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Palliative and Supportive Care Validation of the Mexican version of the EORTC QLQ-CR29 in patients with colorectal cancer

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Abstract

Background. The evaluation of the quality of life (OoL) of patients with colorectal cancer (CRC) is an essential measure to measure the impact of the disease and treatments on the lives of patients. However, in Latin America there is no validated and reliable instrument to assess this construct.

Objectives. This study aims to validate the EORTC QLQ-CR29 instrument in the Mexican population with CRC.

Methods. This study aims to validate the EORTC QLQ-CR29 instrument in the Mexican population with CRC. The study used an instrumental design and a nonprobabilistic sample due to availability, made up of 251 patients with CRC, with an average age of 54.7 \pm 12.28 years. Exploratory and confirmatory factor analyses were performed, as well as concurrent validity tests.

Results. The exploratory factorial analysis yielded 4 factors that explained 51.64% of the variance, with a Cronbach reliability coefficient of .766 and an Omega index of .725. The confirmatory factor analysis indicated that the proposed theoretical model fits the data almost perfectly, with an error close to 0, which shows that it is a balanced and parsimonious instrument to measure the QoL of the patients with CRC.

Significance of results. The EORTC QLQ-CR29 instrument proved to be a valid and reliable instrument for use in clinical care and research directed at patients with CRC in Mexico. Its use is recommended by multidisciplinary health teams in oncology in Mexico, since it allows knowing the patient's perspective on the impact of CRC on their life, guiding therapeutic decision-making and being a primary outcome measure.

Introduction

The prevalence of colorectal cancer (CRC) is alarming, being the main cause of morbidity and mortality in oncology (International Agency for Research on Cancer [GLOBOCAN] 2020) and constituting a relevant public health problem (García-Espinosa et al. 2020). In its evolution, CRC can be asymptomatic, but once the disease is advanced, the symptoms may vary depending on the location of the tumor (Cubiella et al. 2018).

Quality of life (QoL) is an important indicator in the evaluation of health outcomes in cancer patients, being a multidimensional construct that includes physical, social, and psychological domains, as well as symptoms associated with the disease and its treatment (Aaronson 1987; Moinpour et al. 1989; Testa and Simonson 1996). Since a large number of patients with CRC experience a variety of side effects and symptoms related to the disease and its treatment, their QoL may be affected at different points in cancer care (Kristensen et al. 2019; Lapinsky et al. 2019).

Among the most common physical side effects in CRC patients are diarrhea and chronic pain, urinary incontinence, fatigue, and sexual difficulties (El-Shami et al. 2015; Simard et al. 2019; Yde et al. 2018). These symptoms can persist for years after diagnosis, as in the case of intestinal problems (Jansen et al. 2010; Ramsey et al. 2002). In addition, psychosocial effects such as anxiety and depression (Mitchell et al. 2013; Peng et al. 2019), emotional distress

(Dunn et al. 2013; El-Shami et al. 2015), risk of suicide (Lloyd et al. 2019), and sexual dysfunction have been reported (El-Shami et al. 2015).

Therefore, having an instrument to assess HRQoL specifically for patients with CRC is essential in the clinical, research, and institutional setting, as it is an outcome measure based on the patient's perception of the impact of the disease on their life. To assess the QoL of cancer patients, the European Organization for Research and Treatment of Cancer (EORTC) has developed measurement instruments. In the specific case of CRC, the EORTC group developed a specific module to assess QoL in this neoplasm; the EORTC QLQ-CR29 (Whistance et al. 2009). The advantage of this instrument is that it contains a large number of specific items and subscales to measure side effects, symptoms, and key functional areas in this cancer group, as well as a specific section for patients with or without stoma. This increases the content validity of the EORTC QLQ-CR29 in comparison with other scales.

The evaluation of QoL in patients with CRC is fundamental in the improvement of medical and psychological care. It is not only a relevant indicator for predicting morbidity and mortality, but it is also a significant parameter in therapeutic decision-making and an important outcome measure in the long term (Fallowfield 2002; Kristensen et al. 2019; Mansano-Schlosser and Ceolim 2012). In this sense, its evaluation becomes more relevant in the context of Latin America because it is predicted that the increase in its incidence rate will not cease, mainly due to the standard of living of people (a more sedentary lifestyle and unhealthy eating habits), as well as the aging of its population (Torres-Román et al. 2015). Additionally, many factors stand in the way of early diagnosis and timely treatment of CRC in Latin America, including a lack of specialists and insufficient health system infrastructure. The current infrastructure, in many areas of Latin America, often lacks the capacity to provide screening, chemotherapy, and surgery for all patients in a timely manner (Pharma et al. 2014; Torres-Román et al. 2015).

In Mexico there is no valid, reliable, and psychometrically adequate instrument to measure this construct, which makes it difficult to understand the impact of CRC on the lives of patients and, therefore, make informed decisions for their treatment. Therefore, the purpose of this study was to validate the EORTC QLQ-CR29 questionnaire in the Mexican cancer population.

Method

Participants

The present study had a sample obtained by availability in the functional unit of the Instituto Nacional de Cancerología (INCan) Gastroenterology service, during the period from May 9 to August 3, 2022. An instrumental, nonexperimental, cross-sectional design was used (Montero and León 2005). The inclusion criteria established for participation in the research were as follows:

- *Inclusion criteria*: Have a confirmed diagnosis of CRC, present any clinical stage, be in active treatment or under follow-up, and have a Karnofsky score \geq 70.
- *Exclusion criteria*: Exclusion criteria were established for those participants with visual or hearing impairment that prevented them from responding to the surveys, patients with a second primary cancer, and patients with severe physical problems (such as nausea, vomiting, dyspnea, pain, and fatigue) that prevented them from participating.

- *Elimination criteria*: Likewise, elimination criteria were established for those participants who, during the process of filling out the questionnaires, decided not to continue participating in the study.

Ethical aspects

A request was made to the EORTC group for permission to use the QLQ-C30 and CR29 instruments in the study. The protocol was approved by Mexico's Instituto Nacional de Cancerología Research and Ethics Committees with approval number: (022/003/OMI) (CEI/1600/21). This study conforms to the standards of the Declaration of Helsinki. All participants who agreed to participate in the study did so after having read and understood the information provided in the informed consent, and voluntarily signed it.

Instruments

- *Health-related Quality of Life Scale EORTC QLQ-30.* Designed by Aaronson et al. (1993) is used to measure the global QoL of patients through 30 items distributed in 3 dimensions: functional, which includes physical, role, cognitive, emotional, and social functioning; symptoms, including fatigue, pain, nausea, and vomiting; and overall QoL. Cronbach's alpha coefficient ranges from $\alpha = .52$ to $\alpha = .89$, with a Likert-type scale from 1 to 4 and 2 items from 1 to 7. It has been validated in the Mexican cancer population by Onate-Ocana et al. (2009).
- EORTC QLQ-CR29 questionnaire. This tool is designed to measure health-related QoL in patients with CRC, considering the symptoms and functional areas that are associated with this type of cancer and its treatment. This scale includes 29 items that are divided into 4 subscales: bowel function ($\alpha = .70$), urinary frequency ($\alpha = .75$), body image ($\alpha = .84$), and blood and mucus in stool ($\alpha = .69$). The alpha coefficient of these subscales ranges between .69 and .84, which indicates adequate internal consistency. In addition, the questionnaire has separate sections for patients with and without stoma and individual questions that assess functional areas, such as sexual desire in men and women. The scale uses a Likert-type score from 1 to 4, and the questions related to symptoms refer to the previous week, with the exception of the question on sexuality, which addresses the last 4 weeks. The instrument has demonstrated adequate test-retest reliability with r values >.68 and has been validated for use in the Mexican cancer population (Whistance et al. 2009).

Procedure

Cultural adaptation

Initially, an evaluation of the EORCT CR29 (version 2.1) in the Spanish language of Spain, provided by the EORCT group, was carried out by 11 oncology experts belonging to the disciplines of psychology and nursing, to receive feedback and recommendations on wording and language appropriate to the target population. Changes were made to the instrument to improve comprehension of the instructions and questions.

Then, the questionnaire was adapted to Mexican Spanish through a pilot test carried out in 30 patients with CRC from the functional unit of the INCan Gastroenterology service. A structured interview was used to identify possible confusing or offensive expressions, and to assess understanding of the questions, instructions, and response options (Mora-Rios et al. 2013). Therefore, the modifications made consisted of substituting terms that are more common in the Spanish of the Mexican population. For example, the elimination of the word "barriga," leaving only "estomago," the substitution of the expression "hinchazón" for "inflamación." In addition, a definition of colostomy and ileostomy was added at the end of the instrument, since they are technical terms that are sometimes not understood by patients. Finally, the final version of the EORCT CR29 was obtained after receiving few suggestions from patients.

Statistical analysis

Data analysis was carried out using the statistical program SPSS version 26. Since the EORTC QLQ-CR29 comprises 4 scales composed mostly of 2 items, a principal component factor analysis with Varimax rotation was performed and adjusted to 4 factors, corresponding to the 4 functional subscales of the original scale. The 17 items that were answered by all the participants (items 31-47) were considered, regardless of whether they had a stoma or not and of their gender, with the purpose of determining the configuration of the items in the proposed scales. For this analysis, the following criteria were used: (a) factor loadings \geq .40; (b) a minimum number of items per-factor was not established; and (c) internal consistency coefficients for each Cronbach's alpha factor \geq .50. The relationship between the EORTC QLQ-CR29 instrument and the concurrent measurements with the EORTC QLQ-C30 was evaluated using the Pearson correlation coefficient. Likewise, internal consistency was obtained using Cronbach's alpha and the Omega coefficient.

We proceeded to assess the fit of the 4-factor model by means of a confirmatory factor analysis using the maximum likelihood method (Abd-El-Fattah 2010; George and Mallery 2019; Kline 2015): The analysis included the identification and specification of the model, the estimation of standardized parameters, such as R2 correlations, covariances, modification indices, and critical proportions of the differences, followed by the evaluation of the fit by observing the acceptable limits of the estimators. Various fit indices were estimated, including: the X2 index, the X2/df ratio, the goodness-of-fit index (GFI), the Tucker–Lewis index (TLI), and the corrected goodness-of-fit index (AGFI), as well as the comparative goodness-of-fit index (CFI), (Ullman 2006) which is considered the best indicator for samples equal to or greater than 200. Finally, the root mean square of the approximation error (RMSEA) was also calculated.

Results

A nonrandom sample composed of 251 individuals, of both genders and with a diagnosis of CRC, whose average age was 54.7 ± 12.28 years (see Table 1), was used.

Factor structure

The sample used in the analysis was considered adequate, according to the value of the Kaiser–Meyer–Olkin test, which was .732 (p = .001). An exploratory factorial analysis was performed using the principal components method, and varimax rotation and adjusted to 4 factors with the 17 items. An explained variance of 51.64% was found, and 4 factors were identified and named: Psychological affectations, Physical symptoms, Blood and mucus in the stool, and Urinary symptoms, as seen in Table 2.

Internal consistency

An internal consistency analysis of the EORTC QLQ-CR29 instrument was performed, obtaining a Cronbach's alpha coefficient of .766 (95% CI: .722–.806) and an Omega coefficient of $\omega = .788$, for the 17 items of the test questionnaire. Likewise, alpha coefficients of $\alpha = .573$ to .771 were obtained in the 4 factors identified in the factor analysis, with Omega coefficients of $\omega = .650$ –.788.

External validity

Regarding the correlations between the EORTC QLQ-CR29 and the EORTC QLQ-C30, it was observed that in most cases these were low (r < .40), however, in some areas with more related contents, higher correlations were found to be high ($r \ge .40$) (see Table 3). In relation to the 4 subscales of the EORTC QLQ-CR29, statistically significant negative correlations were found with the overall QoL of the EORTC QLQ-C30 (Pearson's *r* from -.199 to -.399, p < .01). Table 3 is a breakdown of the highest correlations identified in each subscale.

Confirmatory factor analysis

The relative comparative goodness-of-fit indices (CFI, TLI, and AGFI) are significantly close to the ideal value of .95, confirming the acceptability of the model compared to the null. The PCFI value, which is close to 1 and is greater than .5, indicates that the proposed model is more parsimonious and efficient than the null model (Hu and Bentler 1998).

Furthermore, the root mean square residual (RMR) index is close to 0 and less than .06 (RMR = .044), confirming that there is virtually no difference between the observed and the predicted covariance matrix, suggesting that the discrepancy between the proposed model and the actual data is almost nonexistent or very low (Abd-El-Fattah 2010).

In general, the adjusted chi-square value at 111 degrees of freedom was much less than 3 (ideally less than 3) (chi-square = 1.410), with a *p*-value less than .05, confirming an excellent absolute fit of the model to the observed data (Abd-El-Fattah 2010). In addition, a value close to 0 is observed in the RMSEA index (RMSEA = .040 [.024-.055]), which indicates that the model has almost 0 error (Abd-El-Fattah 2010). These results are summarized in Figure 1 and Table 4 of the final model.

Discussion

The incidence of cancer is not distributed evenly throughout the world, as infection-related malignancies are gradually being replaced by those related to rapid social, economic, and demographic changes. These changes are due to the adoption of lifestyles and behaviors commonly associated with Westernization (Fidler et al. 2017), which is reflected in the increase in CRC, which is one of the clearest markers of this oncological transition (Fidler et al. 2017).

In Latin America and the Caribbean, CRC occupies third place with the highest incidence and is expected to continue to increase in the future (GLOBOCAN, 2020). This increase is partly due to the adoption of unhealthy lifestyles, characterized by dietary patterns low in fiber and high in animal fats, red and processed meats, high alcohol consumption, smoking, and physical inactivity

 Table 1. Clinical and sociodemographic characteristics of a sample of 251 participants with CRC

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Comorbidity Chemotherapy + radiotherapy 48 19% Yes 73 29% Another 2 1% No 178 71% Awaiting treatment 8 3% Type of comorbidity Follow-up 7 7% Marnofsky 7% Same and the same and	High	102	41%	Surgery + chemotherapy + radiotherapy	49	19%
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Yes 58 23% COVID has had					240	96%
	Mental health care throughout	the lifespan		2	11	4%
No 193 77% Yes 69 27%	Yes	58	23%	COVID has had		
	No	193	77%	Yes	69	27%

Palliative and Supportive Care

Table 1. (Continued.)

		Age in years: $\overline{X} = 54.7$,	range 23–93		
Variable	f	%	Variable	f	%
Type of mental health care			No	177	70%
Psychology	47	19%	Death of loved one b	y COVID	
Psychiatry	5	2%	Yes	70	28%
Both	5	2%	No	181	72%

Table 2. Psychometric properties and exploratory factor analysis of the EORTC QLQ-CR29

Cronbach's alpha coefficient $lpha=$.766 (95% CI: .722–.806)					
Omega = .725 Total evaluations	Factorial loading				
Total explained variance = 51.64% Psychological Aspects Subscale		Factorial	loauing		
Alfa de Cronbach $\alpha = .771$ Omega $\omega = .788$	Tot	al explained v	ariance $= 17.30$)%	
C29_45. Have you felt physically less attractive as a result of your disease or treatment?	.896	.034	.056	.059	
C29_46. Have you been feeling less feminine/masculine as a result of your disease or treatment?	.852	.009	.095	.002	
C29_47. Have you been dissatisfied with your body?	.846	.095	.004	.029	
C29_44. Have you worried about your weight?	.480	.098	.242	.156	
C29_43. Were you worried about your health in the future?	.423	.180	.269	.103	
C29_41. Have you lost hair as a result of your treatment?	.896	.288	192	.072	
Physical Symptoms Subscale					
Alfa de Cronbach $\alpha = .648$ Omega $\omega = .650$	Tot	al explained va	ariance = 12.19	9%	
C29_37. Did you have a bloated feeling in your abdomen?	.194	.745	038	.060	
C29_35. Did you have abdominal pain?	.085	.728	.160	.073	
C29_40. Did you have a dry mouth?	032	.629	.117	.047	
C29_42. Have you had problems with your sense of taste? (e.g. loss or changes in the taste of food)	.119	.552	.093	.007	
Blood and Mucus in the Stool Subscale					
Alfa de Cronbach $\alpha = .690$ Omega $\omega = .658$	Tot	Total explained variance $= 11.54\%$			
C29_38. Have you had blood in your stools?	.054	.143	.783	.041	
C29_39. Have you had mucus in your stools?	.150	.021	.761	.029	
C29_36. Did you have pain in your buttocks/anal area/rectum?	.049	.121	.716	.109	
Urinary Symptoms Subscale					
Alfa de Cronbach $\alpha = .573$ Omega $\omega = .667$	Tot	al explained va	ariance $=$ 10.60)%	
C29_31. Did you urinate frequently during the day?	.169	004	.093	.799	
C29_32. Did you urinate frequently during the night?	035	107	.139	.770	
C29_33. Have you had any unintentional release (leakage) of urine?	.083	.089	023	.516	
C29_34. Did you have pain when you urinated?	.030	.313	.029	.486	

(Figuero et al. 2021; Granados and Herrera 2016; Kolligs 2016). In 2017, approximately two thirds of the population of Mexico (more than 50 million people) were overweight or obese, and in 2018 approximately 10,000 cases of colon cancer were diagnosed, of which approximately 15% could be attributed to a high body mass index (Soerjomataram and Bray 2021).

Due to the increase in the incidence of CRC, the health system must be resized to face this challenge in the future (Álvarez-Escobar 2019). The evaluation of the QoL of patients with CRC is essential to know their perspective on the impact of the disease and the treatment on their lives, which helps to make therapeutic decisions and becomes a primary outcome measure.

Table 3. Correlations between the EORTC QLQ-CR29 and EORTC QLQ-C30 instruments

					QLQ C30					
		Functional Scales					Symptom Scales			
QLQ-CR29	QoL	PF	RF	EF	CF	SF	FA	NV	PA	
ESCALAS										
Psychological Aspects	338**	.274**	.290**	.418**	.276**	.309**	.323**	.174**	.303**	
Physical Symptoms	399**	.333**	.326**	.527**	.270**	.129*	.573**	.418**	.478**	
Blood and Mucus in the Stool	323**	.310**	.277**	.215**	.063	.159*	.279**	.215**	.319**	
Urinary Symptoms	199**	.282**	.153*	.185**	.153*	.209**	.245**	.055	.162*	
ITEMS										
Flatulence (stoma)	.026	006	020	.114	.142	.248*	.160	.152	.017	
Fecal incontinence (stoma)	227*	.137	.164	.248*	.079	.120	.305**	.267**	.199*	
Sore skin (stoma)	235*	.076	.189	.304**	.246*	.201*	.207*	.161	.195	
Stool frequency at day (stoma)	284**	.228*	.246*	.286**	.184	.156	.317**	.100	.167	
Stool frequency at night (stoma)	096	.112	.118	.124	007	.015	.122	005	070	
Embarrassment (stoma)	067	.040	.086	.166	.138	.142	.171	.131	.027	
Problemas con el cuidado de Estoma (stoma)	307**	.320**	.324**	.406**	.179	.431**	.302**	.236*	.268**	
Flatulence (no stoma)	166*	003	.005	.175*	.208*	.097	.004	.027	.072	
Fecal incontinence (no stoma)	189*	.181*	.135	.205*	035	.084	.115	.024	.151	
Sore skin (no stoma)	280**	.220**	.183*	.163*	.135	.233**	.131	.197*	.259**	
Frecuencia deposiciones día (no stoma)	154	.202*	.150	.171*	.027	.075	.153	.114	.224**	
Frecuencia deposiciones noche (no stoma)	122	.149	.062	.153	.077	.082	.181*	.127	.185*	
Embarrassment (no stoma)	283**	.270**	.270**	.253**	.200*	.095	.248**	.319**	.311**	
Impotence	081	.213*	.194*	.133	018	.226*	.248**	.109	.200*	
Dyspareunia	052	076	024	074	037	.075	095	.179*	.015	
Sexual interest (men)	180*	.191*	.152	.066	.185*	.006	.253**	.141	.104	
Sexual interest (women)	180*	.190*	.161	.163	.092	086	.265**	068	.172	

*Correlation is significant at the .05 level. **Correlation is significant at the .01 level.

The original QLQ-CR29 incorporates 4 multi-thematic scales and 19 individual items that assess the range of symptoms and common problems in patients with CRC. However, some previous validations have not included exploratory factor analysis (EFA) (Arraras et al. 2011; El Alami et al. 2020; Ihn et al. 2015; Lin et al. 2017; Magaji et al. 2016; Montazeri et al. 2017; Nowak et al. 2011; Shen et al. 2018; Wickramasinghe et al. 2020). In this sense, the German validation (Stiggelbout et al. 2016) has identified 7 factors through an EFA, although some of them were not theoretically interpretable.

On the other hand, in the present validation in the Mexican population, an EFA and a confirmatory factor analysis were performed, which allowed grouping a greater number of items in the 4 factors of the QLQ-CR29. In the *Psychological Aspects* subscale, image and concern for weight/health were grouped; in the *Physical Symptoms* subscale, pain, abdominal swelling, and taste disturbances were grouped together; in the *Urinary Symptoms* subscale, urinary frequency, painful urination, and urinary incontinence were grouped; and in the subscale *Blood and mucus in the stool*, pain in the rectum was incorporated. This grouping of items decreases the number of unique items, improves the reliability of the scale, and provides evidence of the validity of the structure by integrating the items in a theoretically interpretable manner.

The QLQ-CR29 questionnaire was shown to have acceptable psychometric properties, similar to previous validations carried out in other studies (Arraras et al. 2011; El Alami et al. 2020; Ihn et al. 2015; Stiggelbout et al. 2016). The results of the confirmatory factor analysis suggest that the proposed theoretical model adjusted almost perfectly to the data of the sample used in this research and the structural indicators (CFI, RMR, and RMSEA) indicate that it is a balanced model with minimal error that measures in a pertinent way the QoL of patients with CRC.

Small modifications were made in the wording of the questionnaire to make it more easily understandable for the Mexican population, because the way of asking questions and the language used are sources of bias, as well as cultural factors that lead to the same question being valid or not in one language or another, or even in different countries that share the same language (Carvajal et al. 2011). These modifications focused on improving

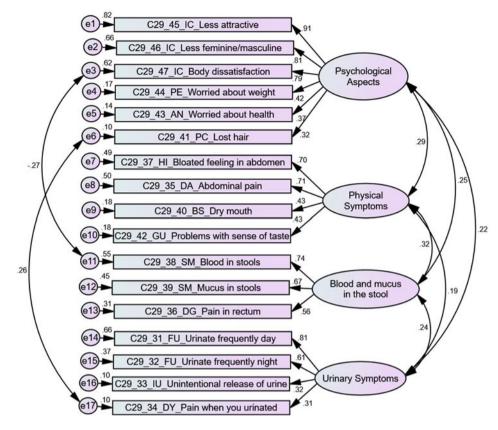


Figure 1. Four-factor first-order confirmatory factor analysis model with 17 items of the EORTC QLQ-CR29.

Table 4. Indices obtained from confirmatory factor analysis confirmatory factor analysis model with 17 items of the EORTC QLQ-CR29

χ^2 (gl)	CMIN/DF	PCFI	RMR	CFI	TLI	GFI	AGFI	SRMR	RMSEA
156.482 (111)	1.410	.777	.059	.952	.942	.933	.907	.0599	.040(.024–.055)

the acceptance of the questionnaire by the participants, reducing attrition and minimizing the amount of data lost.

The EORTC QLQ-CR29 stands out from other QoL assessment instruments in oncology due to its specific focus on patients with CRC, covering relevant aspects such as intestinal problems, urinary symptoms, and sexual difficulties. Although there is an alternative to the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) scale (Ward et al. 1999), the latter has fewer items and specific subscales to measure side effects, symptoms, and key functional areas in this cancer group, in addition to lacking a specific section for patients with or without stoma. Therefore, the EORTC QLQ-CR29 has superior content validity compared to the FACT-C.

In summary, the EORTC QLQ-CR29 is recommended for the evaluation of the QoL of Mexican cancer patients with CRC in different settings, including clinical, research, and institutional care. The use of this instrument allows reliable and valid results, to be obtained and allows the comparison of results at the national and international levels.

In future studies, it is suggested to evaluate the stability of the instrument over time, analyzing whether the instrument is sensitive to the effects of medical and/or psychosocial interventions, as well as conduct additional research to explore the impact of QoL in patients with CRC in relation to other constructs such as overall disease survival, symptomatology emotional and therapeutic adherence.

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Competing interests. The author(s) declare none.

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