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The ROME COPD exacerbation proposal works! Time to move forward

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Introduction

Reliable definitions and severity classification for acute medical events are essential for clinicians to establish the diagnosis, assess prognosis, and guide appropriate therapy. They are also essential when conducting epidemiological or clinical studies, to allocate patients, resources, and treatments according to severity phenotypes. These guiding principles do not exist for exacerbations of chronic obstructive pulmonary disease (COPD), where there is more than one definition, and where the severity is classified after its occurrence, by the type and site of health care provided to the patient.

The current maze

The first definition states "COPD exacerbations are episodes of increasing respiratory symptoms, particularly dyspnea, cough and sputum production, and increased sputum purulence."[1] The second offers an important modification by adding that "A COPD exacerbation is an acute event characterized by worsening of the patient's respiratory symptom that is beyond the day-to-day variation that leads to a change in medications."[2] Because of its practicality (need to change medications), this definition has gained traction in clinical trials aimed at preventing exacerbations. According to this definition, the event is considered "mild" if the patient is treated (potentially self-managing) only with inhaled short-acting bronchodilators, "moderate" when the patient receives antibiotics, systemic corticosteroids or both, and "severe" when the patient visits an emergency ward or is hospitalized.[3] Particularly, the post hoc classification of "severe," because patients are hospitalized, is insufficiently granular to capture the implications of exacerbations in this multimorbid patients whose reasons for admissions maybe more than the severity of the exacerbation itself. Without denying the therapeutic progress that has been made in the prevention of COPD exacerbations so defined, treatment of the episodes per se remain unchanged.[3] Because the definitions are based entirely on subjective symptoms and the severity classification is based on healthcare resource utilization, there are regional variations in clinical practice and healthcare infrastructure that influence the treatment options and location of care for patients experiencing exacerbations.[3]

In medical emergencies, the severity of the event needs to be defined at the point of care, so the patient can be guided on the appropriate treatment environment (ambulatory or hospital) and medical therapy. Likewise, in the research arena, a precise classification of the severity of the episode at the time the patient is enrolled can help evaluate different therapeutic approaches for the different severity episodes. This is not the case currently, where guidelines recommend treating all exacerbations with a similar pharmacological approach, with the only variation being the recommended use of ventilator support for acidotic ventilatory failure.[4] COPD exacerbation episodes are likely to be heterogeneous, due to the comorbid nature and severity of the underlying host, the intensity of the inflammatory response, or the trigger of the event. However, the resulting stress placed on the ventilatory system influences measurable physiological and biological variables that can help determine the overall person's compromise. In the end, the prognosis of the patient will depend on the severity of the episode itself and the health reserve of the host.

The ROME proposal

In 2021, following a modified DELPHI method, an international group of experts proposed the new ROME definition of a COPD exacerbation, which included a classification of the severity of the episode at the point of care, using objective measurements of symptoms, signs, physiological variables and blood sampling (if available).[5] The variable's thresholds included, can be objectively measured with available tools, obtained from available studies. The panelists agreed that measurement of objective markers

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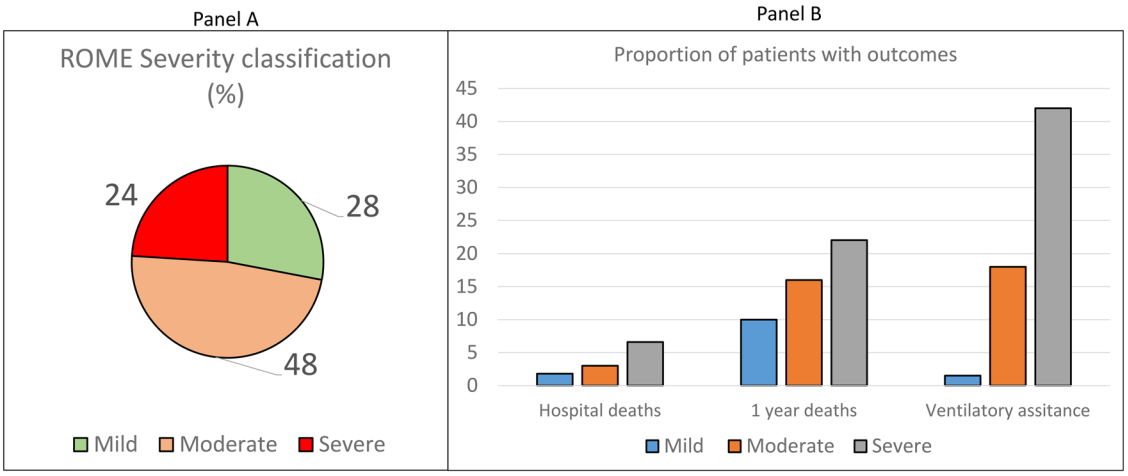

Figure 1 Data from 9997 hospitalized COPD patients, evaluated either emergency ward or in the hospital itself in 6 different studies. Panel A shows that the proportions of patients with different degrees of severity when evaluated using the ROME classification. All of these patients would have been classified as having a severe exacerbation with the current criteria. Panel B shows the discriminative properties of three different outcomes when the severity was classified using the ROME criteria. From references.[4–10]

helps separate a more severe event that most likely needs an emergency room or in-hospital visit, from a less severe event, likely associated with outpatient treatment. The proposal was reviewed by the Global Initiative for Obstructive Lung Diseases (GOLD) and adopted as a recommendation since 2023.

The proof is in the pudding

Publications from 6 countries[6–11] have validated the applicability and usefulness of the ROME proposal in the emergency room or hospital setting in 9997 exacerbating COPD patients. The first important finding, shown in Figure 1, Panel A, is that close to 30% of patients hospitalized across all countries (currently classified as SEVERE events), had only a mild episode according to the ROME classification. This misclassification introduces confounders when these patients are included in clinical trials evaluating the impact of therapies on severe (hospitalized) events. These results also suggest that the reason for those admissions may not be related to the severity of the event itself. This may be the reason why there is a mortality of 2% in these "mild" exacerbations compared with close to no mortality in patients classified as "mild" using the current classification, which by definition excludes hospitalization as an outcome. Prospective studies are needed to confirm this hypothesis. Secondly, as shown in Figure 1, Panel B, the ROME severity classification predicted well in-hospital and 1-year mortality, need for ventilatory support, ICU admissions, and length of hospital stay. Thirdly, in one prospective study conducted in 9 Emergency Rooms, the easier to calculate ROME severity classification was superior to the DECAF score in predicting outcomes.[9] Fourth, the studies documented that it is possible to measure the variables included in the ROME proposal. Collectively, these studies show that the ROME definition and severity classification of COPD exacerbations can be used clinically to stratify patients and predict outcomes, remembering though, that the ROME proposal is meant to evaluate the severity of the actual respiratory event and not the severity of the patient in general. It may be time to plan prospective studies not only in the in-hospital setting, but also in the outpatient setting to test the usefulness of the ROME proposal in the overall care of COPD patients.

Conclusion

The rapidity with which the data of close to 10,000 patients have validated the potential use of the proposed ROME definition and classification of severity of COPD exacerbations, suggests that the field is ready to accept this change. The studies here referenced agree that the proposal is applicable at the emergency room or in-hospital point-of-care, the variables included are measurable and importantly, that the obtained on-site information predicts ulterior health outcomes. All roads seem to lead to ROME, and the challenge is to test its value in all patients with COPD thought to have an exacerbation.

Author contribution

BRC and LMF wrote the intial draft. All of the authors had participated in the generation of the original Rome proposal. All authors reviewed and contributed to finalizing the manuscript. They all approved the final version of the wor.

Conflicts of interest

Please see the ICMJE disclosure forms, which have been provided as supplementary material.

Artificial intelligence disclaimer

No artificial intelligence was used in the generation of the manuscript, or the figure.

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