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Validity and reliability of the RAC adult infection risk scale: A new instrument to measure healthcare-associated infection risk

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Abstract

Healthcare-associated infections represent a public health problem, and they have repercussions for patient safety. The aim of this study was to determine the psychometric properties of the Rodríguez–Almeida–Cañon (RAC) adult infection risk scale, focusing on the construct and predictive validity and reliability. The study enrolled 278 patients at a large hospital in southern Brazil. The research process involved the following three phases: construct validation, assessing predictive validity, and assessing reliability. Confirmatory factor analysis showed a good fit using a two-factor model with 15 items. The logistic regression analysis showed an association between the scale score and prediction of developing healthcare-associated infections (odds ratio: 1.18; 95% confidence interval: 1.08–1.28). The Cronbach's alpha was 0.72 for intrinsic factors subscale and 0.71 for extrinsic factors subscale. A high level of inter-rater agreement (intraclass correlation coefficient ≥0.97) was found for both subscales. The Bland and Altman method showed narrow agreement limits, demonstrating good agreement between evaluators. The findings of this study showed that the RAC adult infection risk scale is a new, reliable, and psychometrically valid instrument to assess healthcare-associated infections risk. Future research using this scale may lead to a better understanding of the healthcare-associated infections risk and assist health professionals in decision-making for interventions to improve patient safety.

KEYWORDS
infection control, nursing, patient safety, psychometrics, risk assessment

1 | INTRODUCTION

Healthcare-associated infection (HAI) is a growing public health problem that affects patient safety, quality of health services, and the economic burden for patients and health institutions (Haque et al., 2018). It is also a legal, social, and ethical problem because of the effects it has on the lives of patients and the risks to which they are exposed (Magill et al., 2014; Gastmeier et al., 2012; Geffers & Gastmeier, 2011). Furthermore, HAIs result in prolonged hospital stays, long-term disability, increased resistance of microorganisms to antimicrobials, massive additional costs for health systems, high costs for patients and their families, and unnecessary deaths (World Health Organization, 2016).

There is a growing body of evidence on strategies for reducing HAIs and their global burden (Allegranzi et al., 2011; World Health

Organization, 2011). In this context, a World Health Organization report shows that death from HAI occurs in about 10% of affected patients. Moreover, on average at any given time 7% of patients in developed and 10% in developing countries will acquire at least one HAI (World Health Organization, 2011). The European Center for Disease Prevention and Control estimated that more than 2.6 million new cases of HAI occur every year in Europe (Chigusa et al., 2016). In the United States of America, it was estimated that around 1.7 million patients are affected by HAIs each year, representing a prevalence of 4.5% (World Health Organization, 2011). The burden of HAIs was also recently highlighted in southeast Asian countries showing an overall prevalence of 9.0% (Ling et al., 2015). Limited data are available from low- and middle-income countries, but the prevalence of HAI is estimated to be between 5.7% and 19.1% (Allegranzi et al., 2011).

National HAI surveillance systems exist in several high-income countries and data are usually available through national reports or multicentre studies published in the scientific literature (World Health Organization, 2011). Although HAIs are the most frequent adverse events in healthcare, most low- and middle-income countries lack surveillance systems for HAI, and those that do have them struggle with the complexity of the problem and the lack of uniform criteria for diagnosis (Allegranzi et al., 2011; World Health Organization, 2011). To prevent and control the spread of HAIs worldwide, the Centers for Disease Control and Prevention and other international agencies work together on the development of tools, recommendations, and programs for infection prevention strategies to help protect patients (Centers for Disease Control and Prevention CDC, 2018).

According to the World Health Organization (World Health Organization, 2012), HAIs are directly related to medical care and there are several low-cost, straightforward strategies that can effectively reduce the likelihood of acquiring a HAI. These strategies include the use of scales and clinical scores to help health professionals decide on appropriate interventions based on the HAI risk, thus having an impact on patient safety. However, there is a scarcity of validated tools available to assess HAI risk, particularly in developing countries. (Allegranzi et al., 2011).

Known risk factors for HAIs are immunosuppression, previous antibiotic use, length of surgical procedure, reoperation, invasive procedures, comorbidities, and transfer from another care unit (Cardoso et al., 2014; Rodríguez-Acelas et al., 2017). There are some models and scores for assessing specific clinical infections, such as surgical site infections (Van Walraven & Musselman, 2013) and bloodstream infections (Herc et al., 2017). However, there is no known single scale or score that assesses the main risk factors for the development of HAIs.

To this end, the Rodríguez–Almeida–Cañon (RAC) Adult infection risk scale (Rodríguez-Acelas et al., 2019) was recently developed to be applied in the Brazilian population (Streiner & Kottner, 2014). The development of this new scale was based on a comprehensive literature review and expert opinion. The developed scale has 15 items regarding patient characteristics and healthcare to be provided for hospitalized patients. The items related to the patient are gender, age, smoking, alcohol consumption, nutritional classification, comorbidities, nonsurgical injury or wound, and physical mobility. The items related to the care process comprise: previous hospitalization, transfer, hospitalization unit, length of stay, surgery during hospitalization or in the last 12 months, invasive procedures, and previous pharmacological and/or nonpharmacological therapy. The evaluation of the items was based on the classical test theory (DeVellis, 2017; Muñiz, 2010), and for each item, values varied from 0 to 3 depending on the response categories for each of the variables. These scale categories were based on the results of a meta-analysis that identified the main risk factors independently associated with the development of HAI (Rodríguez-Acelas et al., 2017). The RAC adult infection risk scale is shown in the supplementary file.

Subsequently, the RAC adult infection risk scale was subjected to face and content validation by a committee of 23 experts with experience in HAI (Rodríguez-Acelas et al., 2019). The content validity of the scale was tested using the content validity index (CVI). The items were maintained, but some modifications were necessary to improve the clarity of some items. The CVI of the items ranged from 0.83 to 1.0 and the mean CVI of the scale was 0.90 (Rodríguez-Acelas et al., 2019).

The purpose of this study was to determine the psychometric properties of the RAC adult infection risk scale (Rodríguez-Acelas et al., 2019), focusing on the construct and predictive validity and reliability of the scale.

2 | METHODS

2.1 | Design

This prospective study was conducted in a public tertiary university hospital in southern Brazil, with 831 beds and a wide range of specialties. This hospital has been accredited by the Joint Commission International since 2013. The study was conducted in three phases between November 2017 and June 2018. The first phase focused on scale construct validation, the second phase included predictive criterion validity (PCV), and the third phase involved reliability testing. The study was approved by the Research Ethics Committee (160231) and the institution where the study was conducted. All participants provided verbal and written informed consent.

2.1.1 | Sample and data collection

The study included 278 patients who met the following inclusion criteria: (i) age ≥18 years; (ii) either sex; (iii) hospitalized in clinical or surgical units, or emergency department; (iv) had no infection on admission; and (v) hospitalization ≥72 h until discharge, death, or infection.

The data were collected daily by two researchers using an online questionnaire composed of sociodemographic data (age, sex, race,

education, marital and professional status), general clinical data (comorbidities, hospitalization unit), and the RAC adult infection risk scale. All patients were independently assessed by both evaluators on the same day. Data were obtained through an interview with the patients, physical examination, and consultation of the electronic medical record during admission and hospitalization. Clinical relevance data related with the items of the RAC adult infection risk scale were also collected. The outcome of HAI during patients' hospitalization was confirmed through diagnostic tests (blood or fluid test, cultures) and the medical diagnosis of infection was made by the patient's treating physician or opinion of the hospital's infection control committee.

The researchers' training was conducted under the guidance of one of the investigators responsible for the project and who also participated in data collection. In addition, before the start of the project, a pilot study was carried out to evaluate data collection methods, recruitment times of eligible patients, time of application of the scale and the feasibility of the research field site. All research materials were reviewed daily by the principal investigator.

2.2 | Phase 1: Construct validity

The construct validity of the RAC Adult Infection Risk Scale was verified using confirmatory factor analysis (CFA) (Schmitt, 2011). CFA was performed with the Promax oblique rotation method, and we used the robust weighted least squares estimator, suitable for the analysis of categorical variables (Li, 2016). The Kaiser–Meyer–Olkin (KMO) index and Bartlett's sphericity test were used to evaluate the appropriateness of the factor model and sample size for the factor analysis. KMO values exceeding 0.5 were considered adequate (Dziuban & Shirkey, 1974). CFA is a method commonly used in scale-development studies to test the suitability of theoretical models (Perry et al., 2015). In addition, CFA can be used to examine structural validity, such as whether a construct is unidimensional or multidimensional and how the constructs are related (Harrington, 2009). Model fit was assessed using the following fit index: root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), comparative fit index (CFI), and Tucker–Lewis index (TLI). RMSEA and SRMR values ≤0.08 and CFI and TLI values ≥0.90 indicate an acceptable model fit (Hu & Bentler, 1999).

2.3 | Phase 2: Predictive criterion validity

For the PCV, some authors (DeVellis, 2017) suggest that selection of the external criterion or a gold standard can be either a critical measurement instrument or even a clinical variable. In this study, a logistic regression analysis was performed to assess whether the score on the RAC adult infection risk scale was able to predict the development of HAI.

2.4 | Phase 3: Reliability

The reliability aspect refers to the stability, internal consistency, and equivalence of a measurement (De Souza et al., 2017). The assessment was conducted based on the following three parameters: (i) internal consistency, which is measured through Cronbach's alpha coefficient, for which values between 0.7 and 0.9 are desirable (Streiner et al., 2016); (ii) inter-rater agreement, which is calculated using the intraclass correlation coefficient (ICC), with a satisfactory ICC of ≥0.75 (De Souza et al., 2017; De Vet et al., 2006); and (iii) level of agreement or equivalence through Bland and Altman's 95% agreement limits (Bland & Altman, 2012; Bland & Atlman, 1986).

2.5 | Data analysis

The data were collected in a spreadsheet in the Microsoft Excel® program and all analyses were conducted in Stata version 15.0® (StataCorp LP.). For categorical variables, the absolute and relative frequencies are presented, and for quantitative variables, the mean and *SD* are used to describe the sample. Normal distribution of the continuous data were assessed using the Kolgomorov–Smirnov and Shapiro–Wilk tests. The variables were compared between the groups through student's t and χ^2 tests. All hypothesis tests were performed with a 5% alpha level.

3 | RESULTS

3.1 | Sociodemographic and clinical characteristics of the participants

This prospective study consisted of patients who were hospitalized in the emergency department, surgical unit, or general clinical unit. Table 1 presents the comparison of sociodemographic and clinical characteristics of the participants with (n = 50) and without infection (n = 228). The groups showed significant differences only in the variable neoplastic comorbidity, which was higher in the infected versus the noninfected group (p = 0.03).

Table 2 shows the comparison of the scale items according to the occurrence of HAI. Distribution of comorbidity differed between infected and noninfected groups (p = 0.009). The rates of comorbidities in the immune system were 64% in the infected versus 40% in the noninfected group. The infected group also showed significant differences in relation to the following variables: previous hospitalization (p = 0.009), surgery during hospitalization or in the last 12 months (p < 0.001), and invasive procedures (p = 0.005).

The mean of intrinsic factors subscale score was 9.4 (*SD* = 2.3) for patients with HAI and 8.8 (*SD* = 2.3) for patients without HAI. Additionally, there was a significant difference in the mean of extrinsic factors subscale score between the infected and noninfected groups, 8.4 (*SD* = 2.4) and 6.8 (*SD* = 2.5) respectively (p < 0.001).

TABLE 1 Sociodemographic and clinical characteristics of the participants ($N = 278$)

Variables	With HAI $n = 50$	Without HAI $n = 228$	p
Age, years[a]	58.9 ± (14.8)	58.4 ± (15.8)	0.83
Sex, female[b]	21 (42.0)	120 (52.6)	0.17
Race[b]			0.12
White	47 (94.0)	192 (84.2)	
Black	1 (2.0)	26 (11.4)	
Other	2 (4.0)	10 (4.4)	
Marital status[b]			0.64
Married/lives with companion	25 (50.0)	125 (54.8)	
Single	14 (28.0)	54 (23.7)	
Divorced	5 (10.0)	14 (6.1)	
Widower	6 (12.0)	35 (15.4)	
Schooling, years[a]	9.9 ± (5.2)	9.3 ± (5.2)	0.45
Professional status[b]			0.52
On leave/INSS[f]	6 (12.0)	17 (7.5)	
Retired/pensioned	16 (32.0)	106 (46.5)	
Active	26 (52.0)	90 (39.5)	
Unemployed	1 (2.0)	9 (4.0)	
Others[d]	1 (2.0)	6 (2.5)	
Religion[b]			0.34
Catholic	39 (78.0)	145 (63.6)	
Evangelical	3 (6.0)	32 (14.0)	
Others	7 (14.0)	39 (17.1)	
Without religion	1 (2.0)	12 (5.3)	
Comorbidities[b,c]			
Neurological	6 (12.0)	46 (20.2)	0.24
Cardiovascular	29 (58.0)	145 (63.6)	0.46
Respiratory	4 (8.0)	27 (11.8)	0.43
Endocrine	10 (20.0)	52 (22.8)	0.67
Gastrointestinal	6 (12.0)	49 (21.5)	0.13
Musculoskeletal	9 (18.0)	32 (14.0)	0.47
Genitourinary	8 (16.0)	45 (19.7)	0.54
Neoplasia	26 (52.0)	81 (35.5)	0.03
Other conditions[e]	11 (22.0)	54 (23.7)	0.71
Hospitalization unit[b]			0.91
Emergency	7 (14.0)	29 (12.7)	
Clinical and surgical	33 (66.0)	122 (53.5)	
General clinic	10 (20.0)	77 (33.8)	

Abbreviation: HAI, healthcare-associated infection.

[a]Numerical variable expressed as mean ± standard deviation.

[b]Categorical variable presented in absolute and relative frequency: n (%)

[c]Values exceed 100% because some participants had various diseases.

[d]Spiritist, Umbanda, unspecified.

[e]Circulatory, hematological, immunological and integumentary conditions.

[f]INSS: National Social Security Institute deals with pensions due to death or disability and leaves due to accidents or diseases.

3.2 | Phase 1: Construct validity

A KMO index of 0.61 and Bartlett sphericity test ($p < 0.001$), indicated the suitability for CFA testing. The CFA showed a good model fit for the RAC adult infection risk scale using a two-factor model (intrinsic and extrinsic factors) with 15 items, RMSEA = 0.07, SRMR = 0.08, CFI = 0.92, and TLI = 0.94 (Figure 1).

3.3 | Phase 2: Predictive criterion validity

The PCV assessment through logistic regression analysis showed an association of the score of the RAC adult infection risk scale with the prediction of HAI (odds ratio: 1.18; 95% confidence interval [CI]: 1.08–1.28, $p < 0.001$).

3.4 | Phase 3: Reliability

Internal consistency of the subscales was tested using Cronbach's alpha coefficient, resulting in a value of 0.72 (95% CI: 0.68–0.74) for intrinsic factors subscale and 0.71 (95% CI: 0.69–0.73) for extrinsic factors subscale. A high level of inter-rater agreement was found for both subscales (intrinsic and extrinsic factors), with an ICC of 0.97 (95% CI: 0.96–0.99) and 0.98 (95% CI: 0.97–0.99), respectively.

Level of agreement and the concordance analysis using the Bland and Altman method showed a mean of difference that was normally distributed and close to zero (−0.036, $SD = 0.67$), and had narrow agreement limits (>1.28 and <−1.36) which demonstrated good agreement between both evaluators (Figure 2).

4 | DISCUSSION

The RAC adult infection risk scale showed adequate construct and predictive validity and reliability for assessing HAI risk. The good psychometric performance of our scale may be due to the questions

TABLE 2 Comparison of the scale items according to the occurrence of healthcare-associated infection ($N = 278$)

RAC adult infection risk scale	Occurrence of HAI: Yes ($n = 50$) n (%)	Occurrence of HAI: No ($n = 228$) n (%)	p
Scale/items			
Intrinsic factors subscale			
Gender			0.170[a]
Female	21 (42.0)	120 (52.6)	
Male	29 (58.0)	108 (47.4)	
Age, years			0.470[a]
18–40	5 (10.0)	37 (16.2)	
41–59	19 (38.0)	73 (32.0)	
≥60	26 (52.0)	118 (51.8)	
Smoker			0.490[a]
No	33 (66.0)	147 (64.5)	
Former smoker	1 (2.0)	14 (6.1)	
Active or passive	16 (32.0)	67 (29.4)	
Alcohol consumption			0.130[a]
No or rarely	40 (80.0)	190 (83.3)	
Moderate consumption	5 (10.0)	30 (13.2)	
Heavy consumption	5 (10.0)	8 (3.5)	
Nutritional classification			0.670[a]
Normal	16 (32.0)	88 (38.6)	
Low weight	2 (4.0)	7 (3.1)	
Overweight	32 (64.0)	133 (58.3)	
Comorbidities			0.009[a]
No	2 (4.0)	0 (0.0)	
Up to 2 comorbidities	11 (22.0)	50 (21.9)	
3 or more comorbidities	11 (22.0)	87 (38.1)	
Comorbidities of the immune system and/or transplants and/or cancer	26 (64.0)	91 (40.0)	
Nonsurgical wound or injury			0.450[a]
No	43 (86.0)	195 (85.5)	
Clean	7 (14.0)	25 (11.0)	
Contaminated	0 (0.0)	8 (3.5)	
Physical mobility			0.070[a]
Without assistance	23 (46.0)	145 (63.6)	
With assistance and/or use of auxiliary device	16 (32.0)	49 (21.5)	
Bedridden	11 (22.0)	34 (14.9)	
Extrinsic factors subscale			
Prior hospitalization			0.009[a]
No	35 (70.0)	195 (85.5)	
Yes	15 (30.0)	33 (14.5)	
Transfer			0.580[a]
No	11 (22.0)	68 (29.8)	
From another unit/sector of the hospital of semi-critical areas	6 (12.0)	32 (14.0)	
From another unit/sector of the hospital of critical areas	27 (54.0)	109 (47.8)	
From another institution or homecare	6 (12.0)	19 (8.4)	
Hospitalization unit			0.740[a]
Clinical and/or surgical hospitalization unit	43 (86.0)	200 (87.7)	
Emergency, intensive therapy unit, coronary care unit or similar units	7 (14.0)	28 (12.3)	
Time of hospitalization, days			0.830[a]
1–7	43 (86.0)	196 (86.0)	
8–15	6 (12.0)	24 (10.5)	
16 or more	1 (2.0)	8 (3.5)	
Surgery during hospitalization or in the last 12 months			<0.001[a]
No	23 (46.0)	141 (61.9)	
Clean	7 (14.0)	55 (24.1)	
Clean-contaminated or potentially contaminated	17 (34.0)	26 (11.4)	
Contaminated	3 (6.0)	6 (2.6)	
Invasive procedures			0.005[a]
No	4 (8.0)	62 (27.2)	
Low complexity	18 (36.0)	91 (39.9)	
Medium complexity	5 (10.0)	17 (7.5)	
High complexity	23 (46.0)	58 (25.4)	
Prior pharmacological and/or nonpharmacological therapy			0.070[a]
No	1 (2.0)	14 (6.1)	
Antacids and/or nonsteroidal anti-inflammatory drugs	40 (80.0)	170 (74.6)	
Antifungals and/or antibiotics	2 (4.0)	29 (12.7)	
Immunosuppressant and/or glucocorticoid and/or antineoplastic and/or radiation therapy	7 (14.0)	15 (6.6)	

Abbreviations: HAI, healthcare-associated infection; RAC, Rodríguez–Almeida–Cañon.

[a]χ^2 test.

being easy to understand. Additionally, the choice of items was made based on an extensive literature review and the opinion of health professionals with experience in attending hospitalized patients.

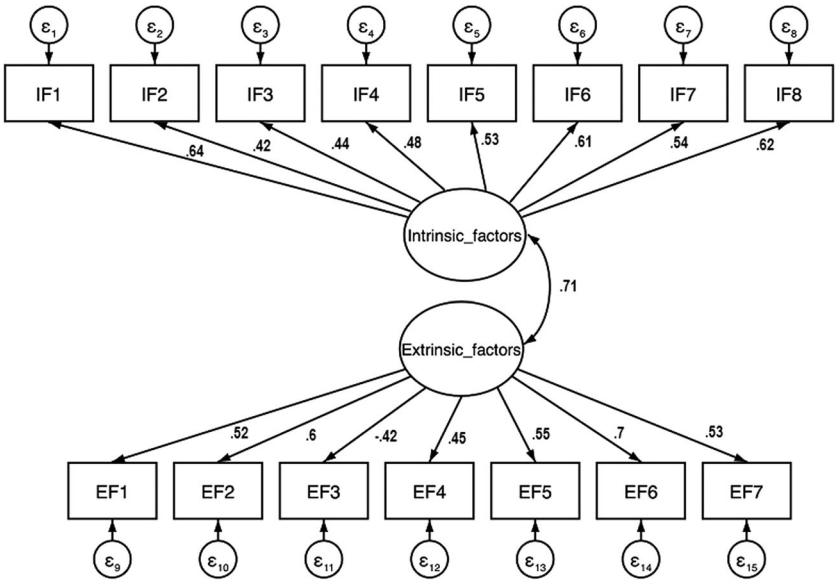

FIGURE 1 Confirmatory factor analysis results showing the standardized estimates with errors for the Rodríguez–Almeida–Cañon (RAC) adult infection risk scale. EF, extrinsic factor; IF, intrinsic factor

This study also identified clinical characteristics of patients at risk for HAIs in a middle-income country. Our results related with the occurrence of HAI, showed significant differences for previous hospitalization, surgery during hospitalization and invasive procedures. These findings were also found in studies conducted in Ethiopia and Singapore (Ali et al., 2018; Cai et al., 2017). Regarding comorbidities of patients, there seems to be variations between studies. In our study, we found no differences between patients with and without infection in relation to several comorbidities, with the exception of neoplasia. Neoplasms, scarcely mentioned as a risk factor for HAIs, appear in a study conducted in four countries in Latin America (Huerta-Gutiérrez et al., 2019). Although a diverse set of hospitals has been included in that study, some clinical services were at higher risk of HAIs, as patients receiving chemotherapy, which reinforces our results.

There are several valid models/scores for assessing risk of infection, such as the surgical site infection risk score (Van Walraven & Musselman, 2013), MPC score (Herc et al., 2017) and the McCabe score (Reilly et al., 2016). Despite these authors using different methods to validate the studies, they both found that these tools performed well for the assessment of the risk of infection, in line with our own study. However, these scores assess the risk of infection in specific clinical situations, whereas our scale can be applied to adult patients without any specific characteristics.

The importance of identifying risk factors for HAI is fundamental to achieving the patient's safety goals during hospitalization (World Health Organization, 2009). Tools that assess this risk are useful and can inform relevant strategies that health professionals can use to achieve the desired balance between risk, benefit, and cost (Fassini & Hahn, 2012). An

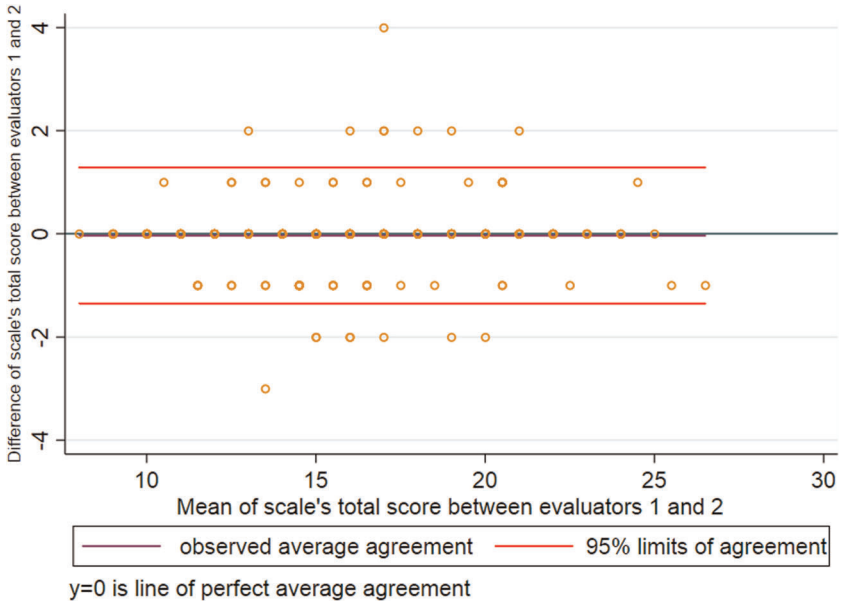

FIGURE 2 The Bland and Altman method comparing the results of the RAC adult infection risk scale score between two evaluators. RAC, Rodríguez–Almeida–Cañon

additional strength of our scale is that it can be easily and quickly applied to evaluate HAI risk in hospitalized adults. The tool can also be used by different healthcare professionals. It should be used at the time of admission or when significant changes in health during patient hospitalization or unit transfer occur, as recommended by other risk assessment scales. The most important point is to ensure a patient's safety and to implement measures or interventions according to the risk score to prevent the occurrence of infections (Herc et al., 2017; Reilly et al., 2016; Van Walraven & Musselman, 2013).

4.1 | Limitations

This study has some limitations. First, this scale was developed in a Brazilian healthcare context. Therefore, cultural differences should be considered if the scale is adapted in another language. Second, patients from specialized units were not included, such as the intensive care unit, post-anesthetic recovery room, and palliative care. However, it is believed that possible selection bias was minimized with the inclusion of clinical and postsurgical patients with different diagnoses and health states. This investigation was conducted at a single study site and due to sample size, we did not evaluate the item response theory. However, the scale demonstrated a good performance overall, after the evaluation of the psychometric properties. Future studies should include a more heterogeneous sample and other research scenarios.

4.2 | Implications

Measuring patients' risk of infection is a topic that generates controversy for health professionals. They must select the most appropriate interventions that contribute to reducing the risk while taking into account that an inadequate assessment of this risk can cause suffering for the patient and their family, as well as increased costs for the healthcare system.

HAIs are considered an indicator of the quality of patient care, an adverse event, and a patient safety issue (Collins, 2008; Hughes, 2008). Infection control needs user-friendly instruments, such as the RAC adult infection risk scale that can contribute to the measurement of compliance to safety guidelines and the implementation of targeted improvement actions according to the identified risk of infection (Willemsen & Kluytmans, 2018).

5 | CONCLUSION

The RAC adult infection risk scale showed adequate psychometric performance. This scale is a promising tool to evaluate HAI. Replication of this study in independent samples is needed to further test the generalizability of the results.

Despite the apparent simplicity of the RAC adult infection risk scale, training for the professionals who will measure the risk of HAI is fundamentally important. It is believed that inadequate understanding of the items may result in an inaccurate evaluation, which will cause the risk classification to fail. This will have negative repercussions on the interventions and the outcomes for patients' health, therefore adequate training is recommended.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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