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ORIGINAL INVESTIGATION

Cross-cultural adaptation and validation of the lowa Satisfaction with Anesthesia Scale for use in Brazil: a cross-sectional study*



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KEYWORDS

Ambulatory surgical procedures; Anesthesia; Conscious sedation; Patient satisfaction; Validation study

Abstract

Background: The Iowa Satisfaction with Anesthesia Scale (ISAS) was developed to assess the satisfaction of patients undergoing sedation with monitored anesthesia care. This study aimed to cross-culturally adapt the ISAS instrument and evaluate the acceptability, validity, and reliability of the proposed Brazilian version (ISAS-Br).

Methods: The cross-cultural adaptation process involved translation, synthesis, back-translation, expert committee review, pre-testing, and final review of the ISAS-Br. A cross-sectional study was conducted, involving 127 adult individuals undergoing ambulatory surgeries with moderate/deep sedation. The acceptability, reliability, and construct validity of the scale were assessed.

Results: The cross-cultural adaptation process did not require significant changes to the final version of the scale. The ISAS-Br demonstrated excellent acceptability, with a completion rate of 99% and an average completion time of 4.6 minutes. Exploratory factor analysis revealed three factors: emotional well-being, physical comfort, and anxiety relief, with respective composite reliability coefficient values of 0.874, 0.580, and 0.428. The test-retest reliability of the ISAS-Br, measured by the intraclass correlation coefficient, was 0.67 (95% confidence interval [95% CI] 0.42 to 0.83), and the Bland-Altman plot showed satisfactory agreement between the measurements.

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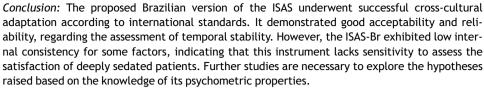
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^{*}The research project for this study was submitted and approved by the Research Ethics Committees of the Federal University of Santa Catarina (CAEE 53334721.2.0000.0121) and the University of South Santa Catarina (CAEE 67752423.0.0000.0261).

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Introduction

Satisfaction of patients with anesthesia and their perception of outcomes is a widely studied measure, becoming an important quality of care indicator. To enhance the quality of care in ambulatory procedures, the American Society of Anesthesiologists created the concept of monitored anesthesia care (MAC) to differentiate sedation performed by a qualified anesthesia provider from that performed by other physicians. In this scenario, comfort, safety, and full recovery are essential to achieve success at all stages of treatment.

In this regard, Dexter et al. ¹¹ developed a reliable and valid tool in American English known as the lowa Satisfaction with Anesthesia Scale (ISAS). This instrument provides a better understanding of sedation outcomes from the patients' perspective and thereby improves their satisfaction with anesthesia. Anesthesia-specific satisfaction questionnaires encompass various dimensions of satisfaction, such as the relationship with the healthcare staff and access to information. ^{5,8,12} However, the ISAS questions specifically refer to the anesthesia experience itself, rather than to the perioperative period like other questionnaires, ^{13,14} making it a useful tool to gather information regarding satisfaction with different drugs and the quality of sedation. ¹¹

The ISAS scale consists of eleven questions that alternately assess negative and positive sensations to avoid acquiescence bias. ¹¹ For each item, responses are given on a six-point Likert scale, and each response generates a score ranging from -3 to +3. The unweighted average of the eleven responses yields the total satisfaction score after reversing the scores of negative questions. Therefore, the higher the score, the greater the patient satisfaction. ¹¹

Since its publication in 1997, the ISAS has been adapted and validated with acceptable psychometric properties by Garcia et al.¹⁵ for Spanish in Colombia and for French in France by Falempin et al.¹⁶ In the literature, it is described as robust and highly acceptable, meeting the criteria of a questionnaire with good psychometric properties.^{17,18} Several studies^{4,19,20} have used this satisfaction scale, including in multicenter studies.^{19,21}

As there is no specific Portuguese instrument in Brazil to assess the quality of sedation, the cross-cultural adaptation of the ISAS is expected to provide a useful tool for measuring satisfaction of Brazilian patients with anesthesia for ambulatory procedures. Furthermore, it may help to identify better anesthetic options in future studies. Therefore, the aim of this study was to perform a cross-cultural adaptation, evaluating the acceptability, validity, and reliability of the Brazilian version of ISAS.

Methods

The methodological approach of this study involved a first stage of cross-cultural adaptation of the ISAS¹¹ from its original English version and a second stage of assessing the psychometric properties of the proposed Brazilian version.

The research project for this study was submitted and approved by the Research Ethics Committees of the Federal University of Santa Catarina (Universidade Federal de Santa Catarina, CAEE 53334721.2.0000.0121) and the University of South Santa Catarina (Universidade do Sul de Santa Catarina, CAEE 67752423.0.0000.0261). All participants signed an informed consent form prior to participating in any of the stages. Permission was obtained from the authors of the original scale to conduct the study.

Cross-cultural adaptation stage

First, the original version of the ISAS was translated into Portuguese by three qualified and independent translators. Two translators without knowledge of the research's theoretical context, one being a Brazilian national fluent in English and the other an American fluent in Brazilian Portuguese. The third translator, a healthcare professional Brazilian native, fluent in English, with theoretical knowledge of the research. Based on the three versions, the researchers synthesized a Portuguese version, considering their common points and reviewing their discrepancies. This synthesized version was sent to two new independent and naïve on the construct translators to perform back-translations. One of them was a native English speaker living in Brazil, and the other was a linguistics specialist. The discrepancies between the translated versions, back-translations and the original were analyzed by a committee of experts, consisting of an anesthesiologist, two epidemiologists, a surgeon, and three medical students. A pre-final version, named ISAS-Br, was developed ensuring clarity, comprehensibility of the questions, as well as semantic, idiomatic, and conceptual equivalence, guaranteeing that the translated version retained the same content as the original version, considering the observations made by one of the authors of the original scale.

The pre-final version of ISAS-Br was used as a pre-test for ten adult Brazilian patients undergoing sedation for ambulatory procedures at the University Hospital of the Federal University of Santa Catarina (Hospital Universitário da Universidade Federal de Santa Catarina, HU-UFSC). The scale was presented preserving its original structure and sequence of the items. The objective was to identify comprehension problems, difficulties in understanding the meaning of each item, scale complexity and to inquire whether the

statements were related to satisfaction with anesthesia. The final version of ISAS-Br was proposed after the committee of experts reviewed the results of the pre-test.

Psychometric properties assessment stage

A cross-sectional epidemiological study was conducted with a minimum sample of 120 individuals, which corresponds to the appropriate proportion based on the scale items. ²² Data collection took place at HU-UFSC and two private clinics, all located in the city of Florianópolis/SC, Brazil, after obtaining authorization from each institution. It was conducted on specific, non-consecutive days at each institution, in accordance with the occurrence of procedures, until an adequate sample size was achieved. All eligible patients scheduled for procedures on these specific days were included.

Patients undergoing sedation (MAC) by an anesthesiologist for any ambulatory procedures were selected. The included patients were Brazilian, literate, and over 18 years of age. Patients undergoing ophthalmic surgery were only included if their postoperative vision was not compromised, allowing them to individually respond to the scale. Individuals diagnosed with any degree of cognitive dysfunction, mental illness, or neurological disease were excluded.

The sedation was conducted at the discretion of the anesthesiologist and the decision to perform local anesthesia was made by the surgeon. The procedure would start once the patient ceased to respond to verbal commands. After the procedure, patients were transferred to the postanesthesia recovery room. Subsequently, at least one hour after their admission to the recovery room, with the patients fully alert and conscious, the attending nurse handed the instructions and ISAS-Br questionnaire to them and stepped away to allow the patients to respond to it comfortably and individually. All professionals involved signed a consent form to acknowledge the research and were not involved with the research. The assistant anesthesiologist only prescribed medication if necessary.

The scale was also completed a second time, through an electronic form, sent on the day following the procedure. This sample corresponded to 20% of the total sample of patients, randomly selected for test-retest analysis purposes. Sociodemographic data were collected through interviews and data regarding preanesthetic consultation, type and time of procedure, and the American Society of Anesthesiologists (ASA) physical status were obtained from the patient's medical records.

Statistical analysis was performed using the Jamovi v.2.3.9 program. Qualitative data were presented as absolute and relative numbers. Quantitative variables were presented as means and standard deviations (SD).

The acceptability of ISAS-Br was assessed by response rates and completion time. Exploratory factor analysis (EFA) is a statistical method rooted in the premise that correlations between variables arise from a shared underlying factor. In the context of patient-reported outcomes, these constructs represent the meaningful dimensions that influence how patients perceive and answer the individual items within a questionnaire. Thus, EFA was used to determine construct validity, evaluating the dimensional structure of the instrument and item adequacy. Initially, two methods were employed to determine if the data could be subjected

to factor analysis: the Kaiser-Meyer-Olkin (KMO) criterion and Bartlett's test of sphericity. For interpreting KMO indices, values greater than 0.5 are considered acceptable. The Bartlett's test of sphericity values with significance levels (p < 0.05) indicate that the matrix is factorable. The parallel analysis method was used to determine the number of factors to be retained, and the maximum likelihood method with varimax rotation for proper factor extraction.

Reliability was assessed through internal consistency and scale stability. Values above 0.6 for the composite reliability coefficient were considered acceptable. Scale stability was determined through test-retest analysis. Values above 0.7 for the intraclass correlation coefficient (ICC) were considered indicative of a strong correlation. However, a high correlation does not necessarily imply that there is good agreement between two methods. So, a Bland-Altman plot was used for a more detailed analysis of the agreement between the test and retest. The adopted level of statistical significance was 5% (p < 0.05).

Results

The cross-cultural adaptation of ISAS followed international protocols, with most items having similar translations. 23,24 The only item that showed discrepancies was item 11 ("I hurt"), which was translated as "Doeu" and "Me machuquei". The committee decided that, to maintain the original emotional meaning, as discussed with the scale author, "Eu sofri" would be more appropriate. The back-translations remained consistent with the original scale, except for this final item, which was appropriately back-translated as "I suffered". Thus, the pre-final version was formed and applied to ten patients as a pre-test. All participants found it easy to respond to, objective, accessible, and understood well the items, and they believed that the items were correlated with the construct of satisfaction with anesthesia. After this process, in the final review, the proposed Brazilian version (ISAS-Br) was approved by the committee without the need for adjustments, as presented in Figure 1.

ISAS-Br was administered to 128 patients to assess its psychometric properties. The sociodemographic and anesthesia-related characteristics are described in Table 1. The participants' ages ranged from 21 to 80 years, with a mean of 47 years (SD = 13.5). The mean procedure duration was 45 minutes (SD = 35.89), ranging from 10 to 170 minutes.

The mean total score of ISAS-Br was 2.59 (SD = 0.54) with a range of -0.27 to 3.0. Table 2 shows the responses for each item. Ceiling and floor effects were observed in all items, with little response variability, with item 7 showing the highest variation and items 8 and 10 showing the lowest. All patients who reported thermal discomfort mentioned feeling cold. Regarding acceptability, 127 out of 128 participants (99%) answered the ISAS-Br completely, with a mean completion time of 4.6 minutes (SD = 2.34).

Regarding construct validity, the Kaiser-Meyer-Olkin measure of 0.63 and the Bartlett's test of sphericity with p < 0.001 indicated that the data matrix could be factorized. EFA was conducted, and it was determined, based on parallel analysis, to retain three factors (see scree plot in Fig. 2). These factors collectively accounted for 39.84% of the total variance. Factor 1, related to emotional well-being,

Cada afirmação da pesquisa descreve uma sensação que você possa ter tido durante sua anestesia.

Para cada item, por favor, marque a resposta que melhor descreve como você se sentiu.

Se você não sentiu o que está descrito na afirmação, marque alguma das respostas de discordância: discordo totalmente, discordo moderadamente ou discordo um pouco.

Se você sentiu o que está descrito na afirmação, marque alguma das respostas de concordância: concordo totalmente, concordo moderadamente ou concordo um pouco.

Não há respostas certas ou erradas.

Marque uma resposta apenas para cada item. Faça isso colocando um X na opção de resposta que melhor dá sua opinião sobre o item.

Ninguém deve ajudá-lo a preencher a pesquisa. Só você deve ler a pesquisa e marcar as respostas que parecem melhor se adequar.

Por favor, não tenha pressa. Queremos que suas respostas sejam precisas.

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☐ Discordo totalmente

☐ Discordo moderadamente

☐ Discordo um pouco

☐ Concordo um pouco

☐ Concordo moderadamente

☐ Concordo totalmente

(mesmas opções de respostas da afirmação 1 nas afirmativas de 2 a 11)

- 2. Gostaria de receber a mesma anestesia novamente.
- 3. Senti coceira.
- 4. Eu me senti relaxado(a).
- 5. Senti dor.
- 6. Eu me senti seguro(a).
- 7. Senti muito frio ou muito calor.
- 8. Fiquei satisfeito(a) com meus cuidados anestésicos.
- 9. Senti dor durante a cirurgia.
- 10. Eu me senti bem.
- 11. Eu sofri.

The Iowa Satisfaction with Anesthesia Scale is copyrighted (Franklin Dexter and the University of Iowa Research Foundation).

Figure 1 Final version of ISAS-Br.

contributed 19.65%, factor 2, associated with physical comfort, contributed 12.90%, and the final factor, addressing anxiety/fear relief, contributed 7.29%. The factor loadings of the items on each factor are described in Table 3.

Regarding scale reliability, the values of composite reliability indicators were 0.874, 0.580, and 0.428 for factors 1, 2, and 3 respectively, calculated considering the factor loadings of each item. In Figure 3, the temporal stability of the ISAS-Br, with 25 participants, is assessed through two plots, illustrating the ICC (Fig. 3A) and Bland-Altman (Fig. 3B) analysis. ICC value

was 0.67 (95% CI 0.42 to 0.83), indicating a moderate to substantial correlation with statistical significance between test scores and retest scores. Bland-Altman plot analysis demonstrated satisfactory agreement between measurements.

Discussion

The American ISAS¹¹ scale has already been validated in Spanish¹⁵ and French,¹⁶ demonstrating adequate psychometric

Table 1 Description of the cross-cultural adaptation study sample of the ISAS-Br (n = 127).

Age	Characteristics	n	(%)
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^a Over four years of study.

properties for assessing anesthesia satisfaction. Being the only scale designed for MAC and aimed at providing accurate information about satisfaction with anesthetics, the present study sought to perform its cross-cultural adaptation, thus proposing the ISAS-Br. It followed all the steps determined by internationally accepted methodology, ^{23,24} resulting in a version that maintained the original meaning of the scale, even resembling the translations in languages of the same Latin origin, such as French and Spanish. ^{15,16}

The psychometric properties of the ISAS-Br were analyzed in a sample of 127 patients, which represents an adequate sample size according to the literature. The demographic characteristics were similar to those of the original American, French, and Spanish versions. In 1,15,16 However, it is noteworthy that 21% of the participants in the ISAS-Br study did not complete elementary education. This implies a low education level, potentially affecting scale interpretation, as patients responded unassisted. Conversely, the healthcare professionals involved, including the anesthetist, surgeon, and nurse responsible for questionnaire distribution, were not part of the research. They were aware that the questionnaire focused on medication evaluation rather than their own work, minimizing potential bias.

The average time to complete the scale was around five minutes, like the original and Spanish versions and slightly longer than the French version. ^{11,15,16} This demonstrated good acceptability, in addition to a 99% response rate.

The average score found was 2.59 (SD = 0.54), higher and with a lower SD than those found by Dexter et al. 11 (2.1, SD = 0.87), Falempin et al. ¹⁶ (2.2, SD = 0.7), Garcia et al. ¹⁵ (2.27, SD = 0.83), and Candiotti et al. (2.0, SD = 0.97). This finding can be explained by the low incidence of negative sensations related to anesthesia, particularly intraoperative pain, which increases discrimination in satisfaction among patients. Additionally, a floor-ceiling effect²⁵ was observed in all items, especially regarding items 8 and 10, which are related to satisfaction and well-being. This response pattern was also evidenced in Falempin et al's study. 16 However, the French version obtained greater response variability compared to the ISAS-Br. This can be explained by the anesthetic depth, as in the present sample the patients expected (sought) deep sedation for their surgery, having been unconscious for parts of the anesthetic, reducing discrimination with the ISAS-Br. Hence, an alternative hypothesis emerges about cultural influence. Many patients in this study strongly agreed with the positive scale items, even while also reporting adverse events. They might have associated negative sensations, particularly pain, with the surgical procedure rather than anesthesia.

The EFA of the Brazilian version revealed three factors explaining satisfaction with moderate/deep sedation. The first factor, linked to emotional support, had "feeling good" with the highest factor loading. "Feeling pain" was the item that made the greatest contribution to the second factor, which was associated with physical comfort. Itchiness and thermal discomfort had minimal factor loadings. This suggests that pain, hurt, and even nausea/vomiting, although associated with physical sensations, are influenced by emotional factors, and may impact satisfaction more than itchiness and feeling cold. Despite their very low contributions to overall satisfaction, items 3 and 7, which are related to potential drug side effects, provide important information

Table 2 Proportion of responses for each item of the ISAS-Br (n = 127).

	Agree very much n (%)	Agree moderately n (%)	Agree slightly n (%)	Disagree slightly n (%)	Disagree moderately n (%)	Disagree very much n (%)	Means subscore
Ithrew up or felt like throwing*	4 (3.1)	0 (0)	1 (0.8)	1 (0.8)	2 (1.6)	119 (93.7)	2.83
3. I itched*	6 (4.7)	0 (0)	6 (4.7)	2 (1.6)	-	113 (89.0)	2.50
5. I felt pain*	4 (3.1)	4 (3.1)	7 (5.5)	1 (0.8)	3 (2.4)	108 (85.1)	2.39
7. I was too cold or hot*	13 (10.2)	8 (6.3)	17 (13.4)	1 (0.8)	4 (3.1)	84 (66.2)	1.49
9. I felt pain during surgery*	5 (3.9)	_	6 (4.7)	_	1 (0.8)	115 (90.6)	2.57
11. l hurt*	4 (3.1)	-	1 (0.8)	1 (0.8)	2 (1.6)	119 (93.7)	2.75

	Disagree very much n (%)	Disagree moderately n (%)	Disagree slightly n (%)	Agree slightly n (%)	Agree moderately n (%)	Agree very much n (%)	Means subscore
I would want to have the same anesthetic again	4 (3.1)	-	3 (2.4)	5 (3.9)	3 (2.4)	112 (88.2)	2.61
4. I felt relaxed	2 (1.6)	2 (1.6)	3 (2.4)	1 (0.8)	3 (2.4)	116 (91.2)	2.69
6. I felt safe	1 (0.8)	_	_	3 (2.4)	5 (3.9)	118 (92.9)	2.87
8. I was satisfied with my anes- thetic care	2 (1.6)	-	1 (0.8)	-	1 (0.8)	123 (96.8)	2.87
10. I felt good	1 (0.8)	-	_	1 (0.8)	3 (2.4)	122 (96.0)	2.75

N.M. Moritz, J.E. Moritz, G.O. Parma et al.

Items 1, 3, 5, 7, 9, 11 are negative/dissatisfaction (order of responses presented in reverse). The Iowa Satisfaction with Anesthesia Scale is copyrighted (Franklin Dexter and the University of Iowa Research Foundation).

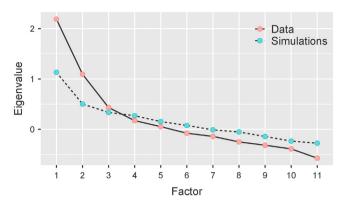


Figure 2 The scree plot displays the eigenvalues generated by the parallel analysis method in the exploratory factor analysis. This method, considered more accurate than others, compared the eigenvalues from the pilot sample (data) with those generated from a random sample of the same size (simulations). The goal is to identify the point at which the observed eigenvalues significantly deviate from the mean eigenvalues of random data. Only eigenvalues greater than those generated in the random sample were retained, indicating the extraction of three factors.

that should be considered, as the instrument is associated with satisfaction with anesthetics. The third factor, possibly linked to anxiety/fear relief, explains questions 2 and 4 about receiving the same anesthesia again and feeling relaxed.

Although the Cronbach's alpha coefficient is widely used for assessing internal consistency, the composite reliability has been presented as a more robust indicator of precision than alpha. This is because, in the computation of composite reliability, the factorial weights of the items can vary, whereas in the alpha coefficient the item loadings are fixed to be equal. ²⁶ Therefore, this indicator was chosen to assess the internal consistency of each factor in this scale due to

variations in item contributions to the satisfaction with anesthesia construct. The emotional well-being factor had high internal consistency, while physical comfort factors and anxiety/fear relief had lower internal consistency.

The results of the test-retest, which yielded an ICC value of 0.67, along with the interpretation of the Bland-Altman plot, demonstrated statistical significance and good stability of the scale. These findings are consistent with the ICC results reported by Dexter et al. 11 (0.74), Falempin et al. 16 (0.74), and Garcia et al. 15 (0.71). In a Canadian study, Fung et al. 20 found a lower ICC (0.57) in a sample of patients undergoing ophthalmic procedures. Considering that the administration time of the scale influences patient recall, 27 the ISAS-Br was administered within the recommended timeframe and repeated (retest) on the day following the procedure.

Although the ISAS aims to assess anesthetic agents, it is complex due to multidimensional satisfaction, making it challenging for patients to distinguish medication effects from anesthesiology care. Furthermore, according to Capuzzo et al. and Fung and Cohen, emotional aspects impact anesthesia satisfaction more than negative sensations. The ISAS strongly depends on pain and there is a paradoxical relationship between pain and patient satisfaction, the findings in this study and the difficulty in transforming satisfaction into something objective are understandable. Nonetheless, the ISAS is an interesting tool, more for its ability to identify potential factors of dissatisfaction and its sensitivity to intervention than for its structure.

Another important aspect to highlight is that due to procedure-related anxiety, some patients request a deeper level of sedation, which can positively influence their level of satisfaction. In this study, the procedure would start after the patient stopped responding to verbal commands, indicating moderate to deep sedation.³⁰ However, the deeper the level of sedation and the higher the doses of sedatives, the lower the ability to distinguish sensations related to drugs during the procedure, affecting the face validity of the ISAS since this instrument measures satisfaction with anesthetics.

Table 3 Factor loadings from the exploratory factor analysis of ISAS-Br after extraction using the maximum likelihood method with varimax rotation and composite reliability indices for each factor.

		Factor				
	1 Emotional well-being factors	2 Physical comfort	3 Anxiety/ Fear relief	Singularity		
Item 10	0.95			0.09		
Item 6	0.83			0.31		
Item 8	0.74			0.29		
Item 5		0.75		0.43		
Item 9		0.69		0.47		
Item 11		0.45		0.80		
Item 1		0.33		0.87		
Item 3		0.16		0.97		
Item 7		0.14		0.97		
Item 4			0.61	0.61		
Item 2			0.43	0.81		
Composite reliability	0.874	0.580	0.428			

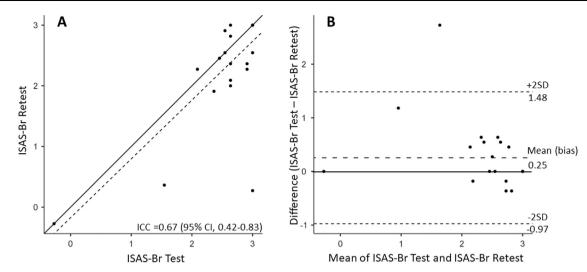


Figure 3 These two plots illustrate the temporal stability of ISAS-Br (n = 25). (3A) ICC is shown in a scatter plot with retest and test scores. Most data points are close to the identity line, randomly scattered around it. This suggests that the test and retest measurements have good correlation. (3B) Bland-Altman plot displaying the relationship between the test vs retest bias (y axis: difference between values from test and retest for each individual) and the theoretical real value (x axis: mean value from test and retest for each individual). The points clustered around the bias line (mean difference = 0.25, p = 0.054), within the limits of agreement (-0.97 to 1.48), indicate that the test and retest measurements have good agreement and consistency. Both plots show that there is no significant systematic bias between them since there is low vertical dispersion and no apparent patterns.

Among the limitations of this study is the non-continuous sampling, which could introduce selection bias. Positively, this sample included different populations, from two private clinics and one public university hospital, increasing its heterogeneity. The high mean score of the ISAS-Br together with the limited response variability also represents a limitation for some statistical tests, particularly those related to variance. These limitations require caution in the analysis of the presented results, and further studies in different populations are recommended to confirm the hypotheses raised in the discussion regarding different sedatives, anesthetic depth, and cultural aspects.

In conclusion, this study successfully adapted the ISAS for the Brazilian context to measure satisfaction with anesthesia from the patient's perspective. The ISAS-Br demonstrated high acceptability and good temporal stability. However, it exhibited limited internal consistency for certain factors, indicating that this instrument lacks sensitivity to assess the satisfaction of deeply sedated patients. Understanding its psychometric properties encourages further research to explore its full potential as an instrument. Likewise, its availability enables researchers to expand their knowledge of patient perceptions with different anesthetic medications and their combinations.

Conflicts of interest

The Iowa Satisfaction with Anesthesia Scale is copyright Franklin Dexter and the University of Iowa Research Foundation. Dr. Dexter receives no funds personally other than his salary and allowable expense reimbursements from the University of Iowa and has tenure with no incentive program. He and his family have no financial holdings in any company related to his work, other than indirectly through mutual

funds for retirement. Income from the Division of Management Consulting work including use of the Iowa Satisfaction with Anesthesia Scale is used to fund Division research. A list of all the Division's consults is available in Dr. Dexter's posted curriculum vitae at https://FranklinDexter.net/Contact_Info.htm.

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