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Impact of an educational intervention on the safety of geriatric patients with atrial fibrillation in use of warfarin

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Abstract

Objective: To identify contributions of an educational intervention on the knowledge of geriatric patients about safety aspects of treatment with warfarin. **Methods**: A longitudinal intervention study conducted in an anticoagulation clinic of a public university hospital located in Minas Gerais, carried out with geriatric patients who had a diagnosis of valvular or non-valvular atrial fibrillation in use of warfarin. The participants answered a questionnaire on general knowledge about the anticoagulant therapy with warfarin, validated in Brazil (OAK test) and analyzed by a committee of specialist judges to select the questions about safety of this instrument in the present study. Afterwards, the patients participated in an educational intervention centered on the patient and on self-care; the outcome analyzed was the test score of knowledge about anticoagulation before (T0), immediately after (T1) and six months after (T2) the intervention. The data were descriptively analyzed using absolute and relative frequencies. The data were descriptively analyzed using absolute and relative frequencies. **Results**: The participants of this study were 43 patients with a mean age of 71±7.6 years old, predominance of females with 25 (58.1%), and mean schooling of 5±4.8 years. Questions 1, 2, 3, 4, 5, 6, 9, 12, 13, 15, 17, 19 and 20 analyzed by the judges had a CVI assessed at 1.0, questions 7, 10, 16 and 18 had a CVI assessed at 0.92, and questions 8 and 14 had CVI values below 0.78 and were rated at 0.75 and 0.58 respectively, thus being excluded from the study. For most of the questions, an improvement in the patients' knowledge about treatment safety was identified after the educational intervention ($p<0.05$). The questions for which no increase in knowledge was identified were related to when to seek medical care in emergency situations and to the risks of bleeding. **Conclusion**: Offering the educational intervention improved the participants' knowledge about the safety of the anticoagulant treatment, considering the OAK test questions that presented CVI values > 0.75, according to the judges' evaluation.

Keywords: warfarin; cardiovascular diseases; atrial fibrillation; drug therapy; aged; health literacy.

O impacto da intervenção educacional na segurança do paciente geriátrico com fibrilação atrial em uso de varfarina

Resumo

Objetivo: Identificar contribuições de uma intervenção educacional no conhecimento de pacientes geriátricos sobre aspectos de segurança no tratamento com a varfarina. **Métodos**: Estudo de intervenção de caráter longitudinal conduzido em uma clínica de anticoagulação de um hospital público universitário localizado em Minas Gerais, realizado com pacientes geriátricos que possuíam diagnóstico de fibrilação atrial valvar ou não valvar em uso de varfarina. Os participantes responderam a um questionário sobre conhecimentos gerais da terapia anticoagulante com varfarina, validado no Brasil (*OAK test*) e analisado por meio de um comitê de juízes especialistas para seleção das questões sobre segurança desse instrumento no presente estudo. Posteriormente os pacientes participaram de uma intervenção educacional centrada no paciente e no autocuidado, o desfecho analisado foi a pontuação do teste de conhecimento sobre anticoagulação antes (T0), imediatamente após (T1) e seis meses após (T2) a intervenção. Os dados foram analisados de forma descritiva por meio de frequências absolutas e relativas. Os dados foram analisados de forma descritiva por meio de frequências absolutas e relativas. **Resultados**: 43 pacientes com idade média de 71±7,6 anos, com predominância do sexo feminino 25; 58,1% e média de escolaridade de 5±4,8 anos participaram do estudo. As questões analisadas pelos juízes 1, 2, 3, 4, 5, 6, 9, 12, 13, 15, 17, 19 e 20 tiveram IVC avaliado em 1,0, as questões 7, 10, 16 e 18 tiveram IVC avaliado em 0,92, as questões 8 e 14 tiveram IVC abaixo de 0,78 e foram avaliados em 0,75 e 0,58 respectivamente, sendo assim excluídas do estudo. Para a maioria das questões identificou-se melhoria no conhecimento dos pacientes sobre segurança no tratamento após a intervenção educacional ($P<0,05$). As questões para as quais não se identificou aumento do conhecimento estavam relacionadas à quando procurar atendimento médico em situações de urgência e aos riscos de hemorragia. **Conclusão**: O oferecimento de intervenção educacional apresentou melhora do conhecimento sobre segurança do tratamento anticoagulante pelos participantes, considerando as questões do OAK *test* que apresentaram IVC > 0,75, segundo avaliação os juízes.

Palavras-chave: varfarina; doenças cardiovasculares; fibrilação atrial; terapia medicamentosa; idoso; letramento em saúde.

Introduction

Combined with better living conditions and reduction in the fertility and birth rates, the increase in longevity contributes to a worldwide phenomenon called population aging, characterizing one of the greatest challenges of contemporary Public Health.[1] In middle-income countries, the World Health Organization (WHO) considers an aged every person as being over 60 years old[2], which is an attribute specified in The Statue of Older Adults in Brazil.[3]

The increase in the aged population brings with it prevalence of Chronic Non-Communicable Diseases (CNCDs). Such change in the population's health profile can contribute to the wide use of health services.[4] Among the most prevalent chronic diseases in older adults, arrhythmias stand out, with atrial fibrillation (AF) being one of the most common heart rhythm disorder. Some predisposing factors lead to the development of AF prevalence, such as hypertension, diabetes, obesity, family history, myocardial infarction and heart failure (HF).[5]

In turn, AF is an important risk factor for the development of strokes. Thus, the use of anticoagulants is indicated for patients with this clinical condition as a measure to prevent thromboembolic events.

Warfarin is an oral anticoagulant (OAC) widely prescribed to prevent thromboembolic events in individuals with AF. Despite the benefits, the patients' adherence and understanding regarding the treatment are key aspects for success of pharmacotherapy.[6] This is due to the great dose-response variability of warfarin and to the multiple interaction with medications and food.[7] The therapeutic dose must be adjusted individually, using the International Normalized Ratio (INR). In general, the target INR for patients with AF is between 2.0 and 3.0. In the long term, it is possible to assess the oral anticoagulant's quality through the Therapeutic Time Range (TTR), a calculation involving a linear interpolation of a historical series of INR values.[8]

Due to physiological changes resulting from aging, older adults are even more susceptible to the occurrence of adverse events resulting from the use of warfarin.[9] Therefore, patient awareness regarding the risks and treatment management contribute to greater safety of pharmacotherapy[10]. A number of studies point to the need to provide effective and accessible educational processes for patients in use of oral anticoagulants.[10,11] It is understood that educational interventions can contribute to increasing knowledge about anticoagulant treatment and to decision-making and prevention of adverse events related to this therapeutic class.[11]

Although the scientific literature presents a gap in relation to studies with a specific focus on educational interventions aimed at older adults in use of anticoagulants, it is believed that they can contribute to improving knowledge regarding the anticoagulant treatment. When considering the increase in life expectancy, the consequent increase in the prevalence of CNCDs, greater need for the use of warfarin by older adults and the possibility of contribution of the educational processes to the safety of older adults in use of warfarin, this study aims at identifying contributions of an educational intervention on the knowledge of aged patients about safety aspects of treatment with warfarin.

Methods

This is a longitudinal intervention study conducted in an anticoagulation clinic (AC) of a university hospital in Minas Gerais. The AC is a reference in the care of medium- and high-complexity diseases. It operates in the multidisciplinary format, with its team comprised by physicians, pharmacists and nurses. The service involves anamnesis with an approach to lifestyle habits, food routine and medications in use, followed by educational guidance and dose adjustment according to the result of the INR test. The institution has anticoagulation protocols to guide certified professionals to conduct the care practice in a standardized manner.

The intervention was carried out through face-to-face groups, with a maximum of fifteen and a minimum of three participants, in addition to telephone contacts between the meetings. For each patient, four meetings were offered, called Culture Circles as proposed by Freire[12], as follows: warm-up, encouragement for critical thinking and conclusion. Specific themes were addressed in each meeting, according to what is indicated in the literature[10,13,14,15], namely: approach to self-care, knowing the health problem and the reason for anticoagulation, interaction of warfarin with medications/self-medication and interaction of warfarin with food. Educational material targeted at patients with low literacy was used, such as feedback technique, a real-size doll simulating a patient and macro-size medication boxes, in addition to pictures that represented the participants' daily issues.[16-19] Telephone contacts were made to contribute to fixation of learning, clarifying doubts or providing help about any obstacles regarding the topic discussed in the meeting.

The intervention proposal was part of a controlled clinical trial carried out between April 2019 and August 2020, and the study protocol was published in 2019[20], with a pharmacist acting as a mediator.

The inclusion criteria were individuals aged at least 60 years old, of both genders, who were under outpatient follow-up for at least six months, diagnosed with valvular or non-valvular AF, in use of warfarin, with TTR below 60.0%, and who received an educational intervention related to the anticoagulant treatment. The individuals excluded were bedridden patients, people with blindness or complete deafness, aphasia or speech difficulties capable of impeding communication, and those with a diagnosis of dementia reported in medical records of previous hospitalizations or outpatient care.

To identify the patients with persistence of TTR < 60.0%, the TTR value was calculated for the period from July to December 2018. Patients who presented TTR in this range and who met the other inclusion criteria were approached in the outpatient care waiting room between January and March 2019 and invited to participate in the study.

The following sociodemographic variables were considered: gender, age, municipality of residence, skin color, schooling in years and indication to use warfarin. These variables were collected by accessing the patients' electronic medical chart in the AC's computerized system.

Knowledge about treatment safety was considered as the outcome variable. For this measurement, the Oral Anticoagulation Knowledge Test (OAK Test) instrument was used, validated in Brazil[21,22] and consisting of 20 questions related to treatment with warfarin, with four answer alternatives and one correct option. Each correct answer equals one point, with a final result varying from 0 to 20 points. Higher scores indicate lower levels of knowledge about the oral anticoagulant therapy. As the OAK test is not directed to safety questions, it was decided to select the

questions about the safety of this instrument through a committee of specialist judges, which is specified below. The safety questions of the test were applied at three different times in the study: before (T0), immediately after (T1) and six months after (T2) the educational intervention.

The inclusion criteria for the judges were as follows: professional pharmacists and/or nurses who work or have already worked in the care of patients under oral anticoagulation, having a professional relationship with the study locus and with no direct participation in the educational intervention. The judges were invited via email and through messages sent via WhatsApp, by means of which the link to the form in *Google Forms* was sent to access the questions.

In the evaluation form directed to the expert judges, it was recommended that each item of the questionnaire was evaluated according to its relation to safety. To such end, each question was presented to the judges invited, together with the following question: "Please identify below which questions you consider to be related to patient safety in relation to the use of warfarin; answer individually according to the following options: I totally disagree, I partially disagree, Indifferent, I partially agree, and I totally agree", in this presentation order. The committee of specialists was allowed 15 days to fill in the form.

Data compilation was performed by calculating the Content Validity Index (CVI), defined by the sum of the relative frequencies of the two answers with the best scores, divided by the maximum value to be obtained in the question[23], with questions that obtained CVI values above 0.78 being considered as acceptable.

The database was developed using Microsoft Excel®, the statistical analysis was performed in the Statistical Package for Social Sciences® (SPSS) software, version 25.0 (2017. Armonk, NY: IBM Corp.), and the variables were evaluated considering a probability of significance of $p<0.05$.

This study is linked to the PhD project entitled "Evaluation of the implementation of an educational intervention for patients with ineffective oral anticoagulation with warfarin seen at a university hospital: A controlled clinical trial", CAAE number 65928316.3.0000.5149. All the participants were informed about the research and invited to fill out the free and informed consent form at the time of recruitment for the study.

Results

In order to standardize and select the questions about safety, the test applied to the participants to assess knowledge about the warfarin therapy was evaluated by 12 judges. The evaluators selected were female (12; 100.0%) with a mean age of 33±7.2 years old and working in the area of patient safety and/or warfarin (Table 1).

In all, 43 individuals met the predefined inclusion criteria for this study. 43 (T0), 43 (T1) and 39 (T2) patients participated in each application phase of the test. The four patients who did not participate in the study at T2 were considered as missing. The reasons for non-participation were evolution to death (2), no consultation during the period (1), and substitution of warfarin for a specific target anticoagulant (1). The mean age of the patients was 71 ± 7.6 years old, with predominance of the female gender (25; 58.1%). Most of them live in Belo Horizonte and self-declared as non-white-skinned. In relation to the educational level, the mean schooling time of those involved was 5 ± 4.8 years. In addition to that, most of the patients were indicated for anticoagulation for non-valvular AF (Table 1).

The 20 questions were individually assessed by each evaluator, selecting only those with a Content Validity Index (CVI) above 0.78. Questions 1, 2, 3, 4, 5, 6, 9, 12, 13, 15, 17, 19 and 20 had their CVI rated at 1.0; questions 7, 10, 16 and 18 had their CVI rated at 0.92; and questions 8 and 14 had their CVI rated at 0.75 and 0.58, respectively. Questions 8 and 14 had CVI values below 0.78 and were not selected by the judges as questions related to patient safety and, for this reason, they were excluded from the database (Table 2).

Table 1. Profile of the evaluators and patients.

Information	All
Profile of the evaluators	**N=12**
Female gender[1] n (%)	12 (100.0)
Age (years old) Mean (SD)	33 (7.2)
Training time (years) Mean (SD)	8 (7.3)
Training n (%)	
Graduation	2 (16.7)
Specialization	5 (41.7)
Master's Degree	5 (41.7)
Works with warfarin (years) Mean (SD)	4 (3.0)
Patients selected for the study	**N=43**
Female gender[1] n (%)	25 (58.1)
Age (years) Mean (SD)[2]	
Female	71 (8.4)
Male	72 (6.5)
Mean (SD)	71 (7.6)
Municipality n (%)	
Belo Horizonte	26 (60.5)
Metropolitan Area	13 (30.2)
Inland of Minas Gerais	4 (9.3)
Skin color n (%)	
White	12 (27.9)
Non-white	31 (72.1)
Schooling (years) Mean (SD)	5 (4.8)
Indication n (%)	
Valvular AF[3]	15 (34.9)
Non-valvular AF	28 (65.1)

[1]Dichotomous variable for for which information about only one category was presented, [2]Standard Deviation, [3]Atrial Fibrillation.

Table 3 shows the result of the patients on each question of the OAK test applied at times T0, T1 and T2. Regarding the questions with the lowest frequency of correct answers, the most frequent items were about when to seek medical care in urgent situations and risk of bleeding. When comparing the time before the intervention (T0) and after the intervention (T1), there was a significant increase in the number of correct answers for questions 1, 2, 3, 4, 5, 7, 9, 10, 12, 16, 19 and 20 ($p<0.05$). In addition, questions 4, 5, 7, 9, 12 and 16 presented a significant increase in the number of correct answers at the moment immediately after the intervention (T1) in relation to after six months (T2).

Table 2. Identification of the safety questions (N=12).

Questions	CVI[1]>0.78	CVI[1]<0.78 (questions excluded)
1. Forgetting to take a warfarin dose	1	-
2. Can you differentiate between different doses of the warfarin tablet using...?	1	-
3. The patient who takes warfarin must get in contact with the physician or the person monitoring the treatment when...	1	-
4. Occasionally eating a big amount of green leaves while taking warfarin can...	1	-
5. Which of the following vitamins interacts with warfarin?	1	-
6. When is it safe to take a medication that interacts with warfarin?	1	-
7. The INR test is...	0.92	-
8. Warfarin can be used to...	-	0.75
9. A patient with INR below the "desired range"...	1	-
10. Taking a medication that contains acetylsalicylic acid (ASA) or another non-steroidal anti-inflammatories, such as ibuprofen, while taking warfarin will:	0.92	-
11. A person who takes warfarin must seek medical care immediately	1	-
12. Not taking a single warfarin dose can...	1	-
13. Drinking alcoholic beverages when in treatment with warfarin...	1	-
14. Once you have established your correct warfarin dose, how often should your INR be tested?	-	0.58
15. It is important for a patient in use of warfarin to be aware of signs of bleeding	1	-
16. What is the best course of action when you forget to take a warfarin dose?	0.92	-
17. Regarding nutrition, people who take warfarin should...	1	-
18. Every time you take your INR test, you must...	0.92	-
19. Which of the following products, which do not require prescription, are more likely to interact with warfarin?	1	-
20. A patient with an INR value above the "desired range"...	1	-

[1]Content Validity Index.

Discussion

In this article, knowledge about patient safety was explored through questions from the OAK test questionnaire selected by judges who work with patients undergoing OAC therapy. The questions chosen by the evaluators address themes about effects, complications and interactions that the anticoagulant therapy with warfarin can cause. The drug administration process is multidisciplinary and requires responsibility from all those involved, so as to promote patient safety. The health team must develop strategies and carry out actions to reduce and prevent possible adverse effects, in addition to improving communication with patients and family members, in order to ensure safety in the provision of care.[24]

The result of the OAK test showed that patient-centered education enhanced their knowledge about the safe use of warfarin. These results also evidence that knowledge remained after a six-month period. The study by Conort (2014) showed that oriented patients improve their knowledge about the treatment, both with regard to the name of the OAC and its administration methods, as well as in the indication and monitoring, warning signs and actions to be taken.[6]

Despite these positive outcomes, the percentage of correct answers regarding when to seek medical care in urgent situations and risk of bleeding remained low. In the study by Moreland (2013) carried out in the United States, it was identified that 21.0% of the patients underestimate the emergency signs, making it difficult to seek medical help in cases of major adverse effects.[25] With regard to the risk of bleeding, the signs of bleeding are recognized by only 12.5% of the patients.[6] This misunderstanding about the risk factors can be related to the low association between the perception of health in general and the cardiovascular risk factors; these patients may not be motivated to change their behavior regarding their health.[26]

It is emphasized that the educational strategy used in the intervention enabled greater exchange of experiences among the participants about their health conditions. A study on the education needs of patients with AF showed that the participation of others in the knowledge process in an environment such as the classroom is preferable and facilitates the correct representation of the disease.[27]

Pharmacists play an important role in the promotion of actions that increase patient knowledge about treatment with warfarin, reinforcing the importance of these professionals in the promotion of health and in patient safety.[6] Educational technology is not restricted to using means; it is a facilitating instrument that provides the multidisciplinary team and the patient with knowledge that favors construction and reconstruction of knowledge.[24]

As a limitation in this article, we can note the reduced number of participants, which does not allow for data extrapolation. Although the study pointed out the positive impact of the intervention on the patients' knowledge, and considering that the study included follow-up of the patients for a period of up to six months after the intervention, it is recommended that other studies are carried out to identify the impact of the educational intervention on the knowledge about long-term safety.

Conclusion

An improvement was identified in the knowledge about the safety of the anticoagulant treatment by the participants, considering the questions of the OAK test that presented CVI values > 0.75, according to the judges' evaluation. Thus, contributions of the patient-centered educational intervention for the knowledge about safety aspects of the anticoagulant therapy were identified in geriatric patients. This study can assist other health institutions and multidisciplinary teams involved in anticoagulation work in the development or application of interventions according to their target audience, which are important for knowledge about patient safety.

Table 3. Result of applying the OAK questionnaire at times T0, T1 and T2.

Questions[6]	T0[1] n(%)	T1[2] n(%)	p-value T0*T1	T2[3] n(%)[4]	p-value[5] T0*T2
Question 1	**Forgetting to take a warfarin dose:**				
yes	32 (74.4)	38 (88.4)	0.38	35 (81.4)	0.045
Question 2	**Can you differentiate between different doses of the warfarin tablet using...?**				
yes	21 (48.8)	22 (51.2)	0.046	22 (51.2)	0.444
Question 3	**The patient who takes warfarin must get in contact with the physician or the person monitoring the treatment when:**				
yes	37 (86.0)	38 (88.4)	0.014	35 (81.4)	0.104
Question 4	**Occasionally eating a big amount of green leaves while taking warfarin can:**				
yes	19 (44.2)	26 (60.5)	0.028	30 (69.8)	0.028
Question 5	**Which of the following vitamins interacts with warfarin?**				
yes	19 (44.2)	23 (53.5)	0.003	20 (46.5)	0
Question 6	**When is it safe to take a medication that interacts with warfarin?**				
yes	20 (46.5)	29 (67.4)	0.259	31 (72.1)	0.558
Question 7	**The INR test is:**				
yes	31 (72.1)	34 (79.1)	0.008	31 (72.1)	0.028
Question 9	**A patient with INR below the "desired range":**				
yes	24 (55.8)	25 (58.1)	0	25 (58.1)	0.053
Question 10	**Taking a medication that contains acetylsalicylic acid (ASA) or another non-steroidal anti-inflammatories, such as ibuprofen, while taking warfarin will:**				
yes	17 (39.5)	21 (48.8)	0.085	21 (48.8)	0.022
Question 11	**A person who takes warfarin must seek medical care immediately:**				
yes	13 (30.2)	22 (51.2)	0.287	22 (51.2)	0.187
Question 12	**Not taking a single warfarin dose can:**				
yes	18 (41.9)	26 (60.5)	0.01	24 (55.8)	0.02
Question 13	**Drinking alcoholic beverages when in treatment with warfarin:**				
yes	30 (69.8)	38 (88.4)	0.153	31 (72.1)	0.238
Question 15	**It is important for a patient in use of warfarin to be aware of signs of bleeding:**				
yes	29 (67.4)	30 (69.8)	0.184	32 (74.4)	0.429
Question 16	**What is the best course of action when you forget to take a warfarin dose?**				
yes	38 (88.4)	37 (86.0)	0.001	37 (86.0)	0.013
Question 17	**Regarding nutrition, people who take warfarin should:**				
yes	33 (76.7)	36 (83.7)	0.524	34 (79.1)	0.324
Question 18	**Every time you take your INR test, you must:**				
yes	28 (65.1)	33 (76.7)	0.22	33 (76.7)	0.108
Question 19	**Which of the following products, which do not require prescription, are more likely to interact with warfarin?**				
yes	16 (37.2)	20 (46.5)	0.001	19 (44.2)	0.216
Question 20	**A patient with an INR value above the "desired range":**				
yes	22 (51.2)	32 (74.4)	0.068	25 (58.1)	0.036

[1]Before the intervention, [2]Immediately after the intervention, [3]Six months after the intervention, [4]Did not participate at T2: 4 (9.3%), [5]Significant statistical value. [6]Dichotomous variable for for which information about only one category was presented.

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Collaborators

ACV, MOO and RCN were responsible for data conception; JSM was in charge of data analysis; TRC, JMC and MAPM were responsible for the design, analysis and interpretation of the data and for writing the article; and JMC, MAPM and CMB were in charge of the relevant critical review of the intellectual content.

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Conflict of interest statement

The authors declare that they have no conflict of interest regarding to this article.

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