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Cross-cultural Adaptation of the Oral Anticoagulation Knowledge Test to the Brazilian Portuguese

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Abstract *Patients' knowledge about oral anticoagulant therapy may favor the achievement of therapeutic results and the prevention of adverse pharmacotherapy-related events. Brazil lacks validated instruments for assessing the patient's knowledge about treatment with warfarin. This study aimed to perform the cross-cultural adaptation of the Oral Anticoagulation Knowledge (OAK) Test instrument from English into Portuguese. This is a methodological study developed in an anticoagulation clinic of a public university hospital. The study included initial translation, synthesis of translations, back-translation, review by the experts committee and pre-testing with 30 individuals. We obtained semantic equivalence through the analysis of the referential and general meaning of each item. The conceptual equivalence of the items sought to demonstrate the relevance and acceptability of the instrument. The process of cross-cultural adaptation produced the final version of the OAK Test in Brazilian Portuguese entitled "Teste de Conhecimento sobre Anticoagulação Oral". There was a suitable semantic and conceptual equivalence between the adapted version and the original version, as well as an excellent acceptability of this instrument.*

Key words *Patient medication knowledge, Questionnaires, Warfarin*

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Introduction

Warfarin is an oral anticoagulant widely used in Brazil and around the world to prevent and treat thromboembolic diseases. The management of this treatment is quite complex due to its narrow therapeutic range and wide dose-response variability, which increases bleeding risk[1,2].

Several studies have indicated that patients with better knowledge about warfarin therapy have better stability of laboratory parameters, such as the International Normalized Ratio (INR)[2,3]. People who use this drug must have adequate knowledge about the therapeutic goal (indication and effectiveness), the use process (dosage, therapeutic regimen, administration method and treatment duration), safety (precautions, contraindications, adverse effects and interactions) and its preservation[4].

The implantation of anticoagulation clinics (AC) is relevant in the healthcare systems, considering the morbidity and mortality observed in individual users of this drug[1]. Access to ACs creates better conditions for individualized care and educational process of the patient. The oral anticoagulation quality is strongly associated with the individual's level of knowledge about own pharmacotherapy[5]. However, there are significant gaps in knowledge about oral anticoagulation in patients treated with warfarin[6].

Previous studies have shown that more than half of the patients have a knowledge deficit about treatment with warfarin[7-9]. Actions aimed at improving knowledge about anticoagulant therapy can significantly increase adherence to treatment and control of the INR[10]. However, these studies have substantial methodological limitations regarding the lack of use of a reliable instrument specifically validated to assess the patients' knowledge about anticoagulant therapy[11].

The Oral Anticoagulation Knowledge (OAK) Test[3] was a validated instrument for English language and translated for use in Saudi Arabia[12], Malaysia[13] and Qatar[14]. Studies demonstrated that the OAK Test is valid and reliable to measure the knowledge of users of warfarin in different cultures, which justifies the proposal to adapt this instrument to the Brazilian culture. Cross-cultural adaptation of instruments is of fundamental importance for epidemiological practice and is essential for generating reliable and comparable data, maintaining the semantic and conceptual equivalence between the original version and the adapted version[15,16].

In a study conducted in the Medline, Embase, Central, Scopus, Lilacs and SciELO databases covering the 1994-2015 period, using the descriptors "questionnaires", "patient medication knowledge" and "warfarin", no instrument for evaluating the level of knowledge about oral anticoagulation with warfarin and that has been correctly adapted for use in Brazil and evaluated for its psychometric properties has been identified.

Therefore, this study aimed to perform the cross-cultural adaptation of the OAK Test instrument into Brazilian Portuguese, evaluating the semantic and conceptual equivalence of the items between the original instrument in English and the Portuguese adapted version.

Methods

Study design and target population

This is a methodological study based on the organization and analysis of data, designed for the evaluation and validation of research instruments and techniques[17]. Research was developed in an AC of a university hospital located in southeastern Brazil, which plays a regional reference role in medium and high complexity care within the Unified Public Health System. The target population included subjects with cardiovascular disease and indication for indefinite warfarin use. Inclusion criteria were 18 years of age or older, Brazilian nationality and duration of treatment with warfarin of over two months. Pretest participants were recruited and interviewed consecutively on AC service days. The cross-cultural adaptation was performed from October to December 2014.

Instrument

The OAK Test was developed in the Northeastern United States[3] and used consistent methods to assess its validity and reliability. It consists of 20 questions with four answer alternatives, with only one correct choice. Each patient's correct answer equals one point, and the final score ranges from zero to 20 points. A higher score indicates a better level of knowledge about oral anticoagulant therapy.

Evaluation of the semantic and conceptual equivalence of the items

After authorization from authors of the original version, the cross-cultural adaptation of the

OAK Test instrument into Brazilian Portuguese was planned according to the method recommended by national and international literature for instrument adaptation[15,18-20]. The semantic evaluation was developed as follows: initial translation, synthesis of translations, back-translation, review by the experts committee and pre-testing[16] (Figure 1).

The first stage consisted of two translations of the original instrument in English into Brazilian Portuguese (T1 and T2). Two bilingual translators whose mother tongue was Brazilian Portuguese performed the translations independently. A translator had training in the area of health, clinical experience and knowledge about the terms and concepts of the instrument. The other translator had no medical or clinical training and no technical knowledge about the analyzed concepts.

T1 and T2 translations were compared and discrepancies identified. The two translators and four other researchers participated in the synthesis of translations. The group used the original instrument and the two versions translated into Brazilian Portuguese and, after consensus, produced a common translation (T12). At this stage, we tried to identify possible difficulties in understanding the instrument. The meaning of words in the different languages (English and Brazilian Portuguese) was thoroughly analyzed with a view to obtain similar effects in individuals of different cultures.

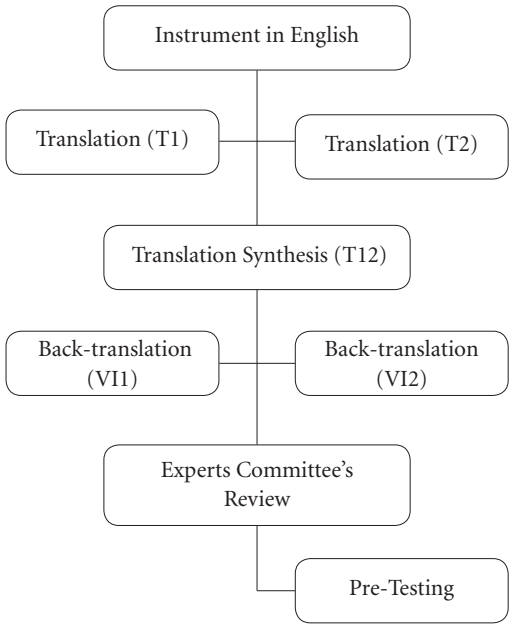

Figure 1. Flowchart of the cross-cultural adaptation process of the instrument Oral Anticoagulation Knowledge (OAK) Test.

The T12 synthesized translation was back-translated into the original language of the instrument (English) by two independent translators, foreigners, born and literate in an English-speaking country, with linguistic and cultural mastering of both English and Brazilian Portuguese. The OAK Test was then adapted. Translators were not aware of research's objectives and did not have access to the original instrument.

Subsequently, a review of the back-translated versions (VI1 and VI2) and the synthesis Portuguese version (T12), using as reference the original version by a committee of experts composed of four researchers, the four participating translators, two health professionals with experience in the management of oral anticoagulation and a linguist. The establishment of this committee was fundamental to obtain a consensus regarding the semantic and conceptual equivalence of the items.

Semantic equivalence refers to the meaning equivalence of words, or to the correct translation of items. The equivalence between the original instrument and the back-translated instrument was evaluated from the perspective of the referential meaning of the terms and constituent words (similarity as to the literal meaning of the constituent terms of the assertive pairs) and the general meaning of each item (similarity as to the idea conveyed by assertions)[21].

To analyze the meanings, experts used a specific form, designed to mask the origin of the evaluated items. For the analysis of the referential meaning, a visual analog scale[22] was chosen. The equivalence between assertive pairs was evaluated continuously, with results varying from zero to 100%, using the following categories: < 80% = non-equivalent, 80-89% = almost equivalent, 100% = maximum equivalence[22].

The evaluation of the general meaning was developed using four levels for classification, namely: unaltered (UA), slightly altered (SA), highly altered (HA) or completely altered (CA)[22].

The analysis of the conceptual equivalence of the items seeks to demonstrate whether they are relevant and acceptable in the original and adaptation-targeted cultures. Therefore, the opinion of experts and the preliminary test of the adapt-

ed version in population samples, as described in the next step, become of great value[21].

Pre-testing was developed by one of the researchers who individually interviewed 30 patients in a suitable place, checking their understanding regarding the adapted version[16]. A questionnaire adapted for use in Brazil[23] was used, which addresses the general impression about the tool in terms of clarity, completion time and possible issues. Sociodemographic data were collected, including sex, age and schooling to characterize the participants.

Statistical analysis

The database was validated by double entry in the EpiData software program (version 3.1, EpiData Assoc, Denmark) and analyzed in the Statistical Package for Social Science program (SPSS for Windows, version 20.0, SPSS Inc., Chicago, Illinois, USA). We performed descriptive statistics of sociodemographic variables using frequency and central tendency measures.

Ethical aspects

This study was conducted in accordance with the Declaration of Helsinki[24]. The Research Ethics Committee of the Universidade Federal de Minas Gerais approved the research project. All participants signed an informed consent form prior to the onset of the research.

Results

The process of cross-cultural adaptation was systematically performed. The stages of translation, synthesis and back-translation were performed without major difficulties and, therefore, there were no significant modifications.

The semantic equivalence was evaluated by the review of the committee of experts, in which the equivalence between items from the back-translated versions and those of the original instrument was evaluated, which evidenced that instruments remained equivalent. As described in Chart 1, 17 (85%) of the 20 items showed maximum equivalence and general significance remained unaltered (UA).

The conceptual equivalence of the items was obtained by the analysis of experts and by the pre-testing. Chart 2 shows the main changes, highlighted in bold, made by the experts committee in the synthesis version translated into Portuguese (T12) and the pre-final version obtained by consensus.

In question 1, in order to keep the original meaning, we chose to use the expression in the sentence "forget about" and in the fourth alternative of response, instead of the verb "to observe", we opted for "be careful with". The word "Coumadin®", which corresponds to one of the trade names of warfarin, was also removed from the translated instrument, and the Brazilian Common Denomination was used[25].

In question 3, the discussion took place around the English term "healthcare provider". In the synthesis version translated into Portuguese, the term "health service" was first used, but because it was a broad term, it was replaced with the expression "which monitors your treatment". We made this change in the other questions containing this term.

Concerning question 7, the term "PT/INR (prothrombin time)" was discussed. It was taken into account that most of the target population only knows the abbreviation INR to designate the laboratory examination for monitoring oral anticoagulation. The term PT (prothrombin time) was then suppressed in this question and wherever it appeared.

Regarding question 9, two expressions identified that evidenced comprehension difficulties by the target population were altered. "Expected range" was replaced by "desired range" and "rash" by "skin reactions".

In question 10, to facilitate the respondent's understanding, the acronym "AAS" was added in the statement because of its common use to designate the acetylsalicylic acid drug. In the last response option, the phrase "you increase your dose" was modified to "increase of your dose of warfarin", avoiding the interpretation of dose self-management by patients, which is not provided for in the clinical protocol of the AC at hand.

According to the experts' analysis, in question 13, the expression "you take your dose of warfarin and alcohol separately" in the synthesis version translated into Portuguese is ambiguous, in which the respondent could interpret it as "simultaneous intake of alcoholic beverages and warfarin tablet". Thus, we opted for the modification of the expression to "you take your dose of warfarin and alcohol at different times".

The terms "effectiveness", "interaction" and "adverse effects", which appear throughout the questionnaire were identified by the experts committee as difficult to understand for the tar-

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Chart 1. Semantic equivalence between the OAK Test version in Brazilian Portuguese and the original in English.

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
1. Missing one dose of Coumadin (warfarin): a) Has no effect b) Can alter the drug's effectiveness c) Is permissible as long as you take a double dose the next time d) Is permissible as long as you watch which foods you eat	1. Não tomar uma dose da varfarina: a) Não tem efeito b) Pode alterar a efetividade do medicamento c) É permitido desde que você tome a próxima dose em dobro d) É permitido, desde que você observe os alimentos que você come	1. Not to take a dose of warfarin: a) Has no effect. b) Can alter the effectiveness of the drug. c) Is allowed as long as you take the next dose in double d) Is allowed, provided you observe the foods you eat	1. Not taking a dose of warfarin: a) Has no effect b) Can alter the effectiveness of the medication c) Is allowed, as long as take the next dose in double d) Is allowed, as long as you watch the food you eat	95%	PA
2. You can distinguish between different strengths of Coumadin (warfarin) tablets by what? a) Color b) Shape c) Size d) Weight	2. Você consegue diferenciar as diferentes doses do comprimido da varfarina utilizando-se da? a) Cor b) Formato c) Tamanho d) Peso	2. You can differentiate the different doses of the warfarin pills by use of? a) Color b) Format c) Size d) Weight	2. You can tell the difference between the different doses of warfarin pills by using the? a) Color b) Shape c) Size d) Weight	100%	IA
3. A patient on Coumadin (warfarin) therapy should contact the physician or healthcare provider who monitors it when: a) Another physician adds a new medication b) Another physician stops a current medication c) Another physician changes a dose of a current medication d) All of the above	3. O paciente que toma varfarina deve entrar em contato com o médico ou o serviço de saúde quando: a) Outro médico acrescenta um novo medicamento b) Outro médico interrompe algum medicamento que estava sendo usado c) Outro médico troca a dose de algum medicamento que já estava sendo usado d) Todas as questões acima	3. Patients taking warfarin should contact your doctor or health service when: a) Another doctor adds a new drug b) Another doctor interrupts a drug that was being used c) Another doctor changes the dose of any medicine that was already being used d) All of the above issues	3. The patient taking warfarin must contact his/her doctor or health service when: a) Another doctor adds a new medication b) Another doctor interrupts a medication that was being taken c) Another doctor changes the dose of a medication that was already being taken. d) All of the above	95%	PA
4. Occasionally eating a large amount of leafy greens vegetables while taking Coumadin (warfarin) can: a) Increase your risk of bleeding from Coumadin (warfarin) b) Reduce the effectiveness of the Coumadin (warfarin) c) Cause upset stomach and vomiting d) Reduce your risk of having a blood clot	4. Ocasionalmente comer grandes quantidades de folhas verdes enquanto toma varfarina pode: a) Aumentar seu risco de sangramento devido ao uso da varfarina b) Reduzir a efetividade da varfarina c) Causar irritação no estômago e vômito d) Reduzir seu risco de ter um coágulo sanguíneo	4. Occasionally eating large amounts of leafy green vegetables while taking warfarin can: a) Increase your risk of bleeding due to warfarin use b) Reduce the effectiveness of warfarin c) Cause stomach irritation and vomiting d) Reduce the risk of having a blood clot	4. Occasionally eating large quantities of green leafy vegetables while taking warfarin can: a) Increase your bleeding risk due to the use of warfarin b) Reduce the effectiveness of warfarin c) Cause stomach irritation and vomiting. d) Reduce your risk of blood clots	100%	IA

it continues

get population. However, keeping them was considered an appropriate procedure and, if there were any issues by the respondent, the interviewer would clarify them until they are fully understood and the question is answered in a convincing manner.

Chart 1. continuation

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
5. Which of the following vitamins interacts with Coumadin (warfarin)? a) Vitamin B 12 b) Vitamin A c) Vitamin B 6 d) Vitamin K	5. Quais das vitaminas abaixo interagem com a varfarina? a) Vitamina B 12 b) Vitamina A c) Vitamina B 6 d) Vitamina K	5. Which of the following vitamins interact with warfarin? a) Vitamin B 12 b) Vitamin A c) Vitamin B 6 d) Vitamin K	5. Which of the vitamins below Interact with warfarin? a) Vitamin B 12 b) Vitamin A c) Vitamin B 6 d) Vitamin K	100%	IA
6. When is it safe to take a medication that interacts with Coumadin (warfarin)? a) If you take the Coumadin (warfarin) in the morning and the interacting medication at Night. b) If your healthcare provide is aware of the interaction and checks your PT/INR ("Protime") regularly c) If you take your Coumadin (warfarin) every other day d) It is never safe to take a medication that interacts with Coumadin (warfarin)	6. Quando é seguro tomar um medicamento que interage com a varfarina? a) Se você toma a varfarina pela manhã e o medicamento que interage à noite b) Se o serviço de saúde está ciente dessa interação e checa seu TP/RNI (Tempo de Protrombina) regularmente c) Se você toma a varfarina em dias alternados d) Nunca é seguro utilizar um medicamento que interage com a varfarina	6. When is it safe to take a medication that interacts with warfarin? a) If you take warfarin in the morning and the medicine that interacts with it at night b) If the health service is aware of this interaction and check your PT / INR (Prothrombin Time) regularly c) If you take warfarin on alternate days d) Is never safe to use a medicament which interacts with warfarin	6. When is it safe to take a medication that interacts with warfarin? a) If you take warfarin in the morning and the interacting medication at night b) If the health service is aware of this interaction and checks your PT/INR (Prothrombin Time) regularly. c) If you take warfarin every other day d) It is never safe to use a medication that interacts with warfarin	100%	IA
7. The PT/INR ("Protime") test is: a) A blood test used to monitor your Coumadin (warfarin) therapy b) A blood test that is rarely done while on Coumadin (warfarin) c) A blood test that checks the amount of vitamin K in your diet d) A blood test that can determine if you need to be on Coumadin (warfarin)	7. O exame de TP/RNI (Tempo de Protrombina) é: a) Um exame de sangue usado para monitorar seu tratamento com a varfarina b) Um exame de sangue que é raramente feito durante o uso da varfarina c) Um exame de sangue que verifica a quantidade de vitamina K na sua dieta d) Um exame de sangue que determina se você precisa tomar a varfarina	7. An examination of PT / INR (Prothrombin Time) is: a) A blood test used to monitor your treatment with warfarin b) A blood test that is rarely done during warfarin c) A blood test that checks the amount of vitamin K in your diet. d) A blood test that determines whether you need to take warfarin	7. The PT/INR (Prothrombin Time) is: a) A blood exam used to monitor your treatment with warfarin b) A blood exam that is rarely done while using warfarin c) A blood exam that verifies the quantity of vitamin K in your diet d) A blood exam that determines if you need to take warfarin	100%	IA
8. Coumadin (warfarin) may be used to: a) Treat people that already have a blood clot b) Treat people that have high blood sugar levels c) Treat people with high blood pressure d) Treat people with severe wounds	8. A varfarina pode ser usada para: a) Tratar pessoas que já tem um coágulo sanguíneo b) Tratar pessoas que tem aumento de açúcar no sangue c) Tratar pessoas com hipertensão arterial d) Tratar pessoas com ferimentos graves	8. Warfarin can be used for: a) Treating people who already have a blood clot b) Treating people who have higher blood sugar c) Treating people with hypertension d) Treating people with serious injuries	8. Warfarin can be used to: a) Treat people that already have a blood clot b) Treat people that have an increase in blood sugar c) Treat people with high blood pressure. d) Treat people with severe injuries	100%	IA

it continues

Chart 1. continuation

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
9. A patient with a PT/INR ("Protime") value below their "goal range": a) Is at an increase the risk of bleeding b) Is at an increase the risk of having a clot c) Is more likely to have a skin rash from the Coumadin (warfarin) d) Is more likely to experience side effects from Coumadin (warfarin)	9. Pacientes com o TP/RNI (Tempo de Protrombina) abaixo da "faixa esperada": a) Tem risco aumentado de sangramento b) Tem risco aumentado de formar novo coágulo c) Tem maior probabilidade de ter erupções cutâneas devido ao uso da varfarina d) Tem maior probabilidade de apresentar efeitos adversos devido ao uso da varfarina	9. Patients with PT / INR (Prothrombin Time) below the "expected range": a) Have an increased risk of bleeding b) Have an increased risk of forming new blood clots c) Are you more likely to get rashes due to warfarin use. d) Are you more likely to have adverse effects due to the use of warfarin	9. Patients with PT/INR (Prothrombin Time) below the "expected level": a) Have an increased risk of bleeding b) Have an increased risk of forming a blood clot c) Have a higher probability of having skin rashes due to warfarin use d) Have a higher probability of presenting adverse effects due to warfarin use	100%	IA
10. Taking a medication containing aspirin or other non-steroidal anti-inflammatory medications such as ibuprofen (Motrin® / Advil®) while on Coumadin (warfarin) will: a) Reduce the effectiveness of the Coumadin (warfarin) b) Increase your risk of bleeding from the Coumadin (warfarin) c) Cause a blood clot to form d) Require you to increase your dose of Coumadin (warfarin)	10. Tomar um medicamento que contenha ácido acetilsalicílico ou outros anti-inflamatórios não esteroides, como ibuprofeno enquanto estiver tomando a varfarina irá: a) Reduzir a efetividade da varfarina b) Aumentar seu risco de sangramento devido ao uso da varfarina c) Causar a formação de coágulo sanguíneo d) Exigir que você aumente sua dose da varfarina	10. Taking a medicine containing acetylsalicylic acid (aspirin) or other anti-inflammatory drugs, like ibuprofen while taking warfarin will: a) Reduce the effectiveness of warfarin b) Increase the risk of bleeding due to warfarin c) Cause the formation of a blood clot d) Require you to increase your dose of warfarin	10. Taking a medication that contains acetylsalicylic acid or other non-steroid anti-inflammatory drugs, like ibuprofen, while taking warfarin will: a) Reduce the effectiveness of warfarin b) Increase their bleeding risk due to warfarin use c) Cause the formation of blood clots d) Force you to increase your dose of warfarin	100%	IA
11. A person on Coumadin (warfarin) should seek immediate medical attention: a) If they skip more than two doses of Coumadin (warfarin) in a row b) If they notice blood in their stool when going to the bathroom c) If they experience a minor nosebleed d) If they develop bruises on their arms or legs	11. Uma pessoa que usa a varfarina deve procurar atendimento médico imediatamente: a) Se ela deixar de tomar a varfarina por duas vezes seguidas b) Se ela observar sangue nas suas fezes quando vai ao banheiro. c) Se ela tiver um pequeno sangramento nasal d) Se ela apresentar hematomas nos braços e pernas	11. A person who uses warfarin should seek medical attention immediately: a) If they stop taking warfarin for two times in a row b) If they notice blood in their stool when going to the bathroom. c) If they have a small nose bleed d) If they have bruises on arms and legs	11. A person who takes warfarin must seek medical attention immediately: a) If he/she stops taking warfarin two times in a row b) If he/she observes blood in his/her feces when going to the bathroom c) If he/she has a small nose bleed d) If he/she presents bruises on the arms and legs	100%	IA

it continues

Chart 1. continuation

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
12. Skipping even one dose of your Coumadin (warfarin) can: a) Cause your PT/INR ("Protime") to be above the "goal range" b) Increase your risk of bleeding c) Cause your PT/ INR ("Protime") to be below the "goal range" d) Decrease your risk of having a clot	12. Deixar de tomar uma única dose da varfarina pode: a) Fazer com que seu TP/ RNI (Tempo de Protrombina) fique acima da "faixa esperada" b) Aumentar seu risco de sangramento c) Fazer com que seu TP/ RNI (Tempo de Protrombina) fique abaixo da "faixa esperada" d) Diminuir seu risco de ter um coágulo	12. Failure to take a single dose of warfarin can: a) Make your PT / INR (Prothrombin Time) go above the "expected range" b) Increase the risk of bleeding c) Make your PT / INR (Prothrombin Time) go below the "expected range" d) Reduce the risk of having a blood clot	12. Stopping taking a single dose of warfarin can: a) Make your PT/INR (Prothrombin Time) rise above the "expected level" b) Increase your bleeding risk c) Make your PT/INR (Prothrombin Time) fall below the "expected level" d) Diminish your risk of having a blood clot	95%	PA
13. Drinking alcohol while taking Coumadin (warfarin): a) Is safe as long as you separate your dose of Coumadin (warfarin) and the alcohol consumption b) May affect your PT/ INR ("Protime") c) Does not affect your PT/INR ("Protime") d) Is safe as long as you are on a low dose	13. Ingerir bebidas alcoólicas enquanto estiver tomando a varfarina: a) É seguro, desde que você tome sua dose da varfarina e do álcool separadamente b) Poderia afetar seu TP/ RNI (Tempo de Protrombina) c) Não afeta seu TP/ RNI (Tempo de Protrombina) d) É seguro desde que esteja usando baixas doses da varfarina	13. Drinking alcoholic beverages while taking warfarin: a) Is safe, provided you take your dose of warfarin and alcohol separately b) Can affect your PT / INR (Prothrombin Time) c) Does not affect your PT / INR (Prothrombin Time) d) Is safe provided you are using low doses of warfarin	13. Drinking alcoholic beverages when taking warfarin: a) Is safe, as long as you take your doses of warfarin and alcohol separately b) Can affect your PT/INR (Prothrombin Time) c) Does not affect your PT/ INR (Prothrombin Time) d) Is safe as long as you are taking low doses of warfarin	100%	IA
14. Once you have been stabilized on the correct dose of Coumadin (warfarin), about how often should your PT/ INR("Protime") value be tested? a) Once a week b) Once a month c) Once every other month d) Once every 3 months	14. Uma vez que você tenha estabilizado sua dose correta da varfarina, com que frequência o valor do seu TP/ RNI (Tempo de Protrombina) deve ser testado? a) Uma vez por semana b) Uma vez por mês c) Em meses alternados d) Uma vez a cada 3 meses	14. Once you have stabilized your correct dose of warfarin, how often the value of your PT / INR (Prothrombin Time) should be tested? a) Once a week b) Once a month c) On alternate months d) Once every 3 months	14. Once you have stabilized your correct dose of warfarin, how often should your PT/INR (Prothrombin Time) be tested? a) Once a week b) Once a month c) Every other month d) Once every three months	100%	IA
15. It is important for a patient on Coumadin (warfarin) to monitor for signs of bleeding: a) Only when their PT/ INR ("Protime") is above the goal range b) At all times c) Only when their PT/ INR ("Protime") is below the goal range d) Only when you miss a dose	15. É importante para um paciente em uso da varfarina monitorizar sinais de sangramento: a) Apenas quando seu TP/RNI (Tempo de Protrombina) estiver acima da "faixa esperada" b) A todo momento c) Apenas quando seu TP/RNI (Tempo de Protrombina) estiver abaixo da "faixa esperada" d) Apenas quando você deixar de tomar uma dose	15. It is important for a patient on warfarin to monitor signs of bleeding: a) Only when your PT / INR (Prothrombin Time) is above the "expected range" b) At all times c) Only when your PT / INR (Prothrombin Time) is below the "expected range" d) Only when you stop taking a dose	15. It is important for a patient using warfarin to monitor signs of bleeding: a) Only when his/her PT/ INR (Prothrombin Time) is above the "expected level". b) All the time. c) Only when his/her PT/ INR (Prothrombin Time) is below the "expected level" d) Only when you do not take a dose	100%	IA

it continues

Chart 1. continuation

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
16. The best thing to do if you miss a dose of Coumadin (warfarin) is to? a) Double up the next day b) Take the next scheduled dose and tell your healthcare provider c) Call your healthcare provider immediately d) Discontinue Coumadin (warfarin) altogether	16. A melhor coisa a ser feita se você deixar de tomar uma dose da varfarina é? a) Dobrar a dose no dia seguinte b) Tomar a próxima dose programada e informar seu serviço de saúde c) Ligar para o seu serviço de saúde imediatamente d) Descontinuar o uso da varfarina completamente	16. The best thing to do if you fail to take a dose of warfarin is? a) Doubling the dose the next day b) Take the next scheduled dose and inform your health care c) Call your health care immediately d) Discontinue use of warfarin altogether	16. The best thing to do if you do not take a dose of warfarin is? a) Double the dose the next day b) Take the next scheduled dose and inform your health service c) Call your health service immediately d) Discontinue the use of warfarin completely	100%	IA
17. When it comes to diet, people taking Coumadin (warfarin) should: a) Never eat foods that contain large amounts of vitamin K b) Keep a diary of all of the foods they eat c) Be consistent and eat a diet that includes all types of food d) Increase the amount of vegetables they eat	17. Quando se trata da alimentação, as pessoas que tomam varfarina devem: a) Nunca ingerir alimentos que contenham grandes quantidades de vitamina K b) Manter um diário de todos os alimentos ingeridos diariamente c) Ser consistente e ter uma dieta que inclua todos os tipos de alimentos d) Aumentar a quantidade de vegetais que consomem	17. When it comes to food, people taking warfarin should: a) Never eat foods that contain large amounts of vitamin K b) Keep a diary of all foods eaten daily c) Be consistent and have a diet that includes all food types d) Increase the amount of vegetables they consume	17. When dealing with one's diet, people who take warfarin must: a) Never eat food that contains large quantities of vitamin K b) Keep a diary of all the food eaten daily c) Be consistent and have a diet that includes all types of foods d) Increase the quantity of vegetables that they consume	100%	IA
18. Each time you get your PT/INR ("Protime") checked, you should: a) Skip your dose of Coumadin (warfarin) on the day of the test b) Avoid eating high fat meals on the day of the test c) Avoid foods high in vitamin K on the day of the test d) Let your doctor know if you missed any doses of Coumadin (warfarin)	18. Cada vez que você checar seu TP/RNI, você deve: a) Deixar de tomar sua dose de varfarina no dia do exame b) Evitar ingerir comidas gordurosas no dia do exame c) Evitar alimentos com grandes quantidades de vitamina K no dia do exame d) Informar seu médico se você deixou de tomar alguma dose da varfarina	18. Every time you check your PT / INR, you should: a) Stop to take your dose of warfarin on the day of the exam b) Avoid eating fatty foods on the day of the exam c) Avoid foods with large amounts of vitamin K on the day of the exam d) Inform your doctor if you have stopped taking any dose of warfarin	18. Every time you check your PT/INR, you must: a) Not take your dose of warfarin on the day of the exam b) Avoid eating fatty foods on the day of the exam c) Avoid foods with large quantities of vitamin K on the day of the exam d) Inform your doctor if you did not take your normal dose of warfarin	100%	IA
19. Which of the following over-the-counter products is most likely to interact with Coumadin (Warfarin)? a) Nicotine replacement therapies b) Herbal / Dietary supplements c) Allergy medications d) Calcium supplements	19. Qual dos seguintes produtos, que não precisam de receita, é mais provável de interagir com a varfarina? a) Terapias de substituição de nicotina b) Ervas/Suplementos dietéticos c) Medicamentos para alergia d) Suplementos de cálcio	19. Which of the following goods, which do not need a prescription, is more likely to interact with warfarin? a) Nicotine replacement therapies b) Herbs / Dietary Supplements c) Medicine for allergy d) Calcium supplements	19. Which of the following non-prescription products is most likely to interact with warfarin? a) Nicotine substitution therapies b) Diet Herbs/ Supplements c) Allergy medications d) Calcium Supplements	100%	IA

it continues

Chart 1. continuation

Original instrument	Synthesis translation into brazilian portuguese	Back-translation VI1	Back-translation VI2	A1	A2
20. A patient with a PT/ INR("Protime") value above the "goal range": a) Is at an increased risk of having a clot b) Is more likely to have drowsiness and fatigue from Coumadin (warfarin) c) Is at an increased risk of bleeding d) Is less likely to experience side effects from Coumadin (warfarin)	20. Um paciente com TP/ RNI (tempo de protrombina) acima da "faixa esperada": a) Apresenta risco aumentado de formar um coágulo b) Apresenta maior probabilidade de sentir sonolência e fadiga devido ao uso da varfarina c) Apresenta risco aumentado de sangramento d) Está menos sujeito a experimentar efeitos adversos devido ao uso da varfarina	20. A patient with PT / INR (prothrombin time) above the "expected range": a) Presents an increased risk of forming a clot b) Is more likely to experience sleepiness and fatigue due to the use of warfarin c) Presents an increased risk of bleeding d) Is less likely to experience adverse effects due to the use of warfarin	20. A patient with PT/ INR (Prothrombin Time) above the "expected level": a) Presents an increased risk of forming a clot b) Presents a higher probability of feeling drowsy and tired due to warfarin use c) Presents an increased risk of bleeding d) Is less subject to adverse effects due to warfarin use	100%	IA

OAK, Oral Anticoagulation Knowledge; TP, Tempo de Protrombina; RNI, Relação Normalizada Internacional; SA, slightly altered; UA, unaltered.
A1 – Evaluation in terms of the percentage of concordance of the referential meaning. A2 – Evaluation of the general meaning.

Chart 2. Comparison between the synthesis version of OAK Test translated into Brazilian Portuguese and the pre-final version after evaluation by the experts committee.

Item	Synthesis version translated into Brazilian Portuguese (T12)	Pre-final version
1	*Não* tomar uma dose da *varfarina*: □ d. É permitido, desde que você *observe* os alimentos que você come	*Esquecer de* tomar uma dose da *varfarina*: □ d. É permitido, desde que você *tenha cuidado com* os alimentos que você come
3	O paciente que toma varfarina deve entrar em contato com o médico ou o *serviço de saúde* quando:	O paciente que toma varfarina deve entrar em contato com o médico ou *quem acompanha o tratamento* quando:
7	O exame de *TP/RNI* (Tempo de Protrombina) é:	O exame de *RNI* é:
9	Pacientes com a TP/RNI (tempo de protrombina) abaixo da *faixa esperada*: □ c. Tem maior probabilidade de ter *erupções cutâneas* devido ao uso da varfarina	Um paciente com a RNI abaixo da *faixa desejada*: □ c. Tem maior possibilidade de ter *alterações na pele* devido ao uso da varfarina
10	Tomar um medicamento que contenha *ácido acetilsalicílico* ou outros anti-inflamatórios não esteroides, como ibuprofeno enquanto estiver tomando a varfarina irá: □ d. Exigir *que você aumente sua dose* da varfarina	Tomar um medicamento que contenha *ácido acetilsalicílico (AAS)* ou outros anti-inflamatórios não esteroides, como ibuprofeno, enquanto estiver tomando a varfarina irá: □ d. Exigir *aumento de sua dose* da varfarina.
13	□ a. É seguro, desde *que você tome sua dose da varfarina e do álcool separadamente*	□ a. É seguro, desde *que você tome sua dose da varfarina e do álcool em momentos diferentes*

OAK, Oral Anticoagulation Knowledge; TP, Tempo de Protrombina; RNI, Relação Normalizada Internacional.

With the pre-testing of the pre-final version of the OAK Test in Brazilian Portuguese via face-to-face interview, it was possible to verify the adequate level of language used and comprehend the translation. The instrument's mean time of response was 10 minutes.

Regarding the characteristics of the pre-testing participants (Table 1), most were female (66%), median age 55 years and incomplete elementary school education (67%).

There were no difficulties in understanding the items during interviews. All 30 (100%) par-

ticipants answered the general impression questionnaire about the instrument and rated it as good, evaluating all issues as important for anyone using warfarin. Most participants (23; 77%), classified the subjects as easy-to-understand, and only seven (23%) participants classified the questions as fairly understood.

No participant made suggestions to change or add questions. Thus, at the end of pre-testing, there was good acceptance of the instrument among the participants, and there was no need to modify items.

As a product of the cross-cultural adaptation process, we obtained the final version of the OAK Test in the Brazilian Portuguese language version entitled "Teste de Conhecimento sobre Anticoagulação Oral" (Chart 3). This version will be used in a representative sample of Brazilian patients using warfarin to validate the instrument by evaluating its psychometric properties, which will reflect its validity and reliability. This step may confirm whether or not the psychometric properties of the original version have been retained in the adapted version.

Discussion

The process of cross-cultural adaptation was carried out according to the methodology suggested in the literature[15,16,18] and used by a study that had the same objective of culturally translating and adapting the OAK Test to another country[13]. Systematization was conducted and the process was considered satisfactory in all stages.

Cross-cultural adaptation seeks to ensure the development of an adapted instrument that is equivalent to the original instrument and that can be used by most of the population[19].

A minimum of two independent translations were performed in the initial translation and back-translation stages, which allows the detection of errors and divergent interpretations of ambiguous items in the original version[15].

The committee of experts reached a consensus on the semantic and conceptual equivalence of items in the review stage. It was possible to have ample and rich discussion about the instrument itself, including its objectives, ways of completing and obtaining clear and accessible language. The synthesis version of the translations was considered adequate, since there were no meaning discrepancies in the back-translations.

The process used allowed the evaluation of all changes made at each stage and enabled specialists' global perception regarding the referential meaning and the general meaning[19].

Thus, the 20 questions of the OAK Test were adapted, preserving the meaning of words between two different languages and ensuring semantic equivalence[21]. As a result, a pre-final version of the instrument with greater clarity and adequate that was used in the pre-testing stage was obtained.

There was good acceptability of the instrument and the concept explored in each question of the translated instrument has the same meaning for the target culture, that is, the concept is relevant for both cultures, as observed by other authors[15,21] and the OAK Test in the Brazilian Portuguese version can be administered even to people with low schooling.

As main limitation of the study, we emphasize that the OAK Test was designed to be self-applied and for individuals with at least seven schooling years. However, due to the low educational level of some individuals included in the study, we decided to administer the instrument as an individual interview, which extended the time of its application. Interviews were conducted in a standardized way by one interviewer only, in order not to interfere with the respondents' answers. However, we emphasize that semantic equivalence is not related to the methods of application of scales and that these do not interfere in the performance of the instruments[26].

Thus, if it is valid for the Brazilian population, the adapted instrument may be used in the

Table 1. Characteristics of the pre-testing sample, Belo Horizonte, 2014.

Characteristics	Sample (n=30)
Sex, n (%)	
Female	20 (66%)
Male	10 (34%)
Age (years) [Median (interquartile range)]	55 (43-69)
Age groups (years), n (%)	
< 45	11 (37%)
45-60	8 (27%)
61-75	9 (30%)
≥ 76	2 (6%)
Education, n (%)	
Incomplete elementary school	20 (67%)
Complete elementary school	5 (17%)
Complete high school	1 (3%)
Complete graduation	4 (13%)

Chart 3. Final version of OAK Test translated into Brazilian Portuguese.

Teste de Conhecimento sobre Anticoagulação Oral
Instruções: Para cada questão, marque um X na caixa próxima à resposta que considera correta ou àquela que melhor completa a frase corretamente. Por favor, responda todas as questões.
1. Esquecer de tomar uma dose da varfarina: □ a. Não tem efeito □ *b. Pode alterar a efetividade do medicamento* □ c. É permitido desde que você tome a próxima dose em dobro □ d. É permitido, desde que você tenha cuidado com os alimentos que você come
2. Você consegue diferenciar entre diferentes doses do comprimido da varfarina utilizando-se de? □ *a. Cor* □ b. Formato □ c. Tamanho □ d. Peso
3. O paciente que toma varfarina deve entrar em contato com o médico ou quem acompanha o tratamento quando: □ a. Outro médico acrescenta um novo medicamento □ b. Outro médico interrompe algum medicamento que estava sendo usado □ c. Outro médico troca a dose de algum medicamento que já estava sendo usado □ *d. Todas as respostas acima*
4. Ocasionalmente comer uma grande quantidade de folhas verdes enquanto toma varfarina pode: □ a. Aumentar seu risco de sangramento devido ao uso da varfarina □ *b. Reduzir a efetividade da varfarina* □ c. Causar desconforto no estômago e vômito □ d. Reduzir seu risco de ter um coágulo sanguíneo
5. Qual das vitaminas abaixo interage com a varfarina? □ a. Vitamina B 12 □ b. Vitamina A □ c. Vitamina B 6 □ *d. Vitamina K*
6. Quando é seguro tomar um medicamento que interage com a varfarina? □ a. Se você toma a varfarina pela manhã e o medicamento que interage à noite □ *b. Se quem acompanha seu tratamento está ciente dessa interação e checa seu RNI regularmente* □ c. Se você toma a varfarina em dias alternados □ d. Nunca é seguro utilizar um medicamento que interage com a varfarina
7. O exame de RNI é: □ *a. Um exame de sangue usado para monitorar seu tratamento com a varfarina* □ b. Um exame de sangue que é raramente feito durante seu tratamento com a varfarina □ c. Um exame de sangue que verifica a quantidade de vitamina K na sua dieta □ d. Um exame de sangue que determina se você precisa tomar a varfarina
8. A varfarina pode ser usada para: □ *a. Tratar pessoas que já tem um coágulo sanguíneo* □ b. Tratar pessoas que tem aumento de açúcar no sangue □ c. Tratar pessoas com hipertensão arterial □ d. Tratar pessoas com ferimentos graves
9. Um paciente com a RNI abaixo da "faixa desejada": □ a. Tem risco aumentado de sangramento □ *b. Tem risco aumentado de formar coágulo* □ c. Tem maior possibilidade de ter alterações na pele devido ao uso da varfarina □ d. Tem maior possibilidade de apresentar efeitos adversos devido ao uso da varfarina
10. Tomar um medicamento que contenha ácido acetilsalicílico (AAS) ou outros anti-inflamatórios não esteroides, como ibuprofeno, enquanto estiver tomando a varfarina irá: □ a. Reduzir a efetividade da varfarina □ *b. Aumentar seu risco de sangramento devido ao uso da varfarina* □ c. Causar a formação de coágulo sanguíneo □ d. Exigir aumento de sua dose da varfarina

it continues

Chart 3. continuation

11. Uma pessoa que toma varfarina deve procurar atendimento médico imediatamente: □ a. Se deixar de tomar mais de duas doses seguidas de varfarina □ *b. Se observar sangue nas fezes quando vai ao banheiro* □ c. Se tiver um pequeno sangramento nasal □ d. Se apresentar hematomas nos braços e pernas
12. Deixar de tomar uma única dose da varfarina pode: □ a. Fazer com que seu RNI fique acima da "faixa desejada" □ b. Aumentar seu risco de sangramento □ *c. Fazer com que seu RNI fique abaixo da "faixa desejada"* □ d. Diminuir seu risco de ter um coágulo
13. Ingerir bebidas alcoólicas enquanto estiver em tratamento com a varfarina: □ a. É seguro, desde que você tome sua dose da varfarina e do álcool em momentos diferentes □ *b. Pode afetar sua RNI* □ c. Não afeta sua RNI □ d. É seguro desde que esteja tomando uma dose baixa de varfarina
14. Uma vez que você tenha estabilizado sua dose correta da varfarina, com que frequência o valor do seu RNI deve ser testado? □ a. Uma vez por semana □ *b. Uma vez por mês* □ c. Uma vez a cada dois meses □ d. Uma vez a cada três meses
15. É importante para um paciente em uso da varfarina estar atento a sinais de sangramento: □ a. Apenas quando sua RNI estiver acima da "faixa desejada" □ *b. A todo momento* □ c. Apenas quando sua RNI estiver abaixo da "faixa desejada" □ d. Apenas quando esquecer de tomar uma dose
16. A melhor coisa a ser feita se você esquecer de tomar uma dose da varfarina é? □ a. Dobrar a dose no dia seguinte □ *b. Tomar a próxima dose programada e informar quem acompanha seu tratamento* □ c. Ligar para quem acompanha seu tratamento imediatamente □ d. Interromper o uso da varfarina completamente
17. Quando se trata da alimentação, as pessoas que tomam varfarina devem: □ a. Nunca ingerir alimentos que contenham grandes quantidades de vitamina K □ b. Manter um diário de todos os alimentos ingeridos por elas □ *c. Ser consistente e seguir uma dieta que inclua todos os tipos de alimentos* □ d. Aumentar a quantidade de vegetais que elas comem
18. Cada vez que você fizer seu exame RNI, você deve: □ a Deixar de tomar sua dose de varfarina no dia do exame □ b. Evitar refeições com comidas gordurosas no dia do exame □ c. Evitar alimentos com grandes quantidades de vitamina K no dia do exame □ *d. Informar seu médico se você deixou de tomar alguma dose da varfarina*
19. Qual dos seguintes produtos, que não precisam de receita, é mais provável de interagir com a varfarina? □ a. Terapias de substituição de nicotina □ *b. Ervas/Suplementos alimentares* □ c. Medicamentos para alergia □ d. Suplementos de cálcio
20. Um paciente com um valor de RNI acima da "faixa desejada": □ a. Apresenta um risco maior de formar um coágulo □ b. Apresenta maior possibilidade de sentir sonolência e fadiga devido ao uso da varfarina □ *c. Apresenta um risco maior de sangramento* □ d. Apresenta menor possibilidade de experimentar efeitos adversos devido ao uso da varfarina

public health services to quickly assess the patient's level of knowledge about warfarin treatment. In addition, research results among different countries could be compared, adding value to the decision-making process.

Conclusions

The cross-cultural translation and adaptation process of the OAK Test for Brazilian culture followed internationally recommended steps and was successfully carried out. The results obtained showed that the Brazilian and American versions are conceptually equivalent.

The application of instruments using recognized scientific methods will allow the analysis of the relationship between patients' knowledge and quality of oral anticoagulation control. The results obtained may help in the identification of deficits and in the structuring of health education activities to improve knowledge about pharmacotherapy and, consequently, favor a successful treatment.

Collaborations

MFS Praxedes, SM Paiva, DD Ribeiro, MS Marcolino, MHNG Abreu and MAP Martins contributed during the review process of the manuscript and the approval of its final version.

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