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LOLATAO, an Artificial Intelligence-Based Virtual Assistant for Clinical Follow-Up of Atrial Fibrillation (AF) Patients on Oral Anticoagulant Therapy: (OAT): A Feasibility Study

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LOLATAO, An Artificial Intelligence-Based Virtual Assistant for Clinical Follow-up of Atrial Fibrillation (AF) Patients on Oral Anticoagulant Therapy: (OAT): A Feasibility Study

Running Title: AI-Based virtual Assistant in an Oral Anticoagulation Unit

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Abstract: The aim of this study was to evaluate for the first time the feasibility of implementing LOLA, a speech AI-driven conversational assistant, in monitoring and managing OAT in patients with non-valvular. Methods. In 2023, we conducted a pilot prospective observational study of patients with AF and TAO. All patients received a first contact call from LOLATAO, and then monthly calls, following a predefined protocol by the hematologists . At the end of the study, a satisfaction questionnaire was carried out. Results: Fifty patient. The mean age was 75 years with 33% women. One-third of the patients (n=16) were with antivitamin K treatment and two-thirds (33) with DOACs. A total of 579 calls were made with a median follow-up of 278 days. LOLATAO had high rates of acceptability (85%), adherence (90%) and satisfaction (>95%). 42% of the patients reported at least one forgetfulness dose in the last month, 18% (reported having a scheduled intervention needing bridging therapy. In patients with VKAs , 94% (n=15) reported at least once being unaware of their TRT and, 75% (n=12) of patients reported having a TRT<65%. Those patients in whom TRT was <65% were switched to DOACs. LOLA saved a total of 10 hours per month for the hematologists in the follow-up. **Conclusions:** The study suggests that LOLATAO seems to be a tool to help in the management of chronic follow-up of patients with AF and OAT that reduces the burden of care with high rates of acceptance and satisfaction by patients.

Keywords: virtual assistant ; artificial intelligence; oral anticoagulation ; atrial fibrillation

Introduction

Atrial fibrillation (AF) is the most frequent arrhythmia in adults and its prevalence is expected to double in the next 30 years [1–3]. Also, AF increases five-fold the risk of stroke [4]. Oral anticoagulation therapy (OAT) decreases the risk of cardioembolic stroke and all-cause mortality in patients with non-valvular AF [5–10]. Thus, OAT is the gold standard for the prophylaxis of AF-related stroke [6–8]. Effective OAT implies a lifelong clinical follow-up, including regular assessments of bleeding risk, drug interactions, side effects, dosing adjustments, and control of adherence. Clinical guidelines advocate for a patient-centric and multidisciplinary approach to integrated AF care. This approach emphasises structured follow-up intervals, ranging from every 1 to 6 months, tailored to individual patient factors [6–8,11].

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The growing healthcare burden associated with AF poses challenges for healthcare centres in implementing this comprehensive care model. Digital health tools facilitate coordination among various specialties (such as cardiologists, haematologists, general practitioners, and nurse-led teams) and enhance patient engagement through home-based services [8,12,13]. Multiple e-health solutions have already been used in AF across all stages of the disease with promising results, from screening and diagnosis through mobile or wearable ECG devices [14–18], to computerised decision-making support systems for antithrombotic therapy optimisation [19–22] and point-of-care monitoring of anticoagulation for patients using AVKs [23–25], to mobile health (mHealth) interventions to increase treatment adherence [26,27], manage cardiovascular modifiable risk factors [22,28–31] and improve patient's disease literacy [22,26,27,32].

Conversational agents are a type of mHealth intervention that facilitate automated telephone communication with patients and can therefore enhance health care accessibility and improve the reach of clinical services over face-to-face consultation [33–37]. Due to this heterogeneity, it is very difficult to establish a standardised method for evaluating conversational agents in the health care setting. That is why results from the studies evaluating conversational agents have shown promising but inconsistent effects on their accuracy, user acceptability and effectiveness. Most of the health care conversational agents reported in the literature were predominantly unidirectional and non-AI-driven [33–35] and those incorporating AI technologies were mostly text-based even though speech interactions seem to be more natural and comfortable [36,37]. There are few examples of speech AI-driven virtual assistants in medicine. The importance of these systems falls on its understanding of what the user says (speech recognition), the ability to plan an appropriate reaction (natural language processing), and articulating the response (natural language generation). [38–41].

Nevertheless, voice- assistants like Lola from TUCUVI focus more on customization and adaptation to the specific needs of the user in different clinical contexts. These medical assistants can significantly aid in reducing the workload of healthcare professionals and enhancing patient care efficiency.

Despite this progress, our literature search reveals a critical gap, no AI-driven automated telephone interventions exist for AF patients or monitoring anticoagulation treatment. [30–33,42–45]. Our study aims to address this void and evaluate the potential impact of AI-driven conversational agents in these specific contexts.

Given the existing evidence, the aim of this study was to evaluate for the first time the feasibility of implementing LOLA, a speech AI-driven conversational assistant, in monitoring and managing OAT in patients with non-valvular AF.

Material and Methods

Study Design and Population

From 1st January 2023 to 31st December 2023, we conducted an observational prospective study in our Anticoagulation Unit of our Digital unit [46,47] the University Vinalopó Hospital. Approval was obtained from the local ethics committee. (date 22-10-2022, Code ID:LOLA_TAO). Patients were recruited consecutively in our ambulatory facilities. The inclusion criteria included: (1) aged ≥ 18 years, (2) a documented diagnosis of non-valvular AF, (3) receiving OAT, (4) had a mobile phone that was able to receive calls, and (5) were competent in the Spanish language. Participants were excluded from the study if they (1) had a medical illness with anticipated life expectancy of <6 months, (2) were unable to provide written consent, or (3) had a concomitant illness or physical impairment (for example hearing impairment), or mental condition that in the opinion of the study team or the primary physician could interfere with the conduct of the study, including outcome assessment.

The study was based on the use of an AI-based voice virtual assistant (LOLA), a medical device from the company Tucuvi Care SL. It is compliant with European GDPR and certified by ISO 27001 and ENS. It is a voiced-based conversational technology that performs AI-driven automated phone calls. This technology simulates human conversations with proper responses to dialogue. LOLA can

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analyse verbal speech using VRS and NPL. Then, it uses a speech-to-text algorithm to obtain and codify data in a structured database. (See Figure 1).

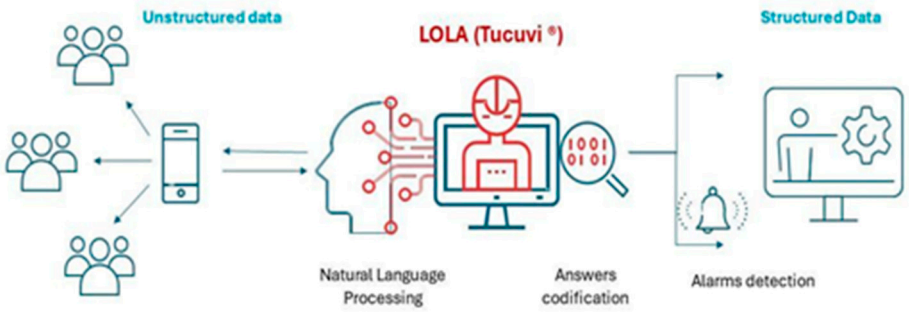

Figure 1. Lolatao At A Glance.

The protocol study workflow, chronogram and the different protocols designed by OAT Treatment are represented in Supplemental Figure 1.

First, the medical team established a protocol of questions and possible answers for each type of OAT and defined which answers to interpret as an "alert" by the virtual assistant. (See Supplemental Table 1). Then, regular screening of upcoming patient appointments was conducted by the research team to identify potential participants during a 6-month period (From January to June 2023). These participants were approached (1) face-to-face during their visit to obtain written consent, or (2) over the telephone before they attended their scheduled appointment. If they met the inclusion criteria a research staff member arranged a personal meeting with the prospective participants. All interested participants received an information sheet and a consent form describing the study and providing sufficient information for the participant to decide regarding study participation. Afterward, the consent form was signed by both the participant and the research staff before the participant undertook any study procedure. Eligible individuals who provided informed consent were asked to complete a baseline assessment and demographic data were collected. After baseline data collection, patients were registered in Tucuvi Dashboard, an AI web platform (See Supplemental Figure 2), and were assigned a predefined protocol according to the type of OAT.

Table 1. Demographic Characteristics and Type of OAT Treatment.

Demographics						
	AVKs (n=16)		**DOACs** (n=33)		**Total** (n=49)	
	Male	Female	Male	Female	Male	Female
Age (mean, range)	n=12	n=4	n=29	n=11	n=33	n=16

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Type of DOAC (n=33)						
Edoxaban (n, %)	7 (21%)					
Rivaroxaban (n, %)	11 (33%)					
Apixaban (n, %)	12 (36%)					
Dabigatran (n, %)	3 (9%)					

Once the patients were included in the web platform, outreaches from LOLA occurred at 24 to 48 hours from the baseline assessment to welcome the patient to the study and inform about the follow-up process (Initial phone call) and then monthly until the end of the 12-month follow-up period (follow-up phone calls). When LOLA detected that an answer fulfilled the definition of alert, a notification was sent to the physician in charge of the patient. Then, the physician reviewed the answer and medical history of the patient and decided whether to perform an intervention or not. At the end of the study, the patients received a phone call with a satisfaction questionnaire (final phone call).

The primary outcome of the study was to assess the acceptability, adherence, and satisfaction of implementing LOLA, an AI-based conversational agent to follow-up AF patients on OAT. The secondary outcomes were to analyse the usability and clinical utility of LOLA. The summary of the parameters evaluated are in Table 2. Acceptability was evaluated measuring the percentage of patients that signed the informed consent of the total of eligible patients. During follow-up, the adherence to the program was evaluated monthly through program engagement metrics (number of answered telephone calls, number of completed telephone calls). Usability of the patients was evaluated by measuring the duration time of each phone call and the usability of the medical doctors by measuring the number of alerts revised and interventions performed. Intervention and alert use metrics were automatically collected through the AI-based conversational agent system and website analytics. Clinical outcomes were evaluated monthly by measuring the number of clinical situations detected, the concordance between the alerts detected and the clinical condition referred by the patient and the number of hours of the medical team saved by the AI-conversational agent. The clinical situations detected were classified as: medication adherence (self-reported), health events (self-reported and medical records) and healthcare service use (self-reported, medical records). The medical team revised the concordance between the alerts detected and the medical records/patient contact to assess if the alerts detected were related to actual clinical events. The number of hours of the medical team saved by LOLA was calculated automatically as a formula based on total calls made to the patients and the time that the doctor would have needed to conduct a follow-up call. To calculate the time spent by a doctor vs. LOLA, it was taken into account that LOLA is 20% more efficient than a human being in terms of follow up visits. On the other hand, the time it would take a person to prepare for the call is also taken into account, (almost 2 minutes). Satisfaction was evaluated at the end of the study by a study-specific questionnaire, Net Promoter Score (NPS) y Customer satisfaction (CSAT) performed also through LOLA. [48,49]

Table 2. patient and Clinical Outcomes.

OAT Adherence			
Medication doses missed	**AVKs (n =16)**	**DOACs (n=33)**	**Total (n=49)**
0	10 (63%)	18 (55%)	28 (58%)

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1	4 (25%)	5 (15%)	9 (18%)	
2	1(6%)	7 (21%)	8 (16%)	
≥3	1(6%)	3 (9%)	4 (8%)	
Health Events				Concordance (n, %)
≥1 Bleeding event	14 (88%)	5(15%)	19(39%)	19 (100%)
Bridging therapy	1(6%)	8(24%)	9(18%)	9 (100%)
Renal function impairment (TFG <60)	-	14(42%)	NA	8 (57%)
Unknown TRT	15(94%)	NA	NA	15 (100%)
TRT <65%	12(75%)	NA	NA	9 (75%)
Healthcare service use				
Emergency department	5(31%)	12(36%)	17(35%)	17 (100%)
Hospitalization	0(0%)	3(9%)	3(6%)	3 (100%)

Statistical Methods

We calculated descriptive statistics, including means, medians and ranges. Although the sample size was insufficient for meaningful regression analysis, we also tested for differences across age and gender groups using 2-tailed t tests and chi-square tests. The power for these comparisons was low; therefore, this analysis was an exploratory evaluation that may be important to future study design.

Results

This pilot study enrolled a cohort of 50 patients, from which one was excluded posthumously from the analysis. The mean age was 75±16 years-old and most of them were male (33% women). Regarding OAT, one third of the patients were on AVKs (n=16) and two thirds on DOACs (n=33). (See Table 1).

The workflow during the study is resumed in Figure 2. Oral anticoagulant therapy was administered, with a division of one third on Vitamin K Antagonists (AVKs) and two thirds on Direct Oral Anticoagulants (DOACs). Throughout a median follow-up period of 278 days, a total of 579 telephone calls were conducted, comprising 50 initial, 480 follow-up, and 49 final calls, with an average duration of 3 minutes and 17 seconds per call (range: 3.05 -3.81). The study detected 296 alerts, which led to 55 interventions by the medical team. At the end of the study, the team saved more than 110 hours / year by using LOLATAO.

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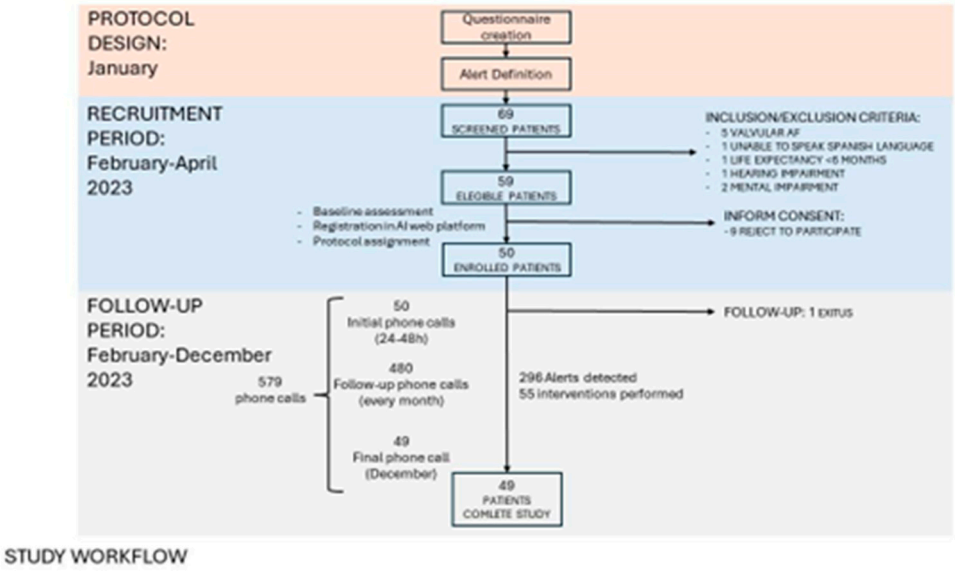

Figure 2. Study Workflow.

LOLATAO demonstrated high acceptability at 85% and adherence at 90%, maintaining these rates consistently over the follow-up period. Despite the number of alerts remaining constant, the frequency of interventions decreased, with only 19% of alerts necessitating an intervention. Clinical outcomes revealed that approximately 40% of patients reported missing at least one dose in the previous month, with no significant difference between AVKs and NOACs. The clinical issues identified included bleeding events, the necessity for bridging therapy, renal function impairment, unknown therapeutic range time (TRT), and TRT below 65%, with the latter two showing lower concordance rates of 57% and 65%, respectively. It is noteworthy that over 90% of patients on AVKs were initially unaware of their TRT, but after education, only a quarter of those who reported a TRT below 65% actually had such rates. (See Table 2). Regarding renal impairment, 40% of the patients were already affected before starting the study, yet none required dose adjustments during the follow-up. Bleeding events occurred in 40% of the cohort within the last month, more frequently among those on AVKs, albeit all incidents were minor. About 20% of patients had scheduled surgical interventions within the forthcoming month, with bridging therapy being more prevalent among those on NOACs due to AVK users planning their surgical procedures during INR control visits. In terms of healthcare service utilisation, 36% of patients visited the emergency department, and 6% required hospitalisation, none of which were related to OAT. LOLA shows a high acceptability and adherence were further evidenced by the 85% participation rate among eligible patients, with more than 90% of follow-up calls answered and completed. The stability of alert numbers contrasted with a decline in interventions, where only 19% of detected alerts led to an intervention. (See Supplemental Figure 3)

Initially, the agreement between LOLATAO and the alerts was low, but as a pilot study as time progressed it improved over time as the assistant was trained to better discriminate alerts, and the medical team adjusted the alerts accordingly. By the end of the study, the concordance was high enough that few interventions or unscheduled visits by the haematologist team were required. Adherence data from the 480 follow-up calls indicated that up to 92% responded to the calls, and 91% completed them. The survey showed a high satisfaction measured by NPS and CSAT (see Table 3).

Table 3. Results of Satisfaction Surveys.

Questionnaire	Result	Explanation

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CSAT	4.63/5	all patients except 1 answered being satisfied or very satisfied with LOLA. 1 patient answered a 3 (neutral)
NPS	44.73%	38 patients answered this question. Only 5 of them gave a punctuation lower than 7

Discussion

To the best of our knowledge, this is the first evaluation of an AI conversational technology to support AF anticoagulation-integrated care , and our findings contribute to the growing body of research on the use of AI in healthcare. Our findings achieve the primary goal of the study, demonstrating the practicality of deploying an AI-Conversational agent for monitoring Oral Anticoagulant Therapy (OAT) in Atrial Fibrillation (AF) patients within the hybrid haematology unit. [46] This aligns with our strategic trajectory of digital transformation, where telemedicine has been successfully integrated into the management of anticoagulated patients in the Anticoagulation (TAO) Unit.[47]. It is noteworthy that LOLATAO enables a more thorough follow-up compared to traditional methods, ensuring higher levels of engagement and adherence. It liberates physicians from the time-intensive follow-up process, allowing prioritisation of care for those in need over stable patients. With only 37% of calls triggering an alert but only 19% needed an intervention, over 60% required no review, enabling us to discern critical alarms and necessitate a telematic visit, thus reducing physician calls by over 60% and, consequently, the healthcare burden.

This investigation is pioneering in presenting data on the viability of a cutting-edge AI-Conversational agent for the standard follow-up of OAT in AF patients. It offers an in-depth assessment of the implementation process, as well as the acceptability, adherence, satisfaction, and clinical value of this digital healthcare intervention. In doing so, it fills a knowledge void regarding the role of AI-Conversational automated monitoring in aiding patients with chronic conditions and, for the first time, establishes a customised follow-up plan tailored to the unique attributes of each patient.

Presently, various virtual assistants exist, each underpinned by distinct machine learning models. For instance, Lola has been documented for tracking COVID-19 patients. A review of clinical trials reveals that merely five studies meet the specified eligibility criteria, yet none resemble the virtual assistant Lola. [39–45]

The study also addresses critical issues concerning the adherence and educational deficit among OAT patients and concurs with extensive research on this topic [50]. Clinically, LOLATAO has underscored the need for diverse healthcare professionals and clinicians to educate patients about the importance of adherence, even post-development of any safety or efficacy outcomes. In conventional anticoagulation units, the high demand for care makes such comprehensive, monthly patient monitoring challenging [50]. For that reason, the haematologist team has played a crucial role in the implementation of LOLATAO in the OAT Unit. LOLATAO needs to be programmed to obtain the better results, so the investigational team, the haematologists, contributed to the process with the clinical expertise providing the essential medical knowledge required to program and fine-tune LOLATAO. So that, they play crucial roles in the implementation and operation of LOLATAO, ensuring that the system is clinically effective, patient-focused, and continuously improving. Their role encompasses both the technical aspects of programming and adjusting the AI system, as well as the human aspects of patient care and education. After the pilot study, now LOLATAO is ready to be implemented in other anticoagulation Units.

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With regards to the significance of the study, it is noteworthy that results underscore the promising role of AI-based virtual assistants in enhancing patient management for FA in TAO, potentially leading to more tailored and efficient healthcare solutions.

This study's limitations include being conducted at a single institution with a small cohort and brief follow-up. It also lacked a control group and had a gender imbalance.

Several Implications of the study are that conversational AI interventions hold the potential to augment clinical care by providing continuous patient support between visits. Future software advancements should aim to integrate such systems with existing electronic medical records in both primary and secondary care settings, representing a significant hurdle for the health information technology industry. Facilitating clinicians' direct access to data gathered by the system, such as risk assessments and symptom evaluations, would mark a pivotal advancement in the integration of AF care.

Therefore, LOLATAO, as an AI-assistant in anticoagulation management, has proven through our pilot study to enable tighter control, reduce care demand without compromising quality, and provide personalised attention, all while achieving high patient satisfaction among anticoagulated individuals.

Also, the information obtained as secondary objectives of the study, gave us the information related to the practical value or usefulness of an artificial intelligence (AI)-driven assistant based on data collected during a preliminary study. Such studies are essential for assessing the actual clinical performance of AI systems, ensuring safety, evaluating human factors, and paving the way for larger-scale trials.

Artificial Intelligence (AI) can significantly enhance healthcare outcomes for patients with FA through various means such as a personalised care due to that LOLATAO can make a vast amounts of patient phone calls and obtain data and provide personalised interventions, leading to improved patient outcomes, also a better effectivity in treatment due to the ability to automate outreach based on patient journeys, support clinical adherence, and engage patients effectively, and what is also very important of the healthcare workforce support, meanwhile LOLATAO automates this task, healthcare professionals can focus more on meaningful interactions with patients, positively affecting health outcomes.

In summary, AI-driven assistant LOLATAO has the potential to transform the care experience for OAT patients by offering personalised, efficient, and integrated healthcare solutions. The use of LOLATAO in clinical practice may reduce the need for frequent monitoring and interventions, leading to cost savings and improved patient outcomes and saving the patient multiple visits to health services. Further investigations are essential to evaluate the clinical impact of such interventions.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org

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Conflicts of Interest: No competing interest.

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