Current Medical Science
DOI https://doi.org/10.1007/s11596-022-2544-1
42(2):426-433,2022

Validation and Application of the Chinese Version of the M. D. Anderson Symptom Inventory in Breast Cancer Patients*

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[Abstract] Objective: To validate and use the Chinese Version of the M. D. Anderson Symptom Inventory (MDASI-C) to assess the symptom burden of breast cancer patients in China. **Methods:** A total of 342 breast cancer patients in China participated in this study. Their symptoms were investigated with the MDASI-C from November 2020 to February 2021, and the reliability and validity of this tool were evaluated, respectively. Cluster analysis and correlation analysis were also performed. **Results:** The Cronbach's alpha coefficient values of the symptom and interference items were 0.827 and 0.880, respectively. Construct validity revealed a four-factor structure. The Kaiser–Meyer–Olkin value was 0.760. The Karnofsky Performance Status, treatment phase, and cancer stage of the patients were grouped, and the differences of scores within the groups were significant. In addition, the employment status, education level, and age of the patients were significantly correlated with the symptoms. The correlation analysis of the education level of the patients showed that most of the symptoms and interference items were reduced as the education level was increased. The top three symptoms were disturbed sleep (3.10±2.52), difficulty remembering (2.54±2.30), and fatigue (2.24±2.13). The clinical and biochemical indicators such as body mass index and neutral granulocyte lymphocyte ratio had effects on many symptoms. As the patients' BMI increased, the patients' pain, disturbed sleep, and difficulty remembering were aggravated, and numbness was alleviated. **Conclusion:** The MDASI-C is a reliable and effective assessment tool to evaluate patients with breast cancer in China. The symptoms are related to many clinical and biochemical indicators.
Key words: M. D. Anderson Symptom Inventory; breast cancer; validation; application; quality of life

Recent research data suggest that breast cancer has exceeded lung cancer to rank first in the global cancer incidence[1]. The incidence of breast cancer in China has also increased year by year[2, 3]. Patients with a tumor often suffer from many physical and psychological symptoms such as disturbed sleep, fatigue, pain, and distress. These symptoms tend to have a negative impact on the quality of life of patients[4–6]. More seriously, these symptoms greatly affect the function of the patients and may even lead to patient changes or their abandonment of positive treatment programs[7, 8]. The survival time of patients with breast cancer is longer than that of most of other cancers, so the quality of life of these patients should be of great concern[9, 10]. Therefore, it is very urgent to strengthen the symptom management of patients with breast cancer. However, before this is possible, we need to accurately evaluate their symptoms. Modern symptom assessment has developed into a comprehensive assessment model based on human science, including the tumor size, physical functions, psychological symptoms, and social functions of the patients[11, 12].

It is very important to choose a good assessment tool, such as the M. D. Anderson Symptom Inventory (MDASI)[13–15] when evaluating the symptoms of cancer patients. The MDASI can evaluate almost all common clinical symptoms related to tumors. Currently, the scale has been translated into different languages and used to assess multiple symptoms related to tumors in various countries[16–21]. A systematic review of 57 symptom assessment tools has indicated that the MDASI is better than other assessment tools in terms of both its adaptability and specificity[22]. The Chinese version of the MDASI (MDASI-C) was verified in terms of its reliability and validity by Wang *et al* in 2004[5]. However, in this study, 249 patients comprising more than nine types of solid tumors such as lung cancer, gastrointestinal cancer, and head and neck cancer were included. Among them, there were only 60 breast cancer patients[15]. The purpose of this study was to use

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*This work was supported by the National Natural Science Foundation of China (No. 81672977).

the MDASI-C for breast cancer patients only. We used a greater sample quantity to determine the reliability and validity of the MDASI-C for these patients. More importantly, various parameters that may affect the severity of the symptoms of breast cancer patients were analyzed. In previous studies, most of these parameters have not been analyzed in breast cancer patients. The findings of the current study will help clinicians understand the symptom characteristics of Chinese breast cancer patients in more detail and guide clinical treatment.

1 MATERIALS AND METHODS

1.1 Instrument

The MDASI (19 items, including 13 core items and 6 interference items) was translated into Chinese by Wang *et al* in 2004[15] and can be used directly. The degree of 13 symptom scores is expressed as a number from 0, meaning not existent, to 10, meaning as bad as you can imagine. The degree of six interference scores is also expressed as 0 to 10, indicating no interference to complete interference, respectively. Only the symptoms presented in the past 24 h were assessed.

In addition, patient population features, the cancer stage (Ⅰ *vs.* Ⅱ *vs.* Ⅲ *vs.* Ⅳ) and the Karnofsky Performance Status (KPS ≤70 *vs.* KPS >70) were recorded. The clinical biochemical indicators of each patient, including marital status (married *vs.* single), working status (employed *vs.* retired or unemployed), education level (grade ≤9 *vs.* >9), age (≤50 years old *vs.* >50 years old), body mass index (BMI), hemoglobin (Hb), alkaline phosphatase (ALP), neutral granulocyte lymphocyte ratio, and serum albumin globulin ratio (A/G), were also recorded. The latter 5 continuous variables were not grouped but the correlation directly analyzed between their values and symptoms. The acquisition time of the values of the clinical biochemical indicators was just the amount of time required for the participants to complete the scale.

1.2 Participants

The inclusion criteria were as follows: breast cancer inpatients with a clear pathological diagnosis; aged ≥18 years old; could understand and speak Chinese fluently. Exclusion criteria were as follows: impaired ability to listen, read, or understand because of mental disorders; refusal to participate in the research.

The method of determining the sample in this study was as follows. The sample amount is generally 5–10 times the number of items in the scale. The MDASI scale has 19 items, so the number of participates should be about 150. Of course, a higher number is better. A total of 348 patients who were randomly selected participated in this study and completed the MDASI-C questionnaire. Finally, 342 patients completed valid questionnaires. The survey period was from November 2020 to February 2021.

1.3 Interview

The survey was carried out by three experienced oncologists. They first introduced the purpose and precautions to each participating patient and family, and then they obtained their consent. Each questionnaire was independently completed in 15–20 min.

1.4 Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the Union Hospital Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology. All patients gave their informed consent prior to their inclusion in this study.

1.5 Statistical Analyses

Statistical analyses were performed using version 25 of SPSS statistics software. The MDASI-C reliability was obtained by calculating the coefficient of Cronbach's alpha, from 0 to 1, with a higher value representing a smaller measurement error and indicating a better reliability. If the value was greater than 0.8, the reliability was considered good. The construct validity was established by principal axis factor analysis with direct oblimin rotation. We used oblimin rotation and determined the final factor number according to their eigenvalues, consistency, and clinical significance. The Kaiser–Meyer–Olkin (KMO) test confirmed sample adequacy. If the KMO value was greater than 0.5, then the construct validity was considered acceptable. In addition to the main shaft factor analysis, the known-group validation testing also showed whether the construct validity was reasonable. They were analyzed by comparing the patients' different characteristics (e.g., KPS ≤70 *vs.* >70), treatment phase (in treatment *vs.* before or after), cancer stage (Ⅰ *vs.* Ⅱ *vs.* Ⅲ *vs.* Ⅳ), age (≤50 years old *vs.* >50 years old), education level (grade ≤9 *vs.* >9), and working status (employed *vs.* retired or unemployed)). The relevant heat maps were analyzed with an online analysis tool (https://www.xiantao.love). Cluster analysis was performed using SPSS statistics software to explore the clustering relationships between symptoms.

2 RESULTS

2.1 Patient Characteristics

There were 342 patients who were effectively involved in this study, and their average age was 50.7±10.1 years old. The proportion of patients aged ≤50 years old was 46.8%; the proportion of married patients was 91.8%; the proportion of retired or unemployed patients was 83.6%; the proportion of patients with an education of ≤9 years was 47.4%; the ratios of patients in stage Ⅱ and stage Ⅲ were 42.7% and 33.3%, respectively; the percentages of patients before, in, and after treatment were 64.3%, 32.2%, and

3.5%, respectively; the proportion of patients with KPS >70 was 93.6% (table 1).

Table 1 Main demographics and disease characteristics (*n*=342)

Patient characteristics	
Age	
Mean±SD (years old)	50.7±10.1
Range (years old)	27–75
≤50 years old, *n* (%)	160 (46.8)
>50 years old, *n* (%)	182 (53.2)
Marital status, *n* (%)	
Married	314 (91.8)
Single (including divorced, widowed)	28 (8.2)
Education level (years), *n* (%)	
Grade ≤9	162 (47.4)
Grade >9	180 (52.6)
Employment status, *n* (%)	
Employed	56 (16.4)
Retired or unemployed	286 (83.6)
Cancer stage, *n* (%)	
I	62 (18.1)
II	146 (42.7)
III	114 (33.3)
IV	20 (5.9)
Treatment phase, *n* (%)	
Before treatment	220 (64.3)
In treatment	110 (32.2)
After treatment	12 (3.5)
KPS group, *n* (%)	
Poor (≤70)	22 (6.4)
Good (>70)	320 (93.6)

SD: standard deviation; KPS: Karnofsky Performance Status.

2.2 Internal Consistency

Internal consistency was used for the reliability analysis, which was established using the Cronbach's alpha coefficients. Normally, Cronbach's alpha values of >0.9 are generally rated as excellent, >0.8 as good, >0.7 as acceptable, and <0.6 as doubtful. In the MDASI-C, the total Cronbach's alpha coefficient of all symptom items[13] was 0.827, and that of the interference items[6] was 0.880. These results show that the scale has a good reliability (table 2).

2.3 Construct Validity

The construct validity was established by principal axis factor analysis. The MDSI-C symptoms (13 items) generated four factors: factor 1 contains all physical symptoms (disturbed sleep, pain, fatigue, shortness of breath, change in taste, drowsiness, difficulty remembering, and dry mouth); factor 2 includes gastrointestinal symptoms (vomiting and nausea); factor 3 represents psychological symptoms (distress and sadness); factor 4 is related to neural symptoms (numbness). These data were suitable for factor analysis as the KMO value of the sample was 0.760, which is much larger than the acceptable value of 0.5, indicating good construct validity (table 3).

Table 2 Internal consistency reliability of the MDASI-C

Symptom	Total cronbach's α	Total cronbach's α if item deleted
Core items (13)	0.827	
Pain		0.899
Fatigue		0.898
Nausea		0.906
Disturbed sleep		0.901
Distress		0.896
Shortness of breath		0.903
Difficulty remembering		0.904
Lack of appetite		0.900
Drowsiness		0.904
Dry mouth		0.902
Sadness		0.896
Vomiting		0.907
Numbness		0.910
Interference items (6)	0.880	
Activity		0.896
Mood		0.895
Work		0.896
Relations with others		0.897
Walking		0.898
Enjoyment of life		0.897

MDASI-C, Chinese version of the M. D. Anderson Symptom Inventory

Table 3 Construct validity of the M. D. Anderson Symptom Inventory: baseline factor loadings of the core symptom items (*n*=342)

Symptom	Factor 1	Factor 2	Factor 3	Factor 4
Disturbed sleep	**0.790**	0.054	–0.073	–0.105
Pain	**0.742**	0.047	–0.012	0.144
Fatigue	**0.674**	0.110	0.270	0.022
Shortness of breath	**0.613**	0.041	0.187	–0.119
Change in taste	**0.597**	0.420	0.089	0.311
Drowsiness	**0.595**	–0.031	0.000	–0.112
Difficulty remembering	**0.524**	–0.141	–0.022	0.243
Dry mouth	**0.443**	–0.049	0.308	0.395
Nausea	0.127	**0.925**	0.088	–0.028
Vomiting	0.057	**0.923**	–0.048	–0.031
Distress	0.440	0.022	**0.841**	0.083
Sadness	0.484	0.056	**0.815**	–0.015
Numbness	0.128	–0.010	0.007	**0.889**

Kaiser–Meyer–Olkin (KMO)=0.760. Values in bold indicate that they belong to the same factor.

2.4 Known-Group Validity

Known-group validity analysis showed that the scores of patients aged >50 years old (2.002±2.485) were higher than those of patients aged ≤50 years old (1.709±2.258). The symptom scores of those with an education level >9 years (1.657±2.167) were lower than those with an education level ≤9 years (2.093±2.586). Patients with a KPS of >70 (1.650±2.191) had significantly lower scores than those with a KPS of ≤70 (4.077±3.089). The higher the patient's cancer stage was, the higher the scores were. The patients' symptom scores in treatment (2.523±2.512) were higher than those before and after treatment (1.551±2.256). The

scores of employed patients (1.366±1.927) were lower than those of patients who were retired or unemployed (1.961±2.453). All of the abovementioned differences were significant (P<0.001) (fig. 1).

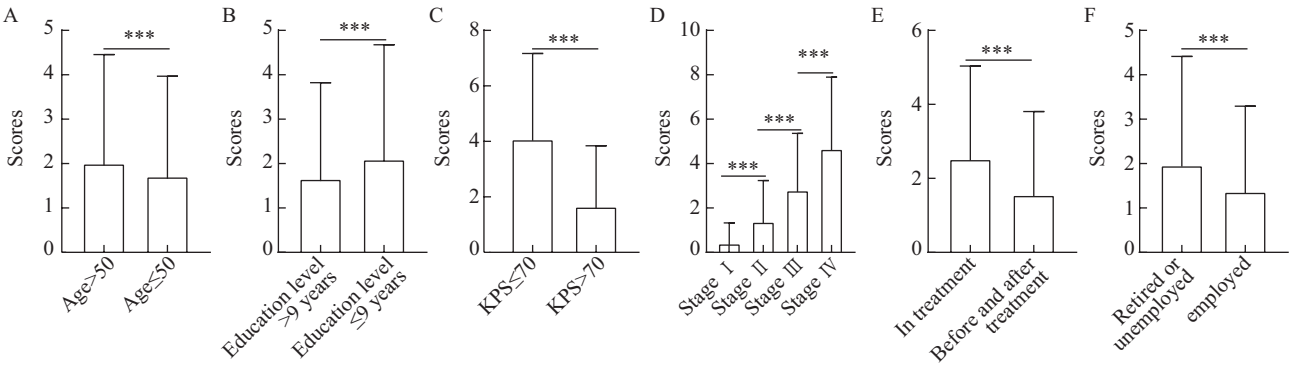

Fig. 1 Known-group validity analysis

A: The scores of patients aged >50 years old (2.002±2.485) were higher than those of patients aged ≤50 years old (1.709±2.258). B: The scores of patients with an education level >9 years (1.657±2.167) were lower than those with an education level ≤9 years (2.093±2.586). C: The scores of patients with a KPS of >70 (1.650±2.191) were lower than those with a KPS of ≤70 (4.077±3.089). D: The higher the patient's cancer stage was, the higher the scores were. E: The scores of patients in treatment (2.523±2.512) were higher than those before and after treatment (1.551±2.256). F: The scores of employed patients (1.366±1.927) were lower than those of retired or unemployed patients (1.961±2.453). ***P<0.001. KPS: Karnofsky Performance Status

2.5 Cluster Analysis

The correlation between symptoms was explored by clustering analysis, which was used to check the similarities of the symptom items (fig. 2). In addition, the relative distances between the symptom groups are shown in fig. 2. Symptoms that were previously related (left side of the figure) were more relevant than the symptoms that were connected later (right side of the figure). As shown in fig. 2, nausea and vomiting, sadness and distress, as well as fatigue and drowsiness were highly correlated.

2.6 Clinical Application

All symptoms of the MDASI-C scale were divided into mild (0–3), moderate (4–6), and severe (7–10). The top three symptom items were disturbed sleep (3.10±2.52), difficulty remembering (2.54±2.30), and fatigue (2.24±2.13). Among them, the proportion of patients with disturbed sleep (7–10) was 14.6%. The top three interference items were work (3.95±2.86), enjoyment of life (2.87±2.85), and relations with others (2.16±2.97); and the percentages of patients with severe scores (7–10) were 19.3%, 14.0%, and 12.9%, respectively (table 4).

As shown in the correlation heat map of fig. 3A, there was a forward correlation between most

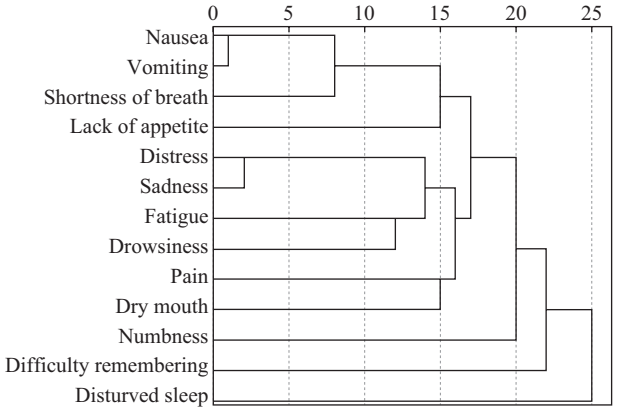

Fig. 2 Hierarchical clustering analysis with a dendrogram showing the relative distances between item clusters

Clusters were formed based on the distance between symptom ratings, which was calculated using squared Euclidian distances. Symptoms that join together earlier (the left side of the figure) are more similar than symptoms that join together later (the right side of the figure).

Table 4 Mean and percentage of patients with moderate and/or severe scores for each item (n=342)

Symptom	Mean score±SD	Score ≤3 (%)	Score >6 (%)
Core items			
Disturbed sleep	3.10±2.52	62.0	14.6
Difficulty remembering	2.54±2.30	70.8	6.4
Fatigue	2.24±2.13	76.0	3.5
Dry mouth	1.91±2.06	87.7	4.7
Distress	1.91±2.32	74.3	4.7
Sadness	1.82±2.27	76.6	4.1
Pain	1.76±2.34	83.0	6.4
Lack of appetite	1.74±2.27	80.7	5.3
Drowsiness	1.58±1.86	85.4	1.8
Numbness	1.53±2.18	84.2	4.1
Shortness of breath	0.85±1.57	94.2	1.8
Nausea	0.58±1.22	95.9	0
Vomiting	0.30±0.86	98.8	0
Interference items			
Work	3.95±2.86	48.5	19.3
Enjoyment of life	2.87±2.85	60.8	14.0
Relations with others	2.16±2.97	72.5	12.9
Mood	1.89±2.31	76.6	4.7
Activity	1.34±2.12	88.3	4.1
Walking	1.33±2.25	88.3	4.7

SD, standard deviation. Data are presented as the median (range) or absolute frequency (%).

Fig. 3 A: Correlation heat map of clinical parameters (KPS status, treatment phase, cancer stage, age, marital status, education level, and working status) and symptoms. B: Correlation heat map of biochemical indicators (body mass index (BMI), hemoglobin (Hb), alkaline phosphatase (ALP), neutral granulocyte lymphocyte ratio (N/L), and serum albumin globulin ratio (A/G)) and symptoms. The figure shows the degree of correlation between each item and other symptom and interference items. Red represents a positive correlation, and blue indicates a negative correlation. The darker the color is, the more obvious the correlation is. KPS: Karnofsky Performance Status

symptom items and interference items. We correlated the patients' age with their symptoms. The results showed that except for gastrointestinal symptoms (nausea, vomiting, and lack of appetite), psychological symptoms (sadness, distress, and mood) and other symptoms were aggravated as the patients' age increased. Symptoms that were closely related with marital status included fatigue, disturbed sleep, dry mouth, distress, shortness of breath, activity, and walking. In addition, the correlation analysis of the education level showed that most of the symptom and interference items were reduced as the education level was increased. However, in addition to difficulty remembering, all other symptom and interference item scores were reduced as the KPS scores increased.

As shown in fig. 3B, we further analyzed the patient biochemical indicators and symptoms. As the patients' BMI increased, the patients' pain, disturbed sleep, and difficulty remembering were aggravated and numbness was alleviated. The items associated with Hb levels were fatigue, disturbed sleep, dry mouth, sadness, mood, relationships with others, and walking. The higher that the A/G of the patients was, the lower the degrees/the scores of their fatigue, sleep disorder, shortness of breath, appetite, dry mouth, emotions, walking, and enjoyment of life ratings were. Furthermore, the items that were closely related to ALP included shortness of breath, difficulty remembering, dry mouth, activity, relations with others, walking, and enjoyment of life; and they were positively correlated.

3 DISCUSSION

Similar to our clinical work, many studies have shown that accurate assessments of the symptoms of malignant tumors, including those of breast cancer patients, are very important[10, 23–25]. Only accurate assessments can sufficiently grasp the symptoms of the patient; therefore, it is important to discover their features so that targeted intervention may be carried out. In this study, we assessed the effectiveness of the MDASI-C in breast cancer patients. At the same time, we also analyzed the factors affecting the degree of symptoms. In this study, 342 patients, comprising almost all types of breast cancer, had a good representation.

The reliability test results suggest that the Cronbach's alpha value was approximately 0.9, which is close to the level of excellent reliability. The KMO value of the construct validity test indicates that the scale has good construct validity. At the same time, we conducted a known-group validity analysis. The results show that the symptom scores of patients aged ≥50 years old are higher and that those with KPS >70 are lower. In addition, the higher the patient's tumor stage was, the more serious the patient's symptoms were. The symptom scores of patients in treatment were also higher. These findings are consistent with previous research results[26–28] as well as clinical observations. Therefore, using the MDASI-C, age, KPS, and cancer stage can distinguish patients, and it is also a commonly used index. Interestingly, we found that the symptom degree of patients with more than 9 years of education was lower and that the symptoms were alleviated with an increase of education level. We determined that patients with a high level of education can rationally deal with their own condition and mentality. Moreover, the correlation heat map shows that the higher the level of education was, the earlier the patient's cancer stage was. That is to say, the cancer stage of the patients with a higher level of education is earlier. At the same time, the symptom scores of employed patients were lower than those of retired or unemployed patients. This may be because patients who are employed will put more time and energy at work, thereby dispersing the attention of their own symptoms.

Previous studies have shown that the symptoms of cancer patients often appear in a cluster[29, 30]. Our cluster analysis results demonstrated that nausea and vomiting, sadness and distress, as well as fatigue and drowsiness were highly related. This is the same as our expectations, and the symptoms were often accompanied, which is also consistent with the clinically observed situation. Furthermore, the related heat maps revealed that there was a forward correlation between most symptom items and the interference items, further illustrating the aggregation between symptoms.

Each item of the patients was statistically analyzed, according to the ratio of mild (≤3) and severe (>6). We found that the proportion of patients with severe sleep disorders was 14.6%, meaning that more than 1/7 of patients suffered serious sleep problems; thus, high attention should be paid to sleep disorders. The severe interference proportions of work, enjoyment of life, and relations with others were 19.3%, 14.0% and 12.9%, respectively. Analysis of the cause may be multifaceted, such as the disease itself and the antitumor treatment. Of course, it may also be related to the changes in work and family after being sick. After all, patients younger than 50 years old will have different degrees of impact due to illness and may even lose their jobs. Enjoyment of life and relations with others are important parts of life quality. If the quality of life of breast cancer patients is to be improved, more attention should be paid to them.

Similar to many literature reports, our research also showed that the biochemical indicators of patients with breast cancer will affect their symptoms to a certain degree, including BMI, Hb, A/G, and ALP[31–33]. Among them, BMI, Hb, and serum albumin reflect the nutritional status of the patient, and ALP is closely

related to the cancer load or stage. Therefore, they will affect the symptoms of the breast cancer patients.

As mentioned above, the MDASI-C was used to assess the symptoms of Chinese breast cancer patients, which were characterized as follows. Firstly, it provides an objective and effective scale for symptomatic precision assessment of Chinese breast cancer patients. Secondly, it can be used for monitoring the symptoms of patients with breast cancer, assisting to discover the changes, and providing precision strategies. Thirdly, it provides a standardized form to avoid the subjective judgment between different hospitals or doctors to assess clinical symptoms. Finally, it can provide examples for the symptom assessment of patients with breast cancer in other non-English-speaking countries.

This study also has some limitations that must be addressed. Firstly, our patients came from the same cancer center. Secondly, we did not add interventions to the research. It would be very meaningful to study the symptom changes in patients with breast cancer before and after a certain intervention. This work will be continued in our follow-up research.

In conclusion, this study shows that the MDASI-C is effective and reliable for assessing the symptoms of Chinese breast cancer patients. The patients' age, education level, work and marital status, KPS, cancer stage, BMI, A/G, ALP, and Hb will affect the degree of symptoms. Using this scale, more targeted interventions can be provided to increase the quality of life of patients with breast cancer while prolonging their survival time.

Conflict of Interest Statement

The authors declare that they have no conflicts of interest.

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(Received Nov. 3, 2021; accepted Dec. 9, 2021)