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Telemonitoring of older anticoagulant users during the COVID-19 pandemic

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Abstract

The COVID-19 pandemic brought challenges to the monitoring of anticoagulant users, especially older adults, making telemonitoring an alternative to provide continuity of care for these patients. The present study aimed to describe the experience of telemonitoring of older anticoagulant users during the COVID-19 pandemic. This is a descriptive study concerning the telemonitoring pharmaceutical service for older adults (≥60 years old) using oral anticoagulants in a private geriatric outpatient clinic (Belo Horizonte). Older people had parameters of effectiveness and safety of anticoagulants monitored monthly by telephone (Apr-Dec/2021). Identified problems generated interventions for the patient or the multidisciplinary team. A total of 425 older adults were included in the service. Most used apixaban (189;41.9%), rivaroxaban (146;34.4%) and warfarin (47;11.1%). There was a mean age of 82.1 years, mostly female (65.2%), most at high risk of vulnerability (69%), and an incidence of 9.9% of COVID-19. There were 219 interventions related to warfarin (average of 4.6 interventions/patient); including requests for an INR test (57.5%), health guidelines (19.6%), dosage change (reduction - 10.5%; increase - 5.9%; suspension - 0.6%), or referral (5.9%). Users of other anticoagulants did not show alterations in the monitored parameters. Eleven older adults suffered falls and 10 required hospitalizations due to thromboembolic or hemorrhagic events. There was no statistically significant difference in hospitalization rates between users of warfarin or other anticoagulants (p=0.314). Monitoring older anticoagulant users is important, especially considering the high level of frailty identified and the thromboembolic and non-thromboembolic risks that COVID-19 brings. Telemonitoring was important, allowing for multiple interventions to be performed.

Keywords: Anticoagulants. Pharmaceutical care. COVID-19. Aged. Telemonitoring.

INTRODUCTION

The process of population aging in Brazil brings new healthcare demands to the geriatric population, which generally has multiple chronic diseases and, consequently, uses multiple medications[1-3]. Thus, older adults are more susceptible to the occurrence of adverse drug events, and such risks are even greater when using oral anticoagulants, which are considered high-alert medications; that is, drugs with greater risk of causing harm to patients when involved in medication errors[4,5].

Oral anticoagulants are used in the treatment or prophylaxis of diseases with high

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prevalence among the older patients, such as atrial fibrillation and thromboembolic events[6]. Warfarin, which is still among the most used oral anticoagulants in the world, has several documented drug interactions and requires laboratory monitoring for follow-up and dose adjustment, giving this drug a complex safety profile[7]. Direct-acting oral anticoagulants (DOACs), such as the direct thrombin inhibitor (dabigatran) and factor Xa inhibitors (rivaroxaban, apixaban, edoxaban), have the advantage of a less variable safety profile, rapid therapeutic effect, lower chance of interactions, and unnecessary periodic laboratory review[8].

Regardless of the type of oral anticoagulant, its proper use among older adults requires intensive monitoring by the multidisciplinary team, which should preferably include a pharmacist. This professional can provide clinical services aimed at monitoring and optimizing anticoagulant pharmacotherapy. The literature brings studies that describe the role of the pharmacist in the management of anticoagulant therapy in adult[9-14] and older patients with a positive impact[15-19].

However, with the COVID-19 pandemic, declared in March 2020, the need to adopt infection prevention and control measures was emphasized, such as the use of masks and social distancing. It is also important to note that advanced age was considered a risk factor for mortality from COVID-19, as well as cardiovascular disease. In this context, the number of face-to-face visits to health institutions, including geriatric outpatient clinics, had to be limited to minimize the incidence of infection in this group of patients[20]. To address this need, services for monitoring and optimizing the use of anticoagulants can be offered in a remote format, with descriptions of successful international initiatives before the pandemic involving adults[21-23] or older adults[24]; and after the start of the pandemic involving adults in general[25].

However, to our knowledge, Brazilian studies that describe pharmaceutical services to optimize the use of anticoagulants involving the older adults exclusively, who adopted the use of telephone communication, or were developed during the context of the pandemic do not exist. It is in this scenario that the present study is inserted, with the objective of describing the results of a pharmaceutical telemonitoring service for older users of anticoagulants during the COVID-19 pandemic linked to a geriatrics outpatient clinic.

METHODOLOGY

This is a descriptive study of a pharmaceutical health condition management service based on telemonitoring of older people using oral anticoagulants.

Place of Study

The study was carried out in a private geriatric clinic in Belo Horizonte, Minas Gerais. At the time of the study, the outpatient clinic served approximately 5,000 older people, that is, people aged 60 or over, according to Brazilian legislation, who had an agreement with health plans or purchased a healthcare package from the institution. The multidisciplinary team is made up of geriatricians, cardiologists, nephrologists, endocrinologists, psychiatrists, and family and community physicians, as well as nurses, pharmacists, physiotherapists, speech therapists, nutritionists, and psychologists.

In order to provide services aimed at monitoring these older adults, the multidiscipli-

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nary team offers consultations, therapeutic groups, matrix meetings, and telemonitoring. During the period of the COVID-19 pandemic, telemonitoring services were intensified due to the emergency situation and the need for social isolation.

Health Condition Management Service

The health condition management service was offered to the entire older adults population who use oral anticoagulants and attended at the outpatient clinic. All older users of anticoagulants were therefore included in the service, with no refusals to participate. The pharmacist conducted telephone consultations carried out at least once a month to monitor the effectiveness and safety parameters of anticoagulant drugs. However, a greater number of telephone contacts were carried out due to clinical peculiarities (e.g. identification of altered exams) or individual needs.

For all anticoagulant users, the occurrence of negative outcomes potentially related to anticoagulants was monitored; for example, hospitalization for gastrointestinal bleeding or the occurrence of hemorrhaging. These outcomes are questioned by the nurse for all patients seen at the clinic on a monthly basis, and subsequently documented in the medical record. In the event of the occurrence of these negative outcomes, the pharmacist carried out individualized interventions regarding users of DOAC or warfarin with patients/family members/caregivers and/or health professionals at the outpatient clinic.

All warfarin users were monitored by the pharmacist, upon request and a monthly evaluation of INR tests (international normalized ratio). In addition, via telephone, questions were asked about the occurrence of bleeding and the site of bleeding, as well as about the patients' habits (eating habits, initiation of new medications, and use of alcoholic beverages). After assessing the INR and other safety parameters, during the phone call, pharmaceutical interventions were carried out with the multidisciplinary team and/or the patient/family/caregiver to adjust the use of warfarin according to the user's individual needs.

Population, Data Collection, Variables, and Analysis

The population was defined consisting of all older users of at least one oral anticoagulant, monitored at the service between April and December 2021 (N=425). Data were collected about anticoagulants and documented diseases for patients in the initial evaluation of the analyzed period, allowing us to describe the types of oral anticoagulants used by the older adults (DOAC or warfarin) and their therapeutic indications.

Additionally, to characterize the older population, data were also collected to define the following variables: age, gender, history of falls, history and causes of hospitalization, incidence of COVID-19, and IVCF-20 (Clinical-Functional Vulnerability Index-20)[26]. The IVCF-20 is an instrument that allows for the assessment of functionality, assigning a score from 0 to 40 to the elderly individual, and the higher the value obtained, the greater the risk of clinical-functional vulnerability. It is widely used in frailty screening by health professionals in Brazil, since, through this assessment, it is possible to diagnose all aspects of the health of the older adults in a comprehensive and broad way. It is an instrument developed and validated in Brazil and evaluates the main dimensions that are associated with functional decline and death among older adults: age, self-perception of health, activities of daily living, cognition, mood, mobility, communication, and the presence of multiple comorbidities[26].

Regarding the health condition management service, the number and type of inter-

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ventions to optimize the use of oral anticoagulants were described. The presence of INR exams or changes in these (outside the acceptable range of 1.8 to 3.2; or extreme INR when <1.61 or >4.49) have also been described for warfarin users[21].

All data were collected retrospectively in the electronic system "LifeCode – Intelligence & Health", in which data referring to patients treated at the institution are recorded. The collection in the system was carried out by generating reports with compiled data. As all data came from a digital source (e.g. reports in spreadsheets generated by the institutional computerized system), an intermediate collection instrument was not used, and the collected data were fed directly into a database developed and adjusted for this research according to the peculiarities of the variables identified in the database sources.

The database was initially constituted in Microsoft Excel® software and later transferred entirely to Stata® software, where descriptive analyses of the variables were carried out with determination of absolute and relative frequency or central tendency and dispersion, according to their characteristics. A comparison was also made of the proportions of occurrence of falls and hospitalizations among users of warfarin or DOAC, using Pearson's chi-square test or Fisher's exact test.

Ethical aspects

This study is an integral part of the project "Profile of medication use and deprescription in a geriatrics outpatient clinic", approved by the Research Ethics Committee of UFMG - COEP, on November 30, 2021, under registration CAAE 52595821.1.0000.5149

RESULTS

A total of 425 older people were included in the service, most of them female (n=277; 65.2%) and a mean age of 82.1 ± 8.2 years old (minimum=60; maximum=101). An average IVCF-20 of 18.5 ± 6.8 (minimum=2; maximum=38) was identified, with most older people demonstrating vulnerability (n=293; 68.9%); i.e. IVCF-20 equal to or greater than 15.

During the study period, 42 older people (9.9%) developed COVID-19, and 3 of them were also hospitalized for this reason. The main indication for the use of oral anticoagulation was atrial fibrillation or arrhythmia (n=267; 64.8%) (Table 1).

Most older patients used apixaban (179;41.9%), followed by rivaroxaban (147;34.4%) and warfarin (51;11.1%). The remaining older adults (103;12.6%) used other DOAC (Table 2).

Patients using DOAC were all instructed about the proper use of these drugs, as well as the need to identify the occurrence of common adverse events and report them to clinic professionals. However, no occurrence of adverse events was identified among DOAC users.

A total of 219 interventions were performed on the 48 warfarin users, generating an average of 4.6 ± 3.1 interventions per patient (minimum = 0; maximum = 10). The most frequently performed intervention was requesting an INR test (n=126; 57.5%) (Table 3).

Providing general healthcare orientation was also frequent (19.6%), individualized according to the patient's profile identified

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at the time of the call. On these occasions, guidance was provided on intake of foods rich in vitamin K, use of medication, interactions, among others. Changes or suspension of warfarin doses were also frequent (37 in total – 16.4%), demonstrating the need for frequent and individualized warfarin dose adjustments. The interventions were accepted by the medical team and patients.

During the study period, a total of 138 INR test results were retrieved for older warfarin users; that is, an average of 2.4 ± 2.7 INR exams per older person over the nine months of the study (minimum = 0; maximum = 12). Of these, 104 (75.4%) were in the desirable range for INR. Most older people (n=33; 86.8%) had more than 50% of their INR exams within the desirable range. Only 14 exams had extreme alterations in the results (10.1% of the total exams; average of 0.3 ± 0.6 extreme exams per older person in the 9-month period).

In total, 11 patients (2.6% of all seniors) suffered 59 falls, all of them users of warfarin. There were also 166 hospitalizations during the follow-up period, with 10 of these hospitalizations (6.0%) related to thromboembolic events, involving a total of 9 older people (only 1 older user of warfarin). Two other hospitalizations (1.2% of the total number of hospitalizations) were related to bleeding in a single older user of warfarin. That is, 10 older people (2.4% of the total number of older adults) suffered hospitalization potentially related to the use of oral anticoagulants. There was no statistically significant difference in hospitalization rates between warfarin or DOAC users (p=0.314).

Table 1 – Frequency of indications for oral anticoagulants in a geriatric outpatient clinic (n=425). Belo Horizonte. April to December 2021.

Indications	Absolute frequency (n)	Relative frequency (%)
Atrial fibrillation or arrhythmia	267	62.8
Venous thromboembolism	56	13.2
Others	102	24.0
Total	**425**	**100**

Table 2 – Frequency of anticoagulants used in a geriatric outpatient clinic (n=425). Belo Horizonte. April to December 2021.

Anticoagulant	Absolute frequency (n)	Relative frequency (%)
Apixaban	178	41.9
Rivaroxaban	146	34.4
Warfarin	47	11.1
Dabigatran	29	6.8
Edoxaban	23	5.4
Apixaban + Dabigatran	1	0.2
Warfarin + Rivaroxaban	1	0.2
Total	**425**	**100**

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Table 3 – Frequency of types of interventions performed for warfarin users in a geriatric outpatient clinic (n=219). Belo Horizonte. April to December 2021.

Type of intervention	Absolute frequency (n)	Relative frequency (%)
INR exam request*	126	57.5
General health guidelines	43	19.6
Dose reduction	23	10.5
Dose increase	13	5.9
Referral to another health professional	13	5.9
Dose suspension	1	0.6
Total	**219**	**100**

*INR=International normalized ratio

DISCUSSION

There was a high number of anticoagulant users linked to the outpatient clinic during the study period, especially for atrial fibrillation/arrhythmias or venous thromboembolism, and it is important to highlight the high proportion of older people with vulnerability, which puts them at greater risk of developing adverse events. These results highlight the importance of offering a health condition management service via telemonitoring, especially to protect older adults during the COVID-19 pandemic, since this is an infection that has more serious outcomes among older adults and increases thromboembolic risk[20,27].

The service in question was offered on an emergency basis and could contribute to the care of patients using anticoagulants in a time of global health crisis, as suggested by the Anticoagulation Forum, an important North American organization of service providers related to anticoagulation[27]. Subsequently, in July 2022, the National Pharmaceutical Council (NPC) regulated telepharmacy, which could be performed in the modalities of pharmaceutical teleconsultation, teleinterconsultation, or telemonitoring, thus contemplating the health condition management service offered at the outpatient clinic under study[28].

Apixaban and rivaroxaban were the most used oral anticoagulants. Some studies have shown a better effectiveness and safety profile in older adults for DOACs when compared to warfarin, especially apixaban[29,30]. However, a considerable proportion of the older patients used warfarin (11.1%), demanding intensive monitoring, and reinforcing the importance of the health condition management service in the outpatient clinic, which generated a high average of interventions related to warfarin users (4.6 ± 3.1).

Among the interventions, those related to the request for INR tests (57.5%) stood out, which was only performed when the warfarin user had not previously sent their test. In this context, among patients and caregivers, reports of resistance to performing INR tests due to the pandemic risk were frequently identified, which is a fear identified in a qualitative study with caregivers of Brazilian older people during the pandemic[31]. This type of intervention being the most frequent is also due to the low average number of INR tests delivered during the period by older users of warfarin (2.4 ± 2.7).

Despite the limited number of INR exams,

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the interventions performed and their acceptability, as well as the care provided in the outpatient clinic, reflect a considerable percentage of results within the acceptable range (75.4% of the exams) and a low percentage of exams with extreme results (10.1%). This demonstrates the potential contribution of the pharmaceutical service offered in the control of INR. Future studies should, however, provide documentation of the change in INR soon after the implementation of pharmaceutical interventions, highlighting the clinical results derived primarily from the professional's action.

The incidence of falls and hospitalization potentially related to the use of oral anticoagulants was reduced, as identified in a North American pharmaceutical telemonitoring service for anticoagulant users implemented during the pandemic[25]. Therefore, monitoring is essential to assess the safety profile and effectiveness of the therapy.

The present study has as a limitation the retrospective collection in a secondary data source - the computerized system of the outpatient clinic under study. This type of source depends on the records of different health professionals, which are often lacking in completeness and quality. In addition, the fact that the service depends on a single pharmacist for its execution may have reduced the number of interventions performed.

However, such limitations are offset by the fact that the present study is a pioneer in describing a health condition management service aimed at anticoagulant users in a Brazilian geriatric outpatient clinic. It is also the first to do so in a private geriatric outpatient clinic and/or in a telemonitoring modality in Brazil.

CONCLUSION

The health condition management service in the telemonitoring format was an important alternative in the pandemic context, allowing for the care of a considerable number of older anticoagulant users possessing a high level of vulnerability. The service also made it possible to carry out essential interventions to promote adequate use of anticoagulants.

Author Statement CREdiT

Conceptualization, Methodology, Validation, Formal Analysis, Writing and revision, Visualization: Ferreira LC; Carmo Junior NM; Peixoto GGSL; Aguiar ALP; Valley EA; Azevedo DC; Nascimento MMG. Research, Elaboration of the original draft, Statistical analysis: Ferreira LC; Carmo Junior NM; Peixoto GGSL; Aguiar ALP; Nascimento MMG. Resources, Supervision, Project administration: Carmo Júnior NM; Valley EA; Azevedo DC; Nascimento MMG.

All authors have read and agreed with the published version of the manuscript.

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