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Research article

Cross-cultural adaptation and validation of the Chinese version of the intensive care oral care frequency and assessment scale

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ABSTRACT

Objectives: The objective of this study was to translate the Intensive Care Oral Care Frequency and Assessment Scale into Chinese and to evaluate its reliability and validity in Chinese ICU patients.
Methods: This study was conducted using a cross-sectional survey design in ICUs of three tertiary hospitals in Huai'an and Taizhou from October 2022 to April 2023. The Chinese version of the Intensive Care Oral Care Frequency and Assessment Scale (C-ICOCFAS) was developed by expert consultation and cultural adaptation according to the two-person verbatim translation-back translation criteria described in the Brislin model. Item analysis was conducted using correlation analysis, and validity analysis included content validity, construct validity, and criterion validity. Reliability analyses included Cronbach's alpha coefficient, Guttman split-half reliability, and interrater reliability.
Results: The Chinese version of the scale consisted of one dimension and nine items, consistent with the original version. Exploratory factor analysis showed KMO = 0.891, and the cumulative variance contribution reached 65.534 %. The confirmatory factor analysis indicated a good fit, $\chi 2/df = 2.124$, NFI = 0.950, GFI = 0.942, IFI = 0.973, CFI = 0.973, SRMR = 0.037, and RMSEA = 0.073. The content validity of the scale was 0.97, and the content validity of the items ranged from 0.83 to 1.00; the criterion validity was 0.969; the Cronbach's alpha coefficient was 0.919; the total item correlation coefficient was 0.725–0.831; the Guttman split-half reliability was 0.919; and the interrater reliability was 0.885.
Conclusion: The C-ICOCFAS has good reliability and validity and can effectively guide nurses in the frequency of oral care for ICU patients.
Implications for clinical practice: This tool can significantly improve the level of oral care among ICU patients and further promote the health and safety of patients. These findings can help clinical nursing experts to better understand and master the use of scales and standards to improve nursing.

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1. Introduction

The oral cavity provides an ideal habitat for the growth, reproduction, and colonization of various microorganisms [1]. Furthermore, the oral cavity serves as a route for harmful bacteria to enter the body. Therefore, effective oral health management is necessary to maintain patients' oral hygiene and to prevent the occurrence of oral diseases and systemic diseases.

Effective oral care is especially important for ICU patients, as it establishes the foundation for implementing oral hygiene management, which can prevent complications such as ventilator-associated pneumonia (VAP). Despite its importance, the assessment of the frequency of oral care for critically ill patients in the ICU is frequently overlooked in clinical practice [2]. Neglecting oral care among ICU patients often leads to bacterial colonization, as approximately 70 % of the common pathogenic bacteria causing VAP originate in the patient's oral cavity [3,4]. Such inadequate oral care may result in severe complications, including prolonged mechanical ventilation duration, longer hospital stay, and increased mortality [5]. In contrast, effective oral care can reduce the incidence of VAP in ICU patients, alleviate medical burdens, and accelerate patient recovery and discharge. Therefore, administering appropriate oral care can serve as a cost-effective approach to enhance an ICU patient's overall health management [6,7].

To address this issue, nurses are required to carefully assess the oral hygiene status of patients in clinical work [8,9]. When oral problems are discovered, effective measures should be taken to prevent them from worsening. In 184 three Grade-A hospitals in China, a survey of the current state of oral care for critically ill patients revealed that ICU nurses were less standardized in assessing patients' oral cavities [10]. This may have been due to a lack of time, a lack of nursing staff awareness, or a lack of specific assessment tools [11,12]. Even though there are a few instruments available to evaluate oral care, such as the Oral Assessment Guide and the Beck Oral Assessment Tool [13,14], none of these tools were developed specifically for the oral health management of ICU patients and did not take into account the effects of the specific conditions of ICU patients such as nutritional support, mechanical ventilation, and the use of special medications on oral health status. Thus, an instrument that accurately evaluates the frequency of oral care among ICU patients is extremely important.

Doğu-Kökcü et al. developed the Intensive Care Oral Care Frequency and Assessment Scale (ICOCFAS) [15], which is a personalized tool for assessing the oral health status of ICU patients and determining the frequency of oral care. The ICOCFAS has significant relevance, high reliability, and validity compared to other similar tools. Therefore, to determine the frequency of oral care for ICU patients and to provide valuable guidance for nursing care, we chose to translate and adapt the ICOCFAS to Chinese and subsequently evaluate its psychometric properties among Chinese ICU patients. Despite some challenges in cultural adaptation and professional training, the choice of the ICOCFAS as the instrument for our study was a reasonable decision because its strong relevance and reliability make it a suitable tool for assessing oral health status and determining the frequency of care in ICU patients.

2. Methods

2.1. Design and participants

In this study, we conducted a cross-sectional survey. From October 2022 to April 2023, convenience sampling was used to recruit participants. A questionnaire survey was administered among ICU patients from three Class A hospitals in Huai'an and Taizhou. The inclusion criteria were as follows: (i) age $\geq$18 years, (ii) receiving treatment and care in the ICU and requiring oral care, including bedridden patients and those who could move independently, and (iii) obtaining consent from the conscious patient or a family member of the unconscious patient. The exclusion criteria were as follows: (i) patients whose medical orders indicated that they were not suitable for oral care, and (ii) patients who were participating in similar related studies. According to the sample size rule of thumb, each factor required at least ten subjects for factor analysis [16]. There were nine factors; after accounting for a potential 10 % dropout rate, the estimated sample size was 100 cases. Moreover, the sample size for exploratory factor analysis (EFA) should be at least 100 cases, and the sample size for confirmation factor analysis (CFA) should be at least 200 cases [17]. Therefore, the final number of cases included in this study was 365.

2.2. Instruments

2.2.1. General demographic sheet

The researchers created general information based on references to relevant literature, including age, gender, residential address, intubation/incision, and sedation medication (Supplemental Table 1).

2.2.2. ICOCFAS

The original ICOCFAS was developed by Turkish scholars Doğu-Kökcü et al. The scale includes nine items: age, lips, teeth, tongue, oral mucosa, saliva, cheeks, nutritional support, and ventilatory support [15]. Each item is scored on a 4-point Likert scale, with scores of 1 (normal), 2 (mild), 3 (moderate), and 4 (severe). The total scores range from 9 to 36. One point is added to the total score for each condition necessitating extensive antibiotic and steroid medication, diagnosis of diabetes, low hemoglobin levels, or use of immunosuppressive drugs. The Cronbach's alpha for the original scale was 0.851, indicating good reliability. Nevertheless, the scale's generalizability to other countries and populations has yet to be established.

2.2.3. Modified version of Beck Oral Rating Scale

The scale assesses the following five domains: lips, gingiva and oral mucosa, tongue, teeth, and saliva [18]. The scores for each item

range from 1 to 4, and the total scores range from 5 to 20, with higher scores indicating poorer oral function of the patient (Supplemental Table 2).

2.3. Translation and cross-cultural adaptation of the C-ICOCFAS

To translate the ICOCFAS into Chinese, we contacted the original author, Professor Terzi, via email. Next, we applied the Brislin model [19] and performed the direct translation and back-translation techniques with two translators to format the Chinese version of the scale. Specifically, a native English-speaking professor and a nurse who had studied abroad assumed the responsibility of translating the original scale into Chinese. Following an analytical comparison between the two versions, they made suitable adjustments, resulting in the Chinese version of the scale, titled C-ICOCFAS 1.

Then, two bilingual researchers conducted back-translation, compared the translation results, and engaged in discussion to modify and obtain the back-translated version of the C-ICOCFAS 1. After considering Professor Terzi's advice, subsequent discussions and modifications resulted in the final form of the scale, titled C-ICOCFAS 2.

Subsequently, based on cross-cultural adaptation guidelines [20], we consulted six experts, including three nursing experts and three clinical physicians, with an average experience of 16.17 ± 2.17 years, of whom three held senior titles while the other three held deputy titles. All possessed a master's degree or higher. To address cultural relevance, linguistic clarity, professional conformity, and content validity [21], these experts provided us with feedback and suggestions. By utilizing a four-point Likert scale (1 - not relevant, 2 - somewhat irrelevant, 3 - somewhat relevant, 4 - highly relevant), we calculated both the item content validity index (I-CVI) and the scale content validity index (S-CVI). Based on expert input, we modified items that seemed unclear and finally designed the pretest version of the C-ICOCFAS 3, with conceptual, item-wise, and semantic equivalence to the original scale.

2.4. Pilot testing

Ensuring that the investigators fully comprehend the substance of the scale items and minimize potential errors before undertaking the formal investigation is of great importance. Consequently, in this study, 20 ICU nurses were selected for a pretest to measure their comprehension level of the C-ICOCFAS 3 statements. Based on feedback from the investigators and experts, the language and content of the C-ICOCFAS 3 were modified to develop the final version of the scale and validated before the formal survey (Supplemental Table 3).

2.5. Data collection procedure

This study is anonymous. Before the investigation, the patients themselves or their families were fully informed and provided consent, with corresponding signatures obtained. Additionally, strict measures were implemented to protect their privacy during the whole process. Before conducting the survey, four nurses with the title of supervising nurse received uniform training on the survey method, scale interpretation, and scoring criteria. The investigators used the website Questionnaire Star (https://www.wjx.cn) to conduct a questionnaire survey of 365 ICU patients. Each questionnaire took 1–3 min to complete. The total number of questionnaires returned was 360, with an effective recovery rate of 98.6 %. Among them, 150 questionnaires were used for EFA and 210 for CFA.

2.6. Statistical analysis

SPSS 25.0 with AMOS 24.0 software was used for the statistical analysis of the data. Quantitative data were expressed as the mean ± standard deviation, and categorical data were expressed as the number of cases and percentage (%).

To evaluate the scale comprehensively, we conducted the following analyses. First, the item analysis of the scale was evaluated by the critical ratio (CR) method of high and low groups and the correlation coefficient between the items and the total score. Second, to assess the content validity of the scale, we used the I-CVI and S-CVI methods. Additionally, to evaluate the structural validity of the scale, we employed the EFA and CFA methods. We also used the modified Beck Oral Rating Scale as the criterion validity scale, and Pearson or Spearman correlation analysis was used to measure the criterion validity. Third, we used Cronbach's alpha coefficient, Guttman split-half reliability, and interrater reliability to evaluate the reliability of the scale.

3. Results

3.1. Translation and cultural adaptation

To ensure that the statements are easy to understand and applicable to our context, the C-ICOCFAS was revised by combining the results of direct translation, back translation, expert consultation, pretesting, and study group discussions. Specifically, it was changed from "normal: clean" to "normal: clean/no teeth" in item 3 and from "moderate: insufficient and a little thick" to "moderate: little saliva, somewhat sticky" in item 6. It was also changed from "serious: sticky or no saliva (dry mouth syndrome)" to "sticky or no saliva (dry mouth syndrome)/open mouth breathing" in item 6. In addition, based on expert recommendations, we modified the intensive care oral care frequency scale to the intensive care oral care frequency and assessment scale. The final version of the C-ICOCFAS is shown in Supplementary Table 3.

3.2. Demographic characteristics of the participants

A total of 360 questionnaires were collected in this study, and Table 1 presents the demographic characteristics of the participants. The mean age of the participants was 48.25 ± 14.81 years, and their ages ranged from 23 to 83 years. Of the participants, 188 (52.2 %) were female, and 185 (51.4 %) resided in urban areas. Additionally, 234 participants (65.0 %) underwent endotracheal intubation/incision, and 222 participants (61.7 %) did not receive sedatives.

3.3. Item analysis

Pearson correlation coefficient analysis was performed on each score with the total score, and excluded items with $r < 0.4$ are presented in Table 2 [22]. The results showed that the correlation coefficients between each item and the total score ranged from 0.725 to 0.831, and all correlation coefficients reached statistical significance ($P < 0.001$), indicating that no item needed to be deleted. The 360 questionnaires were sorted by total score, and the lowest 27 % (score <16) and highest 27 % (score >23) were considered the low-score and high-score groups, respectively. Independent sample t-tests were used to compare the CR values of all items between the two groups, and the results showed that the CR values of all items ranged from 14.430 to 21.197, and all items reached statistical significance ($p < 0.001$). Therefore, all items were maintained.

3.4. Validity

3.4.1. Content validity

According to the study's findings, the I-CVI of the scale ranged from 0.83 to 1.00, and the S-CVI value of the scale was 0.97, both of which indicated good content validity (I-CVI ≥0.78, S-CVI ≥0.80) [23,24].

3.4.2. Construct validity

This study employed principal component analysis and the maximum variance rotation method for EFA (Table 3), which extracted a common factor with a cumulative contribution of 62.938 %. KMO = 0.891, Bartlett sphere test $\chi^2 = 936.185$ ($p < 0.01$), and df = 36 indicated that the data were suitable for EFA [25]. Furthermore, CFA was performed using the maximum likelihood (ML) method, but the initial model fit was poor. Therefore, under the guidance of theoretical significance and practical experience, the initial model was modified by adding residual paths e1 and e7 to improve the model fitting. The modified model fit indices are presented in Table 4, and all model fits are within the standard range. In addition, Fig. 1 shows the factor loading range between each item and its corresponding latent variable ranging from 0.65 to 0.85.

3.5. Criterion validity

The correlation coefficient between the modified Beck Oral Rating Scale and the C-ICOCFAS was 0.969, indicating an extremely high correlation. This result suggests that the C-ICOCFAS has better criterion validity [26].

3.6. Reliability

The C-ICOCFAS demonstrated high levels of internal consistency based on Cronbach's alpha coefficient (0.919) and the Guttman split-half reliability (0.919). Additionally, the interrater reliability score was 0.885, indicating the good reliability of the C-ICOCFAS.

4. Discussion

In the ICU ward, due to the critical condition of patients, enhanced frequency and assessment of oral care are essential for patient

Table 1
Demographic characteristics of participants (N = 360).

Variable	Classification	N	%
Gender	Male	172	47.8
	Female	188	52.2
Age group (years)	15~29	67	18.6
	30~49	204	56.7
	50~69	56	15.6
	≥70	33	9.2
Residential address	Urban	185	51.4
	Rural	175	48.6
Intubation/incision	Yes	234	65.0
	No	126	35.0
Sedative	Yes	138	38.3
	No	222	61.7

Table 2
Interitem and item-total correlations for the C-ICOCFAS (N = 360).

Item	1	2	3	4	5	6	7	8	9	M	SD	Item-Total Correlation
1. Age	1									2.153	0.829	0.789**
2. Lips	0.644**	1								2.481	0.838	0.761**
3. Teeth	0.537**	0.436**	1							2.131	0.812	0.725**
4. Tongue	0.530**	0.505**	0.563**	1						2.267	0.948	0.779**
5. Oral mucosa	0.651**	0.563**	0.472**	0.518**	1					2.156	0.869	0.767**
6. Saliva	0.534**	0.514**	0.522**	0.572**	0.473**	1				2.236	0.906	0.755**
7. Cheeks	0.492**	0.549**	0.549**	0.617**	0.521**	0.624**	1			2.314	0.913	0.790**
8. Nutritional support	0.618**	0.506**	0.538**	0.537**	0.603**	0.513**	0.542**	1		2.247	0.856	0.776**
9. Ventilatory support	0.685**	0.657**	0.504**	0.567**	0.630**	0.532**	0.593**	0.679**	1	2.206	0.852	0.831**

Note: M, Mean; SD, Standard Deviation; **P < 0.01.

Table 3
Factor loadings of the C-ICOCFAS (N = 150).

Items	Factor loadings
7 Cheeks	0.875
6 Saliva	0.859
9 Ventilatory support	0.810
4 Tongue	0.791
8 Nutritional support	0.781
1 Age	0.778
5 Oral mucosa	0.764
3 Teeth	0.754
2 Lips	0.715
Eigenvalues	5.664
% Variance	62.938

Table 4
C-ICOCFAS confirmatory factor analysis model fitting results (n = 210).

Fit indicators	X^2/df	NFI	GFI	IFI	CFI	SRMR	RMSEA
Reference value	≤3.00	≥0.90	≥0.90	≥0.90	≥0.90	≤0.05	≤0.08
Initial model	2.727	0.934	0.926	0.957	0.957	0.042	0.091
Modified model	2.124	0.950	0.942	0.973	0.973	0.037	0.073

Note: X^2/df-chi-square distribution/degrees of freedom, NFI-normal of a fit index, GFI-goodness of the fit index, IFI-incremental fit index, CFI-comparative fit index, SRMR-standardized root mean square residual, RMSEA-root mean square error of approximation.

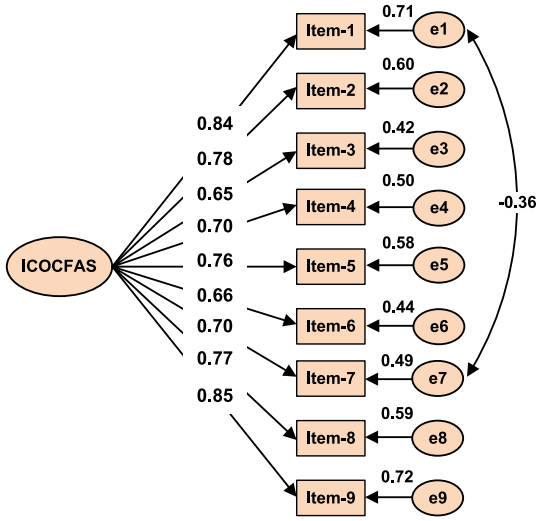

Fig. 1. Confirmatory factor analysis model of C-ICOCFAS (N = 210). Item 1: Age, 2: lips, 3: teeth, 4: tongue, 5: oral mucosa, 6: saliva, 7: cheeks, 8: nutritional support, 9: ventilatory support.

recovery and treatment [3]. Regular oral care not only removes pathogenic microorganisms and residual food from the mouth to avoid problems such as bad breath, dental caries, and periodontal disease but also prevents oral infections and other complications, relieves oral discomfort and pain, improves the patient's immunity, and promotes recovery. Regular oral care is especially crucial for critically ill patients who require mechanical ventilation and are bedridden for long periods [27].

To overcome possible cultural differences and language barriers, we performed cross-cultural translations and adaptations to ensure the accuracy and consistency of the assessment tools used [28]. We consulted six experts in this study and validated the C-ICOCFAS through translation, cross-cultural adaptation, and pilot tests. To investigate the psychometric properties of the C-ICOCFAS, we used the two-person direct reverse translation method of the Brislin model. In the process of translating and culturally adapting the ICOCFAS, we engaged in discussions and close collaboration with health care professionals responsible for conducting oral care assessments. Through in-depth meetings with the experts, we detailed the purpose of the tool and the intended application scenarios and actively solicited their feedback and suggestions. Their comments and experiences provided us with valuable advice for improving the content of the scale and guidance on how to use the scale. This close collaboration ensures that the culturally adapted ICOCFAS meets the needs of health care professionals and is feasible and actionable in clinical settings. After exploration and

validation, the C-ICOCFAS consisted of one dimension and nine items, was easy to understand, and took one to 3 min to complete, thus indicating its good clinical operability and feasibility.

In this study, we evaluated the validity and reliability of the C-ICOCFAS using various methods. Validity refers to whether the scale accurately reflects the desired parameters, while reliability refers to the stability and consistency of the scale. We used content validity, construct validity, and criterion-related validity to assess the validity of the C-ICOCFAS. The results showed that the I-CVI of the C-ICOCFAS was $\geq$0.78, and the S-CVI was 0.90, indicating that the scales and items accurately represented the construct being measured [24]. The EFA results of KMO = 0.891, Bartlett's test of sphericity $\chi^2 = 936.185$ ($p < 0.01$), and df = 36 indicate that the data are suitable for EFA [25]. One common factor was extracted for this study, consistent with the number of common factors in the original scale. Therefore, nine items with factor loading values ranging from 0.725 to 0.831, were retained, with all items having factor loadings >0.40 [29,30]. In addition, we found that the scale did not have double factor loadings, which further confirms the good construct validity of the C-ICOCFAS.

The results of the CFA showed that the initial model was poorly fitted. Therefore, in this study, we modified the initial model according to the theoretical and empirical rules by adding a residual path of e1 and e7. The modified model fit indices were all within the standard range ($X^2/df \leq 3.00$, GFI $\geq$0.90, IFI $\geq$0.90, CFI $\geq$0.90, RMSEA $\leq$0.08, SRMR $\leq$0.05) [31]. Additionally, the factor loadings between the items and their corresponding latent variables ranged from 0.65 to 0.85, which implies that questionnaire items measuring the same factors are consistent with their corresponding factors.

Furthermore, a modified version of the Beck Oral Rating Scale was used as the validity criterion in this study [18]. The C-ICOCFAS was found to be strongly correlated with the modified Beck Oral Rating Scale (r = 0.969) [28], and the coefficient was higher than that reported in the original study (r = 0.791) [15]. This difference could be due to the study's different sample characteristics, such as the oral mucosal structure, disease progression, medication status, and sample size, as well as differences in cultural backgrounds, medical conditions, and lifestyles between countries.

Cronbach's alpha, Guttman's split-half reliability, and interrater reliability were used to assess the reliability of the C-ICOCFAS. The Cronbach's alpha coefficient of the C-ICOCFAS was 0.919, the Guttman split-half reliability was 0.919, and the interrater reliability was 0.885, all of which were within the acceptable range [32]. This suggests that the C-ICOCFAS has good internal consistency and stability and is appropriate as an assessment tool for the oral care of ICU patients in China.

4.1. Limitations

However, there are some limitations to our study. First, the oral mucosal structure of ICU patients changes with the progression of their disease, which affects the daily assessment of the oral cavity. Therefore, the reliability of retesting was not examined in this study. Second, we used a convenience sampling method, and the sample size was limited to three tertiary care hospitals in Huai'an and Taizhou, which restricted geographical representativeness and may have led to biased findings, making it difficult to extend the scale to hospitals in other regions. Therefore, future studies should include multicenter, large-sample surveys to verify the adaptability and scalability of the C-ICOCFAS in ICU patients. Finally, the C-ICOCFAS is essentially an other-rated scale, and the scoring results are easily influenced by subjective factors such as rater age, gender, and years of work experience.

4.2. Implications for practice

In the ICU, a high-risk environment, patients are often bedridden and immobile. Inadequate oral care can easily lead to various oral lesions and infections, further affecting the recovery of the entire body. Therefore, regular oral care is an essential part of the recovery process for ICU patients. To better assess the oral health of patients, the Chinese version of the ICOCFAS has become an extremely important tool. In addition, the scale provides standardized assessment indicators that allow the level of care to be compared and measured between different hospitals and care teams. By calculating the frequency of care, assessing the oral cleanliness of patients, and other indicators, comprehensive and scientific data support can be provided for clinical nursing staff to help them better perform oral care and protect patients' oral health.

For translation and cultural adaptation of the ICOCFAS, a multifaceted exploration and practice process is needed to make it more in line with Chinese habits and actual conditions. In this way, the oral care of ICU patients can be significantly improved, further safeguarding their health and life safety. With the advancement of this work, clinical nursing specialists can better understand and master the use of the scale and its criteria for better nursing care.

5. Conclusion

The C-ICOCFAS was shown to have good validity and reliability after data analysis, with good internal consistency and stability. Therefore, we conclude that the C-ICOCFAS is a reliable and valid oral care assessment tool that can be widely used in intensive care units to help improve oral care, reduce the incidence of oral complications, and improve patient recovery and survival. We recommend the use of this scale as a routine tool for standardized oral care assessment in clinical practice. Additionally, this scale can serve as a reference for the development and adaptation of oral care assessment tools for other populations in the future. In conclusion, the C-ICOCFAS can be used as a reliable and valid oral care assessment tool in clinical practice, which has positive implications for advancing oral care practice within the intensive care unit.

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Ethics declarations

This study was reviewed and approved by Huzhou University, with the approval number: 2022–06–22. All participants (or their proxies/legal guardians) provided informed consent to participate in the study.

CRediT authorship contribution statement

Yuecong Wang: Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Tianxiang Jiang:** Writing – review & editing, Writing – original draft, Validation, Supervision, Data curation, Conceptualization. **Li Shen:** Supervision, Resources, Project administration, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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