ORIGINAL RESEARCH

# Underdiagnosis of COPD: The Japan COPD Real-World Data Epidemiological (CORE) Study

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Purpose: The prevalence of airflow obstruction in Japan is 3.8%-16.9%. This epidemiological study based on a large database aimed to reassess the prevalence of airflow obstruction in Japan and the diagnosis rate of chronic obstructive pulmonary disease (COPD). Patients and Methods: We used data regarding claims from the health insurance union and health checkups provided by JMDC. The present study included a subgroup of individuals aged ≥40 years who underwent health checkups involving spirometry between January and December 2019. The study endpoints were the prevalence of airflow obstruction, COPD diagnosis rate, disease stage, and respiratory function test results.

Results: Among 102,190 participants, 4113 (4.0%) had airflow obstruction. The prevalence of airflow obstruction was 5.3% in men and 2.1% in women. Among the study population, 6.8% were current smokers, while 3.4% were never or former smokers. Additionally, the prevalence of COPD increased with age. Approximately 8.4% of participants with airflow obstruction were diagnosed with COPD. Regarding the COPD diagnosis status, participants with airflow obstruction who were diagnosed with COPD were at a more advanced stage than those not diagnosed. Finally, patients diagnosed with COPD had significantly lower  $FEV_1/FVC$  and  $FEV_1$  (p < 0.0001; Wilcoxon rank sum test).

Conclusion: The epidemiological study based on a large database determined the COPD diagnosis rate related to airflow obstruction. The COPD diagnosis rate was extremely low among individuals who underwent health checkups, indicating the need for increased awareness about this medical condition. Moreover, primary care physicians should identify patients with suspected COPD and collaborate with pulmonologists to facilitate the early detection of COPD and enhance the COPD diagnosis rate.

**Keywords:** COPD, epidemiology, airflow obstruction, prevalence, Japan, real-world data

### Introduction

Chronic obstructive pulmonary disease (COPD) is defined as a lung disease caused by prolonged inhalation exposure to toxic substances, primarily tobacco smoke, and is characterized by airflow obstruction as indicated by respiratory function tests. Airflow obstruction results from a combination of peripheral airway involvement and emphysematous lesions in varying proportions. COPD is clinically characterized by slowly progressive dyspnea during exertion and a chronic cough with sputum; however, some patients may present mild to no symptoms.<sup>1</sup>

According to a patient survey conducted by the Japanese Ministry of Health, Labour and Welfare (MHLW), 200,000 people in Japan are diagnosed with COPD, representing an estimated prevalence of 0.2%-0.4%. Contrastingly, the Nippon COPD Epidemiology (NICE) study<sup>3</sup> reported that 10.9% of the population aged ≥40 years had airflow obstruction and that the estimated prevalence of COPD in Japan is 8.6%, after excluding patients with asthma-related airflow obstruction. Further, among the participants with airflow obstruction, only 9.4% were diagnosed with COPD, indicating a low diagnosis rate. The NICE study was conducted in 2000; therefore, COPD-related circumstances, including demographic shifts such as population aging, alterations in smoking patterns, and changes in COPD

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prevalence, may have evolved after two decades. Health Japan 21 (the second term), which was initiated by the MHLW, has identified the need of increasing awareness regarding COPD. However, there remain limited public awareness regarding COPD despite respiratory function tests being performed during health checkups and screenings.<sup>4</sup>

Currently, large databases of health insurance claims and health checkups are available, which facilitate the analysis of the prevalence, examination, and care of airflow obstruction and COPD. Accordingly, we aimed to reassess the current prevalence of airflow obstruction in Japan and to determine the COPD diagnosis rate.

## **Materials and Methods**

We analyzed data regarding health insurance claims and health checkups from the health insurance union, provided by JMDC, Inc. JMDC, Inc creates databases (JMDC database) using data collected from health insurance unions. The JMDC database comprises the insured person ledger, receipts, and health checkup results. The insured person ledger contains information regarding all insured persons of the health insurance association. Receipts contain information regarding the medical expenses of the health insurance association billed by medical institutions and information on the insured who incurred the medical expenses. Health checkups are conducted by the health insurance association to confirm the health status of the insured; moreover, there are mandatory special health checkups for facilitating the prevention of lifestyle-related diseases among insured persons aged 40–74 years. A large segment of the Japanese population is insured by the Social Insurance Program, which is offered by multiple organizations, including health insurance unions. Health insurance unions are accessible to individuals employed in workplaces eligible for health insurance, provided they are aged <75 years, along with their families.

This study used the JMDC database, which contains pertinent data from records accumulated up to November 2022. We analyzed pertinent data collected between January and December 2019. A subgroup of participants aged ≥40 years who underwent a health checkup during the analysis period and had available respiratory function test data was examined.

The primary endpoint was airflow obstruction prevalence, which was defined by  $FEV_1/FVC < 0.7$  (hereinafter, airflow obstruction group). The secondary endpoints were the diagnosis rate of COPD in the airflow obstruction group, staging according to the percentage predicted value of  $FEV_1$  (% $FEV_1$ ), and spirometry measurements. COPD diagnosis was defined using the International Classification of Diseases 10th Revision codes J41–J44. The specific disease names that corresponded to J41 and J42 were smoker's bronchitis and chronic bronchitis, respectively. Non-respiratory specialists in Japan recognize chronic bronchitis as a type of COPD and often treat COPD under the name "chronic bronchitis" for insurance diagnosis purposes. However, we excluded participants with the standard disease codes for diffuse panbronchiolitis and bronchiolitis obliterans. Diagnoses of asthma (J45) and bronchiectasis (J47), which are also related to airflow obstruction, were analyzed. Data regarding age, sex, and smoking history at the time of the health checkup were collected. Participants who answered that they "had smoked  $\geq 100$  cigarettes in their lifetime or had been smoking for  $\geq 6$  months" and were "smoking in the most recent month" were defined as current smokers. It was difficult to accurately distinguish between never and former smokers using the database.

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Disease staging by %FEV<sub>1</sub> was calculated as follows:<sup>6</sup> Stage by %FEV<sub>1</sub>: GOLD 1 \ge 80\% / GOLD 2 \ge 50\% to < 80\% / GOLD 3 \ge 30\% to < 50\% / GOLD 4 < 30\% %FEV<sub>1</sub> = FEV<sub>1</sub> actual value ÷ FEV<sub>1</sub> expected value × 100 FEV<sub>1</sub> expected value: [men] 0.036 \times \text{height (cm)} - 0.028 \times \text{age} - 1.178, [women] 0.022 \times \text{height (cm)} - 0.022 \times \text{age} - 0.005
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#### Ethical Considerations

The requirement for informed consent was waived owing to the use of anonymized data. This study was approved by the ethics committee of the Riverside Internist and Cardiology Clinic (approval no. RSC-2208RB01).

# Statistical Analysis

Categorical variables are expressed as frequencies and percentages, while continuous variables are expressed as means (± standard deviations) or medians (interquartile ranges). Missing data for dates and health checkup values were not

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imputed. The analysis dataset was created using Amazon Redshift 1.0.43931 (Amazon Web Services, Inc., Seattle, WA, USA). All statistical analyses were performed using SAS (version 9.4, SAS Institute Inc., Cary, NC, USA). The Wilcoxon rank sum and chi-square tests were used for between-group comparisons according to the distribution of items. The proportions by airflow obstruction were stratified by age (40–49, 50–59, 60–69, and 70–74 years) and smoking history (current smokers vs never or former smokers), and the proportions were analyzed using the Cochran–Mantel–Haenszel test, relative risk, and 95% confidence interval. Statistical significance was set at a p value of 0.05.

#### Results

## **Participants**

The participant selection process is shown in Figure 1. The total target population was 102,190.

# Prevalence of Airflow Obstruction and COPD Diagnosis Rate Among People with Airflow Obstruction

Among the 102,190 participants, 4113 had airflow obstruction, representing a prevalence of 4.0% (Figure 2). Table 1 shows the sex, smoking status, and age of the participants. Regarding subgroups, the prevalence of airflow obstruction was 5.3% in men and 2.1% in women, as well as 6.8% in smokers and 3.4% in never or former smokers. The prevalence of airway obstruction increased with age as follows: 2.1%, 4.3%, 8.3%, and 14.4% in the 40–49, 50–59, 60–69, and 70–74 years age groups, respectively. Table 2 shows the number of patients with airflow obstruction stratified by age and status of tobacco use. Among the 4113 participants with airflow obstruction, 346 (8.4%) were diagnosed with COPD (Figure 3A). Among the 346 patients diagnosed with COPD, 141 (40.8%), 3 (0.9%) and 3 (0.9%) were diagnosed with asthma, bronchiectasis, and a combination of asthma and bronchiectasis, respectively. Among the 3767 patients not diagnosed with COPD, 788 (20.9%) and 5 (0.1%) were diagnosed with asthma and a combination of asthma and bronchiectasis, respectively (Figure 3B).

## Stage Classification and Respiratory Function of Participants with Airflow Obstruction

The disease stage of the participants with airflow obstruction diagnosed with COPD was determined based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. Details are provided in Table 3, which indicates

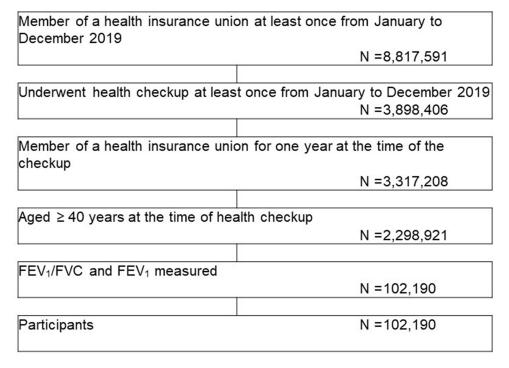


Figure I Flowchart of the participant selection process.

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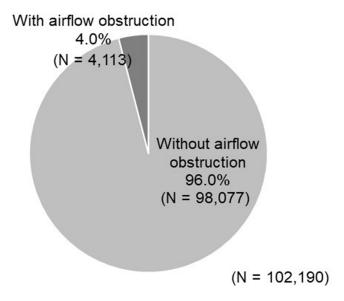


Figure 2 Prevalence of airflow obstruction.

a strong trend toward airflow obstruction in the COPD diagnosis group (p < 0.0001; chi squared test). The COPD diagnosis rates were 6.2% for GOLD 1, 9.6% for GOLD 2, and 21.8% for GOLD 3 and GOLD 4.

Regarding respiratory function tests, the FEV<sub>1</sub>/FVC values for participants without and with a COPD diagnosis were  $65.34 \pm 4.90\%$  and  $62.37 \pm 7.38\%$ , respectively. Moreover, the FEV<sub>1</sub> values were  $2.48 \pm 0.63$  L and  $2.23 \pm 0.59$  L in participants without and with COPD diagnosis, respectively. Both FEV<sub>1</sub>/FVC and FEV<sub>1</sub> values were significantly lower in the participants with COPD than in those without COPD (p < 0.0001; Wilcoxon rank sum test).

Table I Participant Characteristics

	Total	Without Airflow Obstruction	With Airflow Obstruction			
	N = 102,190	N = 98,077	N = 4113			
	n (%)	n (%)	n (%)			
Sex						
Men	61,586 (60.3)	58,343 (59.5)	3243 (78.8)			
Women	40,604 (39.7)	39,734 (40.5)	870 (21.2)			
Smoking history						
Current smokers	19,449 (19.0)	18,135 (18.5)	1314 (31.9)			
Never or former smokers	82,706 (80.9)	79,907 (81.5)	2799 (68.1)			
Unknown	35 (0.0)	35 (0.0)	0 (0.0)			
Age (10-year increments)						
40-49 years	46,269 (45.3)	45,279 (46.2)	990 (24.1)			
50-59 years	40,483 (39.6)	38,737 (39.5)	1746 (42.5)			
60-69 years	13,940 (13.6)	12,778 (13.0)	1162 (28.3)			
70-74 years	1498 (1.5)	1283 (1.3)	215 (5.2)			

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Table 2 Airflow Restrictions Combined with Age and Smoking Status (Excluding Those with Unknown Smoking History)

N = 102,155		Total	Without Airflow Obstruction	With Airflow Obstruction	Cochran-Mantel-Haenszel test
		n	n (%)	n(%)	
40–49 years	Current smokers	9277	8957 (96.6)	320 (3.4)	p<0.0001 Relative risk 2.1267 (1.9967-2.2652)
	Never or former smokers	36,971	36,301 (98.2)	670 (1.8)	
50–59 years	Current smokers	7711	7116 (92.3)	595 (7.7)	
	Never or former smokers	32,766	31,615 (96.5)	1151 (3.5)	
60–69 years	Current smokers	2311	1955 (84.6)	356 (15.4)	
	Never or former smokers	11,621	10,815 (93.1)	806 (6.9)	
70–74 years	Current smokers	150	107 (71.3)	43 (28.7)	1
	Never or former smokers	1348	1176 (87.2)	172 (12.8)	

Notes: p < 0.0001 (Cochran-Mantel-Haenszel test). Relative risk 2.1267 (1.9967–2.2652).

## **Discussion**

Japanese epidemiological studies on COPD have included surveys of patients conducted by the MHLW, general population surveys, and studies of health checkups performed on community residents that examined the prevalence of airflow obstruction. This study was the first large-scale epidemiological study of COPD in Japan, covering approximately 100,000 people throughout Japan using health insurance association-derived receipt data and health examination data. This study is valuable in demonstrating, for the first time, the reality in Japan where only 8.4% of the group with airflow obstruction identified during routine health checkups, despite spirometry being performed in annual health examinations, were diagnosed with COPD.

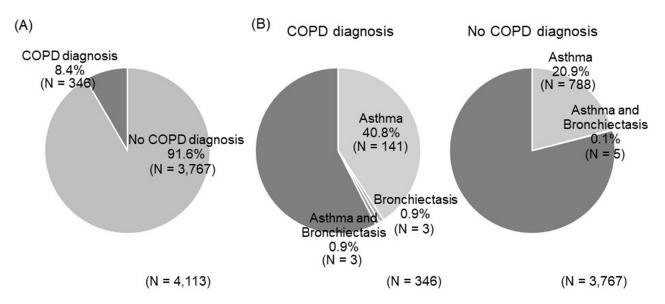


Figure 3 Diagnostic rates in the airflow obstruction group. (A) COPD in the airflow obstruction group. (B) Asthma and bronchiectasis in patients with and without COPD diagnosis.

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Table 3 Disease Staging in Participants with Airflow Obstruction

	COPD Diagnosis (-)	COPD Diagnosis (+)	
	N = 3767	N = 346	
	n (%)	n (%)	
GOLD I	1632 (43.3)	107 (30.9)	
GOLD 2	1802 (47.8)	192 (55.5)	
GOLD 3	105 (2.8)	28 (8.1)	
GOLD 4	6 (0.2)	3 (0.9)	
Non-assessable	222 (5.9)	16 (4.6)	

Notes: p < 0.0001 (chi squared test).

Abbreviation: GOLD, Global Initiative for Chronic Obstructive Lung Disease.

In this study, the prevalence of airflow obstruction was 4.0%. The NICE study<sup>3</sup> reported that the prevalence of airflow obstruction was 10.9%, which is consistent with other reports among community-dwelling Japanese individuals. However, they have been inconsistent reports across studies, which could be attributed to differences in the age and sex distribution of the participants. For example, the Takahata, Nagahama, and Fujiwara-kyo, studies reported that the prevalence of airflow obstruction was 10.6%, 3.8%, and 16.9%, respectively. The prevalence in our study was relatively lower than that reported in other studies.

COPD is caused by prolonged smoking, and its prevalence increases with age, similar to that of airflow obstruction. This condition is particularly notable in older men, with one in four men aged  $\geq 70$  years having airflow obstruction.<sup>7</sup> The data used in this study were obtained from a health insurance union; therefore, there were limited data regarding people aged ≥65 years, it not included participants aged ≥75 years. Therefore, data on participants aged ≥65 years with airflow obstruction were not captured accurately, resulting in a lower overall prevalence. A subgroup analysis of the prevalence of airflow obstruction showed that the prevalence was higher among men, smokers, and individuals of advanced age, which is consistent with previous reports.<sup>3,7</sup> This suggests that our data are representative of the trends in COPD. In the present study, the prevalence of airflow obstruction was higher among current smokers (6.8%) than among never or former smokers (3.4%), which is consistent with previous reports. A study investigating air pollution in a certain Japanese city reported an estimated COPD prevalence of 16%, 29%, and 37% in nonsmokers aged ≥50 years, smokers aged 50–74 years, and smokers aged ≥75 years, respectively. Ourrent smokers with COPD and asthma-COPD overlap (ACO) have shown significantly higher heated cigarette use than those without these respiratory diseases, underscoring the importance of quitting smoking both cigarettes and heated cigarettes. 11 Although smoking is the greatest risk factor for COPD and the health-related importance of smoking cessation has been established, environmental factors such as air pollution influence COPD development.<sup>12</sup> The nature of the data in the present study impedes the discussion of environmental factors, which is one of the limitations of this study.

The COPD diagnosis rate was 8.4% among participants with airflow obstruction. The NICE study reported that 9.4% of participants with airflow obstruction were diagnosed with COPD.<sup>3</sup> This is consistent with our findings of low diagnosis rates of COPD among patients with airway obstruction. A study on people aged 55-74 years with a smoking history who participated in a lung cancer screening program in an underserved area of the United Kingdom reported that 944 out of 2525 people who underwent spirometry had developed airflow obstruction; among them, 475 had been diagnosed with COPD. 13 This indicated that ≈50% of screened patients with airflow obstruction had already been diagnosed with COPD, which is a significant divergence from our results. Since this previous study included current or former smokers aged 55-74 years, it is possible that the population included a larger number of people at an increased risk of COPD than our study population, and thus were more likely to have a COPD diagnosis. This could have attributed to the differences in the findings between the previous and current study, which used a database of 100,000 individuals derived from a Japanese health insurance association. Patients may refrain from seeking further medical attention even when airflow obstruction is detected during routine medical checkups, which may hinder the timely diagnosis of COPD.

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In a study of individuals with a smoking history and no known obstructive lung disease, 21% had undiagnosed airflow obstruction; moreover, within a 5-year follow-up period, Modified Medical Research Council score ≥2, chronic productive cough, worsening respiratory symptoms during the follow-up period, and abnormal spirometry were found to be risk factors for subsequent COPD development.<sup>14</sup> We could not conduct a detailed survey in an undiagnosed population; moreover, the available data were limited by the use of a database derived from the health insurance association. Although it is difficult to compared the previous findings with the present findings, we believe that identifying individuals at risk as indicated in previous studies may facilitate prompt COPD diagnosis.

Health checkups are conducted with the primary objective of early detection and treatment of various diseases, including lifestyle diseases. The NICE study conducted a single respiratory function test on its participants; contrastingly, our participants underwent respiratory function tests during annual checkups. This difference highlights the notion that health checkups are not particularly effective in prompting further medical attention for COPD. Several factors that may contribute toward this phenomenon include insufficient awareness among the general public about COPD and the subtle nature of early symptoms. An online survey conducted by the Japan GOLD Committee since 2009 has consistently revealed low awareness levels of COPD among the general population, with only 34.6% of the respondents acknowledging the condition in 2022. This underscores the imperative need for enhanced public awareness about the disease.

A survey of European and North American nations reported that the COPD mortality rate increases with the advancement of disease staging, with a 1.2-fold, 1.6-fold, and 2.7-fold increase being observed in patients with stage I, II, and III COPD, respectively, compared with controls. <sup>16</sup> Since prognosis worsens with disease progression, the early implementation of appropriate long-term management can potentially improve patient outcomes. <sup>17,18</sup> The Japanese MHLW has identified the reduction of COPD mortality as a goal in Health Japan 21 (Term 3). <sup>19</sup> Although the current COPD mortality rate in Japan is 13.3 per 10,000 people, the MHLW seeks to decrease this figure to 10.0 by 2032 by implementing measures focused on the early detection, treatment, and prevention of COPD exacerbations. Since patients with latent COPD are likely to receive primary care, it is important for primary care physicians in collaboration with pulmonologists to identify suspected patients in order to promote the early detection of COPD and enhance the diagnosis rate.

Among patients diagnosed with COPD, 41.6% and 1.7% also had a diagnosis of asthma or bronchiectasis, respectively, suggesting that COPD and asthma may easily merge. The concept of ACO is based on the ACO guideline issued by the Japanese Respiratory Society (JRS) in 2018, which established the diagnostic criteria for ACO in Japan. Using these diagnostic criteria, ≈25% of Japanese patients with COPD were reported to be diagnosed with ACO. A 2-year multicenter cohort study of Japanese patients with COPD reported that patients with COPD who had ACO as per the JRS criteria were at a higher risk of exacerbations and rapid decline in respiratory function than those without ACO; moreover, it demonstrated that the JRS criteria for ACO were useful in identifying high-risk patients with COPD. This study was based on patients with an asthma diagnosis based on one year of receipts among patients diagnosed with COPD. It is possible that non-respiratory specialists did not perform respiratory function tests and established an asthma diagnosis based on symptoms alone, which may have led to an overestimation of the incidence of complications.

In our study, 43.3% and 30.9% of participants with airflow obstruction without and with COPD had GOLD 1 disease, respectively. Individuals with COPD comprised a higher proportion of patients with GOLD 2 disease or a higher stage than individuals without COPD. This finding suggests that although more patients seek medical attention and are diagnosed following disease progression, many individuals in the early disease stages remain undiagnosed. Furthermore, only 21.8% of individuals with GOLD 3 and 4 COPD were diagnosed, indicating that ≈80% of these individuals remained undiagnosed, even among individuals with severe airflow obstruction. The respiratory function test values of patients with airflow obstruction who were diagnosed with COPD were significantly lower than those without COPD diagnosis. This finding further suggests disease progression in patients diagnosed with COPD.

This study has several limitations linked to the nature of the database used. Firstly, since the data primarily originates from health insurance unions, they lack comprehensive information regarding individuals aged  $\geq$ 65 years, with no available data for individuals aged  $\geq$ 75 years. Consequently, the dataset may not be representative of the older Japanese population. Furthermore, the data only included individuals who underwent respiratory function tests during routine health checkups, and thus excluded individuals whose health checkups did not include respiratory function tests and

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those who did not undergo health checkups despite being eligible dependents of the health insurance union. Therefore, this sample may overrepresent insured individuals who have access to a broader range of health evaluations and undergo more regular assessments of their health status. Secondly, the diagnoses at the time of examination in a medical institution were recorded using disease names based on the claims data, which may not accurately reflect the actual health status of individuals. Finally, we accessed airflow obstruction prevalence using the database derived from a health insurance association. However, it was difficult to statistically analyze whether there is a difference in the prevalence between the present and past studies due to differences in the characteristics of the study population, especially the distribution of age in the study participants.

### **Conclusion**

We conducted an epidemiological study using data from health insurance claims and health checkups provided by health insurance unions to assess the prevalence of airflow obstruction and the COPD diagnosis rate in Japan. The findings underscore the alarmingly low rate of COPD diagnosis even among individuals who undergo regular respiratory function tests as part of their health checkups. This highlights the critical need for increased awareness campaigns surrounding this condition. Moreover, this study emphasizes the pivotal role of primary care physicians and their collaboration with pulmonologists in promoting the early detection of suspected cases and increasing the diagnosis rate of COPD.

### **Abbreviations**

COPD, chronic obstructive pulmonary disease; FEV<sub>1</sub>, forced expiratory volume in one second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; MHLW, Ministry of Health, Labour and Welfare.

## **Author Contributions**

YK, SD, TM, AS, YS, and HS made a significant contribution to the work reported, in the conception, study design, execution, and interpretation. GT and TT made a significant contribution in study design supporting, acquisition of data, analysis. All authors took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; agreed on the journal to which the article was submitted; and agreed to be accountable for all aspects of the work.

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#### **Disclosure**

YK, SD, TM, and AS are employees of Kracie, Ltd. GT and TT are affiliated with JMDC Inc. YS and HS received personal fees from Kracie, Ltd. The authors report no other conflicts of interest in this work.

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