs = 6
- Better with inhalers = 0
- COVID-19 positive = 0


- A 62-year-old businessman had poorly controlled diabetes for over 5 years. He suddenly developed a fever and breathlessness and was sick and air-hungry with arterial oxygen saturation of around 80% with features of sepsis. He was admitted to the local health facility. His airway secretion grew Pseudomonas aeruginosa sensitive to colistin. In addition to parenteral colistin, will you give colistin to this patient through the nebulized route?

Answer: Giving colistin through the inhaled route is off-label. According to Table 3, if the physician thinks it’s necessary, inhaled colistin can be given only by the nebulizer route. Therefore, there is no need to do the scoring here.

- A 55-year-old female police officer with a history of asthma developed a fever and irritating cough for 2–3 days. Her oxygen saturation was stable at above 92%. She had previously been maintained on budesonide/formoterol DPI but had recently stopped treatment. She was found to be COVID-positive on a throat swab RT-PCR test. She was asked to restart her inhaled corticosteroids (ICS) and bronchodilators at home in addition to other drugs. The physician was wondering whether to give ICS/bronchodilators by nebulization. How will you decide, and what decision will you make on this issue?

Answer: Calculate the nebulization score as follows:

- Disease specific = 1.
- Disease severity = 1.
- Previous use of nebulizers = NA.
- Do not comply with MDIs = NA.
- Better with inhalers = 0.
- COVID-19 positive = 0.

Total score = 2. Nebulization = not required. Even if she had tested covid positive, the score would have gone up to 5, which meant nebulization was not required.

- A 78-year-old farmer had a history of chronic cough and breathlessness for over 15 years. He also had Parkinsonism symptoms. He develops acute worsening of his condition with fever, cough, and breathlessness. He was found to be COVID-positive (SARS-CoV-2) on a throat swab RT-PCR test. His oxygen saturation was low–around 86%. He was admitted to the local health center.

Answer: Calculate the nebulization score. Patient score:

- Disease specific, COPD = 2.
- Disease severity, severe = 6.
- Previous use of nebulizers = not known.
- Do not comply with MDIs = 6.
- COVID-19 positive = 3.

Total score = 17. Nebulization = yes, because he is old and suffers from Parkinsonism; unable to use MDIs with spacer.

In Table 2, Point 7 presence of Parkinson’s or stroke makes the patient already eligible for the use of nebulizers. However, if there is a support system at home where a helper can assist in the use of a pressurized MDI with a spacer, this should also be encouraged.

- A 35-year-old female office assistant developed acute episodes of cough, breathlessness, and wheezing during the COVID pandemic period. She was found to be COVID-negative on RT-PCR testing. She had a history of suffering from similar episodes off and on in the past, which used to get better with multiple doses of inhaled salbutamol and budesonide, sometimes with nebulized administration of the drugs. The family telephoned a local doctor for advice on whether they could use nebulization of the same drugs. The physician, who was aware of a scoring method to decide, immediately calculates the score for nebulization and advises accordingly. What score do you give to this patient, and what is your decision?

Answer: Calculate the nebulization score. Patient score:

- Disease specific, asthma = 1.
- Disease severity, mild = 1.
- Previous use of MDIs = 0.
- Do not comply with MDIs = 0.
- Better with inhalers = 7.
- COVID-19 positive = 0.

Total score = 9. Nebulization = not required.

References