

Glucocorticoid Use in Patients Hospitalized with Chronic Obstructive Pulmonary Disease Exacerbations

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Objective of the Study: Systemic glucocorticoid therapy can improve the outcomes of acute exacerbation of chronic obstructive pulmonary disease (AECOPD). The study tried to investigate the use of glucocorticoids in AECOPD patients and the factors associated with the physicians' choice.

Methodology: Patients with AECOPD over two periods were divided by the year of 2017 when GOLD and ERS/ATS Guideline for COPD were updated. Data of patients regarding the study was retrieved from medical records. Descriptive statistical analysis was used for the illustration of glucocorticoids use, and hypothesis testing for comparison over the periods.

Results: Between 2010 and 2016, the proportion of ICS use was 522/640 (81.6%) and 341/452 (75.4%) between 2017 and 2020. COPD severity (GOLD C/D classification), bronchial asthma, percentage of neutrophils, and higher PaCO₂ were factors associated with physicians' prescription of systemic glucocorticoids between 2010 and 2016. While the use of ICS at the stable stage, counts of neutrophils, and higher PaCO₂ were influencing factors between 2017 and 2020. Over the two periods, 1-year recurrent rate decreased from 32.4% to 20.9%, with a significant statistical difference ($P < 0.001$).

Conclusion: The optimized use of glucocorticoids was found after the publication of 2017 ERS/ATS Guideline for COPD, this improvement was associated with a decreased 1-year recurrence rate among AECOPD patients at our institution, underscoring the positive impact of guideline updates on patient outcomes.

Keywords: chronic obstructive pulmonary disease, acute exacerbation, glucocorticoids, treatment selection

Introduction

Acute exacerbation of chronic obstructive pulmonary disease (AECOPD) involves inflammatory responses in the airway and is a major cause of hospitalization and mortality.¹⁻³ Systemic glucocorticoids can improve pulmonary function and oxygenation in patients with AECOPD, shorten recovery time and hospitalization, and reduce the failure rate of early treatments.⁴ Systemic glucocorticoids are recommended by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines,⁴ but no detailed descriptions of time, dosage, mode, and duration of systemic glucocorticoid treatment are provided. In addition, glucocorticoids are associated with significant adverse effects.^{4,5} Peripheral blood eosinophil ratio $\geq 2\%$ can be used to determine who might achieve a better response to systemic glucocorticoids,^{6,7} but prospective studies might not reflect the real-world situation.

A retrospective observational study in China showed that among patients hospitalized with AECOPD, 9.8% did not receive glucocorticoids, 38% received only inhaled corticosteroids, and 56% were treated with systemic glucocorticoids, of whom 40.5% received inhaled and systemic corticosteroids simultaneously.¹ Unfortunately, in that previous study, detailed information on systemic glucocorticoids was not provided (eg when did the first inhaled glucocorticoids

treatment fail, the sequential use of systemic after inhaled glucocorticoids, and the simultaneous use of inhaled and systemic glucocorticoids).

Although systemic glucocorticoids in patients with AECOPD were recommended by guidelines,^{4,5} treatment of a number of patients was inconsistent with those guidelines.¹ Therefore, the characterization of the actual situation and the understanding of why some patients are not treated according to guidelines is essential to formulate a management strategy that fits the actual reality. In addition, COPD is a heterogeneous disease within a given population of patients, and there are differences among ethnic groups.⁴ Future more, with the update of GOLD and ERS/ATS Guideline for COPD in 2017, changes of physicians' decision-making on glucocorticoids and how it affects patients' outcomes have not been investigated. Therefore, the present study aimed to describe the actual treatment situation of Chinese patients admitted to the hospital with AECOPD and explore the factors influencing Chinese clinicians' choice of glucocorticoid treatment patterns, and to investigate longitudinally how the patterns changed over the time, as well as patients' outcome.

Methods

Study Design

This retrospective observational study analyzed AECOPD patients admitted to the Department of Respiratory and Critical Care Medicine of the Hospital from January 1st, 2010 to December 31st, 2020. This study was approved by the institutional ethics committee of Beijing Shijitan Hospital, Capital Medical University (#2018-10-66) and individual consent was waived due to the de-identified nature of the medical records.

Patients

COPD and AECOPD were diagnosed based on the Global Initiative for Chronic Obstructive Pulmonary Disease (2016 Version).⁵ Medical records were retrieved for searching the cases those met the criteria for disease diagnosis. All patients with the diagnosis of AECOPD and hospitalized in our department during the study period were recorded and if a case met one of the following criteria would be excluded from this study: with 1) pulmonary edema, 2) pulmonary hemorrhage, 3) pulmonary fibrosis, 4) lung cancer, 5) pulmonary embolism. The patient's initial admission was considered the baseline, and subsequent readmissions were evaluated for outcomes.

Data Collection

All medical charts are electronic and fully indexed, and searchable. For each eligible patient, detailed data on demographic, clinical, laboratory, drug, and outcomes were extracted from the medical records. Re-admission was also extracted as an outcome.

Subgrouping

The patients were grouped as low-risk (GOLD A/B) and high-risk (GOLD C/D).⁴ The clinical manifestations of AECOPD included acute exacerbation of cough, expectoration, and/or wheezing.⁵ Because of the differences in diagnostic accuracy between CT and X-ray, we only used the two clearer signs (ie, simple chronic bronchitis or chronic bronchitis combined with exudation on imaging). Lung exudate on CT or X-ray was considered a sign of pneumonia.

Statistical Analysis

Data were analyzed using SPSS 20.0 (IBM, Armonk, NY, USA). Continuous variables were presented as means ([SD]) and analyzed using the independent samples *T*-test or the Mann–Whitney *U*-test. Categorical variables were presented as n (%) and analyzed using the chi-square test or Fisher's exact test. Potential factors associated with the selection of glucocorticoids for hospitalized patients with AECOPD were identified by logistic regression models (backward, Wald). In order to minimize the events per variable, variables with a *P*-value <0.10 in univariable logistic regression models were included in the multivariable logistic regression models. *P*-values <0.05 were considered statistically significant.

Results

Demographic and Clinical Characteristics of the Study Population

During the study period (January 2010 to December 2020), a total of 1092 patients were included, in which 640 patients were admitted between 2010 and 2016, and 452 were admitted between 2017 and 2020. The patients were aged 77.0 ([9.1]) and 75.4 ([10.4]) years in 2010–2016 and 2017–2020, respectively. The number and percentage of male was 457 (71.4%) and 335 (74.1%). No statistical significance was found in age or gender over the two periods (Table 1).

Glucocorticoids Use

Corticosteroids (ICS and systemic) use differed over the two periods. ICS use without systemic corticosteroids was found in 346 patients (54.1%) in 2010–2016, while in 271 patients (60.0%) in 2017–2020 ($P=0.045$). Systemic corticosteroids use without ICS was 7 (1.1%) and 6 (1.3%) in 2010–2016 and 2017–2020, respectively ($P=0.726$). The combination of ICS and systemic corticosteroids was applied to 176 (27.5%) and 69 (15.3%) patients over the two periods ($P<0.001$) (Table 1).

For the frequency and dosage of corticosteroids, data between 2010 and 2020 were further analyzed. The systemic glucocorticoids used during hospitalization included methylprednisolone sodium succinate for injection (40 mg/bottle, Pfizer Manufacturing Belgium NV) and methylprednisolone (96.7%) or prednisone/prednisolone (3.3%). The nebulized glucocorticoids were budesonide suspension for inhalation (1mg/2mL, AstraZeneca Pty Ltd.). Based on the equivalent doses of methylprednisolone, the duration of systemic glucocorticoid therapy was 7.4 ([5.7]) days, with a cumulative dose of 214.0 ([178.7]) mg. The cumulative dose did not exceed 200 mg in 156 (60.5%) patients. Systemic

Table 1 Characteristics at Baseline and Outcomes of the Study Population Over Two Periods

	2010–2016 (n=640)	2017–2020 (n=452)	P
Demographics			
Age (years)	77.00±9.12	75.38±10.43	0.831
Male	457 (71.4%)	335 (74.1%)	0.323
GOLD C/D Group	438 (68.4%)	206 (45.6%)	<0.001
History of smoking	494 (77.2%)	272 (60.2%)	<0.001
Use of ICS at stable stage	84 (13.1%)	88 (19.5%)	0.005
Glucocorticoids use			
ICS use without systemic corticosteroids	346 (54.1%)	271 (60.0%)	0.045
Systemic corticosteroids use without ICS	7 (1.1%)	6 (1.3%)	0.726
ICS+systemic corticosteroids use	176 (27.5%)	69 (15.3%)	<0.001
Systemic glucocorticoids use	183	75	
Dose of systemic glucocorticoids (mg)			
40–200	105 (57.4%)	51 (68.0%)	
201–400	64 (35.0%)	19 (25.3%)	
401–1184	14 (7.7%)	5 (6.7%)	
Days of systemic glucocorticoids treatment (days)			
1–5	75 (41.0%)	48 (64.0%)	
6–14	89 (48.6%)	21 (28.0%)	
15–31	19 (10.4%)	6 (8.0%)	
Outcomes			
Respiratory Failure	173 (27%)	119 (26.3%)	0.796
Mechanical ventilation	60 (9.4%)	47 (10.4%)	0.575
Hospital duration (days)	10.67±9.82	9.43±7.08	0.022
Intrahospital mortality	17 (2.7%)	11 (2.5%)	0.855
Recurrence within 30 d after discharge	26 (4.2%)	21 (5.5%)	0.617
Recurrence within 1 year after discharge	202 (32.4%)	91 (20.9%)	<0.001

Notes: Data are shown as mean ± SD, median (IQR), or n (%); $P<0.05$ are shown as bold letters.

glucocorticoids were used for no more than 5 days in 123 (47.7%) patients and more than 2 weeks in 25 (9.7%) patients. The daily dose of ICS varied from 1 to 4 mg (Table 1).

Comparison of Outcome Over the Two Periods

This study examined hospital duration, intrahospital mortality, recurrence within 30 days after discharge, and recurrence within 1 year after discharge. Hospital duration decreased significantly in 2017–2020 compared to 2010–2016 (10.7 ([9.8]) vs 9.4 ([7.1]) days, $P=0.022$). Recurrence within 1 year after discharge decreased by 12.5% over time (32.4% vs 20.9%, $P<0.001$), but there were no significant changes in intrahospital mortality and 30-day recurrence (Table 1).

Clinical Characteristics with Significant Difference Between Glucocorticoids Use or Not

Differences between glucocorticoids-use and no-use patients regarding clinical outcomes, comorbidities, laboratory results, and characteristics of chest CT are described in Supplementary Table 1. For the two periods, patients who were in the high-risk group, or AECOPD ≥ 1 within previous 12 months, or with lower FEV1%pre, or higher PaCO₂ were prescribed with glucocorticoids, and the duration of hospitalization was longer in the glucocorticoid group. While patients who used ICS at stable stage, or non-fever were more prescribed with glucocorticoids in 2017–2020 period.

Factors Associated with Glucocorticoids Prescription for AECOPD

Data were analyzed for comparison between those who received glucocorticoids or not grouped as 2010–2016 and 2017–2020. Multivariable logistic regression found that high-risk group patients, combined with hypertension, increased PaCO₂ might be independent impact factors for glucocorticoids prescription in 2010–2016 (Table 2). Multivariable logistic regression found that AECOPD ≥ 1 within previous 12 months, use of ICS at stable stage, bronchial asthma, combined with hypertension and percentage of eosinophils might be independent impact factors for glucocorticoids prescription in 2017–2020 (Table 3).

Table 2 Factors Associated with Glucocorticoids Use Among Hospitalized Patients with AECOPD (Data of 2010–2016)

Variables	Univariable Logistic Regression			Multivariable Logistic Regression		
	OR	95% CI	P	OR	95% CI	P
Sex (male)	1.659	1.011–2.722	0.045			
Age	1.013	0.991–1.035	0.256			
History of smoking	0.980	0.601–1.599	0.936			
History of chronic cough	1.022	1.005–1.039	0.009			
High-risk patients	2.926	1.925–4.480	<0.001	2.218	1.322–3.424	0.002
≥ 1 AECOPD within the previous 12 month	2.447	1.431–4.184	0.001	1.681	0.934–3.026	0.083
Use of ICS at stable stage	1.300	0.679–2.486	0.428			
Fever	1.265	0.833–1.919	0.270			
Bronchial asthma	1.817	1.016–3.251	0.044			
Hypertension	1.526	1.012–2.303	0.044	1.599	1.047–2.443	0.030
Type 2 diabetes	1.345	0.787–2.297	0.278			
Old tuberculosis	0.794	0.496–1.272	0.337			
Ischemic heart disease	0.864	0.573–1.304	0.486			
Osteoporosis	0.905	0.363–2.252	0.829			
Count of WBC	0.997	0.943–1.054	0.916			
Percentage of Neutrophils	1.019	1.002–1.037	0.032			
Count of Neutrophils	1.013	0.953–1.076	0.688			
Percentage of Eosinophils	1.000	0.939–1.066	0.994			
Count of Eosinophils	0.839	0.416–1.694	0.625			
PaO ₂ (mmHg)	0.998	0.991–1.006	0.637			
PaCO ₂ (mmHg)	1.023	1.010–1.037	0.001	1.016	1.001–1.032	0.032
Exudation on chest CT	0.933	0.578–1.505	0.775			
Chronic bronchitis on chest CT	1.062	0.689–1.636	0.785			

Note: $P<0.05$ are shown as bold letters.

Abbreviations: AECOPD, acute exacerbations of COPD; ICS, inhaled corticosteroid; WBC, white blood cell; CT, computed tomography.

Table 3 Factors Associated with Glucocorticoids Use Among Hospitalized Patients with AECOPD (Data of 2017–2020)

Variables	Univariable Logistic Regression			Multivariable Logistic Regression		
	OR	95% CI	P	OR	95% CI	P
Sex (male)	1.256	0.752–2.098	0.384			
Age	0.982	0.961–1.003	0.094			
History of smoking	1.411	0.909–2.189	0.125			
History of chronic cough	1.002	1.000–1.003	0.034			
High-risk patients	2.093	1.323–3.313	0.002			
≥1 AECOPD within the previous 12 month	2.358	1.486–3.743	<0.001	2.038	1.192–3.484	0.009
Use of ICS at stable stage	4.323	1.931–9.678	<0.001	3.424	1.277–9.180	0.014
Fever	0.465	0.298–0.725	0.001			
Bronchial asthma	6.890	2.718–17.462	<0.001	5.448	1.880–15.791	0.002
Hypertension	1.584	1.023–2.454	0.039	2.186	1.299–3.676	0.003
Type 2 diabetes	1.293	0.748–2.235	0.357			
Old tuberculosis	0.657	0.395–1.092	0.105			
Ischemic heart disease	0.975	0.625–1.522	0.975			
Osteoporosis	0.914	0.377–2.213	0.842			
Count of WBC	0.981	0.918–1.048	0.566			
Percentage of Neutrophils	1.000	0.981–1.020	0.989			
Count of Neutrophils	0.980	0.914–1.050	0.562			
Percentage of Eosinophils	1.129	1.004–1.270	0.043	1.169	1.016–1.344	0.029
Count of Eosinophils	0.943	0.432–2.057	0.882			
PaO ₂ (mmHg)	1.000	0.988–1.011	0.965			
PaCO ₂ (mmHg)	1.037	1.010–1.065	0.007	1.026	0.996–1.054	0.055
Exudation on chest CT	0.879	0.606–1.276	0.498			
Chronic bronchitis on chest CT	1.508	1.016–2.236	0.041	1.564	0.970–2.522	0.067

Notes: P<0.05 are shown as bold letters.

Abbreviations: AECOPD, acute exacerbations of COPD; ICS, inhaled corticosteroid; WBC, white blood cell; CT, computed tomography.

Factors Associated with Glucocorticoids Use Patterns for AECOPD

Data were also analyzed to determine how the glucocorticoids use patterns were influenced. The multivariable analysis showed that high-risk group patients, bronchial asthma, percentage of neutrophils, and increased PaCO₂ were independent factors associated with the clinicians' choice of systemic glucocorticoids for patients in 2010–2016 ([Supplementary Table 2](#)). The use of ICS at stable stage, count of eosinophils, and increased PaCO₂ were independent factors associated with the clinicians' choice of systemic glucocorticoids for patients in 2017–2020 ([Supplementary Table 3](#)).

Demographic and Clinical Characteristics of the Study Population in GOLD C/D Subgroup

No statistical significance was found in the age or gender of patients in the GOLD C/D subgroup over the two periods. Glucocorticoids (ICS and systemic) use differed over the two periods. ICS use without systemic corticosteroids was significantly more in 2017–2020. Systemic corticosteroids use without ICS was more in 2010–2016 without significance. The combination of ICS and systemic corticosteroids was more significantly applied in 2010–2016. Outcomes were similar to those of the whole study population ([Supplementary Table 4](#)).

Discussion

Current guidelines worldwide recommend systemic glucocorticoids for AECOPD,^{4,8} but due to COPD's heterogeneity and potential adverse effects, it is debatable whether all hospitalized AECOPD patients should receive them.^{1,2,9} In the present study, high-risk group patients, bronchial asthma, percentage of neutrophils, and increased PaCO₂ affected the physicians' choice of using glucocorticoids to treat AECOPD before the guideline was modified in 2017. In the

meantime, use of ICS at stable stage, count of neutrophils, and PaCO₂ influenced the physicians' choice of systemic glucocorticoids after the guideline was modified. We found that patients with type II respiratory failure were intended to prescribe systemic glucocorticoids.

In this study, between 2010 and 2016, 529 patients (82.7%) with glucocorticoids (346 (65.4%) with non-systemic glucocorticoids; 183 (34.6%) with systemic glucocorticoids) and 111 (17.3%) without, and between 2017 and 2020, 341 patients (75.4%) with glucocorticoids (271 (60.0%) with non-systemic glucocorticoids; 75 (16.6%) with systemic glucocorticoids) and 111 (24.6%) without. All these proportions were lower than those from the study by Zhang et al.¹ Only 23.6% of the hospitalized AECOPD patients received systemic glucocorticoids in the present study. The average daily dose was 32.57 ([11.07]) mg, and the average course of treatment was 7.37 ± 5.65 days. Thus, systemic glucocorticoids with a safe dose and an appropriate course were consistent with the GOLD guidelines⁵ but lower than that of previous reports.^{1,2} In the present study, the duration of patients treated with systemic glucocorticoids was 13.5 (13.3) days, and mortality during hospitalization was 3.0%, similar to previous studies,¹⁻³ but was higher than in the study by Zhang et al.¹ A study from Europe showed that 42% of the GOLD B and 68% of the GOLD D patients received inhaled glucocorticoids.¹⁰ The real-world data are few and mostly lacking. A real-world study in the UK is currently underway.¹¹ It was worth noting that the new guidelines may be more beneficial to the prognosis of patients after adjusting the medication of COPD with different severities. The reason may be that the stress response of glucocorticoids to COPD patients was too strong, leading to the deterioration of the disease. Reducing the use of glucocorticoids may reduce the complications and uncomfortable symptoms of patients, which was more conducive to the short-term prognosis and rehabilitation process of patients.

In COPD, neutrophils, macrophages, and CD₈⁺ cells play important roles in the inflammation of the airway and structural destruction and remodeling of the lung, particularly for lesions in small airways.¹² Airway inflammation in AECOPD includes neutrophilic and eosinophilic inflammatory reactions,¹³ and 10–25% of the patients with COPD have eosinophilic inflammation.¹⁴ Peripheral blood eosinophil is considered a sensitive and specific biomarker to predict the sensitivity to glucocorticoids.⁶ Glucocorticoids can reduce eosinophil counts, mucus exudation, and related symptom. The previous study suggests that a peripheral blood eosinophil ratio $\geq 2\%$ may be the threshold indicating sensitivity to systemic glucocorticoids.¹⁵ This marker helps differentiate glucocorticoids-sensitive patients.^{6,7} In our study, percentage of eosinophils in peripheral blood also was an independent factor influencing choice of glucocorticoids.

Interestingly, few patients treated with glucocorticoids or systemic glucocorticoids tended to have peripheral eosinophils $\geq 2\%$. In this study, 15.8% of the patients treated with glucocorticoids who used ICS during the stable stage of COPD, inhibiting the response of eosinophils in peripheral blood and local airway.¹⁶ Most patients (59%) were high-risk group patients, but only 25–40% or even as low as 17.9% of the patients with severe AECOPD have eosinophils $\geq 2\%$.¹⁷ AECOPD is typically triggered by infection, which can suppress eosinophil proliferation, resulting in lower eosinophil levels. Prospective studies with larger sample sizes are needed to determine the eosinophil threshold for systemic glucocorticoids in Chinese AECOPD patients.

Asthma-COPD overlap (ACO) consists of several clinical phenotypes common to the two diseases,¹⁸ with eosinophilia found in the sputum and a good response to systemic glucocorticoids.¹⁹ In this study, 20.6% of the patients with COPD also had asthma. Therefore, ACO probably affects the response to systemic glucocorticoids in patients hospitalized with AECOPD, and asthma was independently associated with the selection of systemic glucocorticoids for patients in 2010–2016. Although asthma was not independent factor for choice of systemic glucocorticoids in 2017–2020, it was still independently associated with use of glucocorticoids during acute exacerbation.

The use of ICS during the stable stage of COPD significantly influenced the choice of systemic glucocorticoids for acute exacerbation. Long-term use of ICS in moderate-to-severe COPD patients effectively suppresses airway inflammation and reduces mucosal secretions. However, during AECOPD, airway inflammation worsens, making it challenging for nebulized glucocorticoids to provide rapid relief. Consequently, physicians often opt for systemic glucocorticoids to alleviate symptoms. Lower respiratory tract infections are the primary AECOPD cause, with viral or bacterial infections accounting for 50–70% of the cases. Frequent systemic glucocorticoids use raises the risk of secondary fungal infections, contributing to more AECOPD events and treatment failures. AECOPD patients with pneumonia may not benefit from systemic glucocorticoids, as these drugs can dampen the immune response against pathogens, potentially causing

pneumonia.²⁰ Determining the boundary between pneumonia and AECOPD remains controversial.^{21–23} The present study suggests that for patients with AECOPD manifesting as chronic bronchitis on chest CT, physicians would choose systemic glucocorticoids, while for those manifesting as pneumonia, as shown by lung exudate at imaging, systemic glucocorticoids could be considered more cautiously. With the change in glucocorticoids use pattern that the proportion of ICS use increases accompanied by the reduced usage of systemic glucocorticoids, a trend of lower long-term recurrent rate was observed. This may suggest that clinicians should pay more attention to the compliance of glucocorticoids use according to COPD guidelines.

The study suggests that 1-year recurrent rate significantly decreased in 2017–2020. We analyzed the causes of this difference: on the one hand, it was probably related to the decreased use of systemic glucocorticoids that could cause adverse effects, and, on the other hand, patients were less severe, and the smoking proportion was lower in 2017–2020, which may lead to a bias in the result. This requires research to further validate.

This study has several limitations. It is a hospital-based retrospective study, lacking long-term follow-up data. Not all patients underwent pulmonary function tests due to their condition. The sample size is relatively small as it is a single-center study, although it represents AECOPD patients using systemic glucocorticoids. While factors influencing glucocorticoid selection were identified, multicenter prospective cohort studies are needed to validate these findings. Nevertheless, this retrospective observational study offers insights into the real-world use of systemic glucocorticoids in Chinese AECOPD patients.

Conclusion

This study reveals non-compliance with AECOPD management guidelines in real-world Chinese patients. Factors such as high-risk status, bronchial asthma, neutrophil percentages, and higher PaCO₂ influence systemic glucocorticoid use in AECOPD patients in 2010–2016, while use of ICS at stable stage, count of neutrophils, and higher PaCO₂ influence systemic glucocorticoid use in AECOPD patients in 2017–2020. Patients with type II respiratory failure tended to be prescribed systemic glucocorticoids. These findings reflect the real-life situation in one Chinese hospital and are crucial for aligning management strategies with the actual needs and improving guideline adherence.

Data Sharing Statement

The authors confirm that the data supporting the findings of this study are available within the article and its [Supplementary Material](#).

Ethics Committee Approval

This study was approved by the institutional ethics committee of Beijing Shijitan Hospital, Capital Medical University (#2018-10-66). As the study was retrospective and entirely based on de-identified medical records, and individual informed consent was waived by the committee. The study complied with the Declaration of Helsinki.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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