

# ผลของการใช้คลิปวิดีโอให้ความรู้และโทรศัพท์ติดตามในผู้ป่วยที่ใช้วาร์ฟาริน ต่อผลลัพธ์ทางคลินิก ความรู้ และความร่วมมือการใช้ยา Effects of Educational Video Clips and Follow-up Phone Calls on Clinical Outcomes, Knowledge, and Medication Adherence in Patients on Warfarin

พิมพ์ต้นฉบับ

Original Article

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## บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาผลของการใช้คลิปวิดีโอให้ความรู้และโทรศัพท์ติดตามเปรียบเทียบกับการดูแลแบบปกติในผู้ป่วยที่ใช้วาร์ฟาริน **วิธีการศึกษา:** การวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุม กลุ่มตัวอย่าง คือ ผู้ป่วยในคลินิกวาร์ฟารินศัลยกรรมทรวงอก ที่มีค่า International Normalized Ratio (INR) อยู่นอกช่วงเป้าหมาย 160 ราย สุ่มแบ่งกลุ่มด้วยวิธีแบ่งเป็นบล็อก เป็นกลุ่มควบคุม (ดูแลแบบปกติ) และกลุ่มทดลอง กลุ่มละ 80 ราย การแทรกแซงคือ ให้ความรู้เรื่องวาร์ฟารินผ่านคลิปวิดีโอภาษาไทยหรือมัลติมีเดียร่วมกับโทรศัพท์ติดตามโดยเภสัชกร หลังการแทรกแซงเปรียบเทียบผลลัพธ์ระหว่างกลุ่ม คือ ร้อยละของผู้ป่วยที่มีค่า INR อยู่ในช่วงเป้าหมาย ใช้สถิติ chi-square test ค่าเฉลี่ยระยะเวลาที่ INR อยู่ในช่วงเป้าหมาย (%Time in therapeutic range; %TTR) ความรู้เกี่ยวกับวาร์ฟาริน และความร่วมมือใช้ยาด้วยวิธีนับเม็ดยา ใช้สถิติ independent t-test ส่วนความร่วมมือใช้ยาด้วยแบบวัด MAST ใช้สถิติ Mann Whitney U test **ผลการศึกษา:** 1 เดือนหลังการแทรกแซง กลุ่มทดลองมีร้อยละของผู้ป่วยที่มีค่า INR อยู่ในช่วงเป้าหมาย คะแนนความร่วมมือในการใช้ยา (ทั้งการนับเม็ดยาและ MAST) และคะแนนความรู้ มากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (P-value = 0.039, < 0.001, < 0.001 และ 0.043 ตามลำดับ) 3 เดือนหลังการแทรกแซง กลุ่มทดลองมีร้อยละของผู้ป่วยที่มีค่า INR อยู่ในช่วงเป้าหมาย และ %TTR มากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (P-value = 0.035 และ 0.041 ตามลำดับ) **สรุป:** คลิปวิดีโอให้ความรู้และการโทรศัพท์ติดตามโดยเภสัชกร ทำให้ผู้ป่วยมีค่า INR อยู่ในช่วงเป้าหมาย %TTR ความร่วมมือใช้ยา และความรู้เกี่ยวกับวาร์ฟารินมากกว่าการดูแลแบบปกติ ควรสนับสนุนในคลินิกวาร์ฟารินให้กว้างขวาง

**คำสำคัญ:** วาร์ฟาริน; โทรศัพท์ติดตาม; ค่า INR; ความร่วมมือในการใช้ยา; คลิปวิดีโอให้ความรู้

## Abstract

**Objective:** To evaluate the effects of educational video clips and follow-up phone calls compared to standard care in patients on warfarin. **Methods:** In this randomized controlled trial, 160 patients from a clinic for thoracic surgery and warfarin treatment with International Normalized Ratio (INR) levels outside the target range were randomly assigned to either the control group (standard care) or the intervention group by block randomization (80 each). The intervention included warfarin education via Thai or Malay video clips, along with follow-up phone calls by a pharmacist. Outcomes were compared between groups, measured by the percentage of patients with INR within the target range (using the chi-square test), %Time in Therapeutic Range (%TTR), warfarin knowledge, and medication adherence. Adherence was assessed by pill count (using the independent t-test) and the Medication Adherence Scale for Thais (using the Mann-Whitney U test). **Results:** One-month post-intervention, the intervention group showed significantly higher percentages of patients with INR within the target range and medication adherence scores (pill count and MAST), also better knowledge (p=0.039, <0.001, <0.001, and 0.043, respectively). Three months post-intervention, the intervention group had significantly higher INR within the target range and %TTR compared to the control group (p=0.035, 0.041). **Conclusion:** Video clips and pharmacist follow-up calls significantly improved INR control, %TTR, medication adherence, and warfarin knowledge in patients compared to standard care. This intervention should be continued in warfarin clinics.

**Keywords:** warfarin; telephone follow-up; INR; medications compliance; educational video clip

## Editorial note

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## Introduction

Warfarin is an anticoagulant medication indicated for the prevention and treatment of thromboembolic events. It has a narrow therapeutic index<sup>1</sup>, meaning that its safe and effective use requires careful monitoring. The effectiveness and safety of warfarin therapy are commonly assessed by the International Normalized Ratio (INR). The appropriate target INR for treatment depends on the specific indication for warfarin use. For patients with valvular heart disease

(VHD) or those who have undergone valve replacement surgery with either tissue or mechanical prosthetic valves, the target INR is typically in the range of 2.0 to 3.0. In contrast, patients with high-risk mechanical prosthetic valves should maintain an INR target between 2.5 and 3.5. Along with the INR value, the Time in Therapeutic Range (TTR), which reflects the percentage of time that the INR is within the therapeutic range, is also used to evaluate the

effectiveness and safety of warfarin treatment. Maximizing TTR is crucial to optimizing the therapeutic benefits and minimizing the risks associated with warfarin use. High-quality anticoagulation management (HQACM) is recommended for patients on long-term warfarin therapy or those who have been using warfarin for at least one month, with the standard TTR target set at 60-70%<sup>2</sup>. When INR levels fall outside the target range, patients are at increased risk of adverse events such as bleeding or thromboembolic complications. Therefore, it is essential to maintain INR within the target range to ensure both the safety and effectiveness of warfarin therapy<sup>3</sup>.

Several factors may contribute to INR levels being outside the target range, including medication non-adherence, drug or food interactions with warfarin, alcohol consumption, smoking, and changes in health status such as fever or diarrhea<sup>2</sup>. Research, both locally and internationally, has shown that the most common cause of INR levels outside the target range is medication non-adherence<sup>4,5</sup>. This condition includes failure to take medication or self-discontinuation (75%), incorrect dosing (25%), and the use of medications or supplements that interact with warfarin (9.3%)<sup>5</sup>. The primary cause of non-adherence is a lack of understanding regarding the disease and proper medication usage, accounting for 91.3% of cases<sup>6</sup>.

Pharmacists play a key role in improving medication adherence by providing patients with accurate information about warfarin and closely monitoring their treatment. Literature reviews indicate that providing educational materials, such as Digital Versatile Disks or videos, can significantly improve patients' knowledge about warfarin<sup>7,8,9</sup> and increase their TTR<sup>9</sup>. A study by Ababneh et al. found that warfarin knowledge was positively correlated with medication adherence, and patients who adhered to their medication regimen had better INR control compared to those who did not<sup>10</sup>. Furthermore, educational videos have been used effectively in the management of other diseases, such as diabetes<sup>11</sup>, chronic obstructive pulmonary disease (COPD)<sup>12,13</sup>, osteoarthritis<sup>14</sup>, and in patients with ostomies<sup>15</sup>, leading to increased knowledge. Additionally, studies have shown that telephone follow-up can help patients maintaining their INR within the therapeutic range<sup>16,17,18</sup>. For example, a study by Al Ammari et al. employed WhatsApp to track INR results, with pharmacists following up by phone

to explain the results and adjust treatment plans. This approach resulted in 59.39% of patients achieving their target INR, with 30% maintaining a TTR greater than 70%.<sup>16</sup> Another study by Wipa Thamthinno found that telephone follow-up improved INR results, with 64.44% of patients maintaining INR within the target range.<sup>17</sup> A study by Sudas Na Ayutthaya demonstrated that telephone follow-up after hospital discharge improved INR control and TTR in the intervention group compared to the control group. Pharmacists also identified medication-related issues during telephone follow-ups and provided solutions to enhance patient outcomes.<sup>18</sup> Telephone-based follow-up is a convenient approach that has been well received by patients<sup>17</sup>. Additionally, it is more cost-effective than in-person clinic visits for follow-up<sup>19</sup>. Therefore, telephone follow-up serves as an effective method for monitoring patients on warfarin therapy, helping them maintain INR levels within the therapeutic target range.

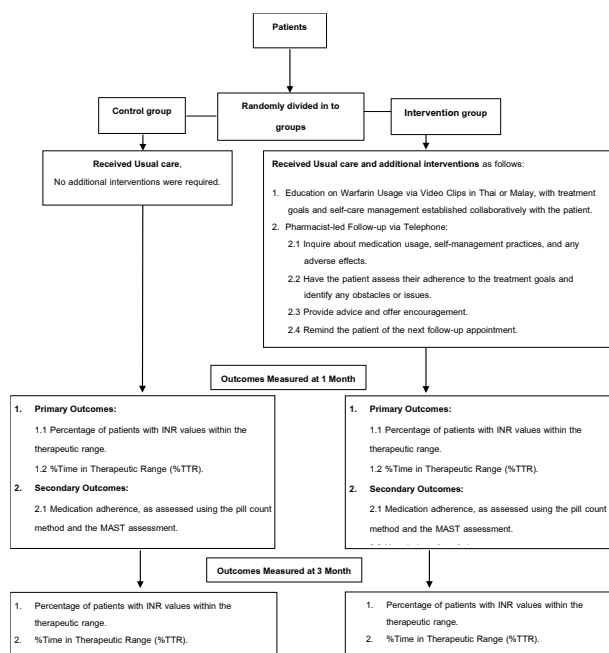
At Yala Hospital's Warfarin Surgery Clinic, from October 1, 2020, to September 30, 2021, only 50.2% of patients had their INR within the target range, which is below the 65% threshold recommended by the Thai Cardiovascular Association.<sup>2</sup> Data collected by the pharmacist at the clinic revealed that the primary cause of INR levels outside the target range was medication non-adherence. The clinic operates twice a week (Monday and Thursday, from 8:30 AM to 12:30 PM) with one physician available each day, serving approximately 350 patients. According to guidelines for oral anticoagulation therapy, patients with INR levels outside the target range should ideally be followed up within two weeks. However, due to the high volume of patients, including those from outlying areas who may have difficulty attending frequent visits, follow-up is typically scheduled every month  $\pm$  one week. Non-adherence to medication can result in prolonged periods of suboptimal INR control, increasing the risk of adverse drug events. Therefore, there is a need for strategies to ensure that patients maintain their INR within the target range and receive continuous follow-up care. The researcher has chosen to combine video-based education about warfarin with pharmacist-led telephone follow-up for patients whose INR is outside the therapeutic range.

To date, no studies have examined the combined use of two adherence-enhancing strategies—video education and pharmacist-led telephone follow-up—in the context of

warfarin therapy. Additionally, Yala Hospital has not implemented this approach. Therefore, this study aims to evaluate the effectiveness of combining video education on warfarin with pharmacist-led telephone follow-up as an adjunct to standard care. The study will assess the impact on clinical outcomes, medication adherence, and patients' knowledge of warfarin, with the goal of applying the findings to improve and develop future protocols for managing patients on warfarin therapy.

## Methods

This research was approved by the Human Research Ethics Committee of Yala Hospital, under protocol number 19/2564, dated February 10, 2022. This is a randomized controlled trial with two groups: an intervention group and a control group. The research profile is illustrated in Figure 1.



**Figure 1** Study profile.

### Research Hypothesis

After the intervention, which includes educational videos on warfarin usage combined with pharmacist-led telephone follow-up as an adjunct to routine care, it is hypothesized that the intervention group will have a higher proportion of patients with INR levels within the therapeutic range, a longer time spent within the therapeutic range, better medication adherence, and increased knowledge of warfarin compared to the control group, which will receive only routine care.

### Population, Sample Size, and Sampling Method

The population of this study includes patients attending the Warfarin Surgery Clinic at Yala Hospital who had INR levels outside the therapeutic range at the time of study enrolment, totaling 168.

The sample consists of patients from the Warfarin Surgery Clinic at Yala Hospital who had INR levels outside the therapeutic range at the time of study enrolment and met the inclusion criteria, totaling 160 patients. Data collection took place between February 14, 2022, and September 30, 2022.

### Sample Size Calculation

The sample size for each group was calculated using a formula to compare the proportions of two independent groups. A significance level of 0.05 (alpha) and a power of 0.80 (beta) were set. The formula used was:  $N/\text{group} = \frac{2(Z\alpha + Z\beta)^2 P(1-P)}{(P_1 - P_2)^2}$  where  $P = (P_1 + P_2) / 2$ . Referencing a randomized controlled trial by Sudas Na Ayutthaya et al., which investigated the impact of pharmacist-led telephone follow-up on warfarin therapy after hospital discharge, the study found that the telephone follow-up group (n=25) had 45.6% of patients within the therapeutic INR range, compared to 24.1% in the control group (n=25) ( $p < 0.05$ ).<sup>18</sup> Substituting values into the formula:

$$P = (0.46 + 0.24) / 2 = 0.35; 2(1.96 + 0.84)^2 0.35(1 - 0.35) / (0.46 - 0.24)^2 = 74.$$

After adjusting for a 10% attrition rate, the final sample size per group is 80, with a total sample of 160 participants.

### Sampling Method

A blocked randomization method was employed, dividing participants into intervention and control groups, each containing 80 participants. The inclusion criteria for the study: 1. Patients from the Warfarin Surgery Clinic at Yala Hospital. 2. Age 18 years or older. 3. Currently using warfarin continuously for more than 3 months, with INR levels outside the therapeutic range on the day of enrolment. This class includes patients with valvular heart disease or those who have undergone tissue heart valve replacement (INR outside the range of 2.0 - 3.0) or mechanical prosthetic valve replacement (INR outside the range of 2.5 - 3.5) for high-risk cases. 4. Willingness to participate in the study. 5. Ability to communicate with the researchers. 6. Owns a mobile phone and is capable of using it. Exclusion criteria include: 1. Patients with psychiatric disorders (ICD-10: F00

- F99). 2. Patients with chronic kidney disease (ICD-10: N17 - N19). 3. Patients with liver diseases (ICD-10: K70 - K77). 4. Patients with thyroid disorders (ICD-10: E00 - E07). 5. Patients referred to other healthcare facilities due to difficulties in follow-up. 6. Patients currently hospitalized as inpatients due to unstable medical conditions that could affect INR values.

#### **Standard Care Protocol for the Warfarin Thoracic Surgery Clinic at Yala Hospital**

The Thoracic Surgery Warfarin Clinic operates every Monday and Thursday from 8:30 AM to 12:30 PM. The process begins with the patient having a blood draw by a medical technologist to measure the INR value. Afterward, the patient meets with a nurse at the entrance of the examination room for thoracic surgery for a medical history interview. Following this, the patient consults with the physician, who prescribes medication. After completing the consultation, the patient goes back to the nurse to receive an appointment slip. The patient will then meet with the clinic's pharmacist in the individual counselling room; (the clinic has two pharmacists, including the researcher). All patients participating in the research will receive standard care from a non-researcher pharmacist. The counselling room is adjacent to the outpatient pharmacy dispensing area. The pharmacist will enquire about the patient's medication regimen to ensure that the patient is taking the medication correctly and consistently and to check for any side effects. If any issues with medication usage are identified or if the physician has prescribed an inappropriate medication, the pharmacist will immediately contact the physician for further consultation. After confirming the appropriateness of the medication, the pharmacist will dispense it to the patient, providing detailed instructions on how to take it. If the physician adjusts the warfarin dosage, the pharmacist will create a label with a picture and explain the dosage instructions. The pharmacist provides the patient with an identity book on the first day of warfarin use. This identity book is supported by the pharmaceutical company and includes information about the warfarin medication (its strength and tablet color), the indications for its use, which patients need it, abnormal symptoms that require notification to the physician or pharmacist, how to take the medication, what to do if a dose is missed, the reasons for blood tests, factors that affect the INR value, foods that affect warfarin, additional behavioral recommendations, and a patient record

table. This table includes the date of medication, dosage, INR value, dosage adjustments, and the next appointment date. The content in the book is written in Thai, and patients can read it independently. The pharmacist will record the INR value and any dosage adjustments in the identity book. The patient will then have the opportunity to ask any questions they may have.

#### **Intervention**

1. The researcher provided education about warfarin to patients in the intervention group using a bilingual video (Thai and Malay). The video was produced by the researcher, using content from the patient's warfarin identity book and additional information about warfarin derived from literature reviews. The video content was reviewed for accuracy and appropriateness by a warfarin clinic pharmacist specializing in internal medicine and a pharmacist with expertise in cardiovascular care. The video content was translated from Thai to Malay using the translation-back translation method by two experts proficient in both Thai and Malay. These experts are Thai nationals who studied at an Islamic school and graduated at the Sanawi level, which qualifies them as proficient in the use of the Malay language.

The video consists of animated visuals with voice-over in both Thai and Malay. Each version of the video includes three episodes:

Episode 1: Introduction to Warfarin. This section explains the medical conditions treated by warfarin, the different brands and strengths of warfarin available on the market, and the colors of warfarin tablets based on their dosage: 2 mg is orange, 3 mg is blue, and 5 mg is pink. The video emphasizes the importance of adhering to the physician's prescribed dosage and not adjusting it independently.

Episode 2: Blood Test for INR Measurement. This segment explains what INR is, the ideal INR range, and what happens if the INR falls outside the target range. It also teaches the patient how to identify adverse drug reactions and manage them.

Episode 3: Foods and Herbs to Avoid and Behavioral Guidelines. This section provides information on foods and herbs that may interact with warfarin, as well as behaviors that could increase the risk of adverse drug reactions, such as vigorous massage.

The warfarin identity book included a QR code that linked to the video, which the researcher presented to the patients via an iPad. The device allowed patients to access the video and review it as needed. Afterward, the researcher provided an opportunity for the patients to ask questions. The researcher and patient collaboratively set treatment and behavioral goals, which included the following: 1. The patient's INR value to fall within the target range at their next scheduled physician visit. 2. Behavioral Goals: To maintain the INR within the target range by adhering to three key practices: 2.1. Consistency in taking the medication as prescribed. 2.2. Avoiding foods, herbs, or supplements that interact with warfarin. 3. Refrain from behaviors that may increase the risk of adverse effects from the medication, such as vigorous physical activities (e.g., forceful massage). The researcher informed the patient that a follow-up call would be made after 14 days, in accordance with the recommended timeframe for monitoring patients whose INR values are outside the target range.

#### Study outcomes

The **primary outcomes** consist of two main components:

##### The Number of Patients with INR within the Therapeutic Range

This is calculated by determining the proportion of patients with their INR values within the therapeutic range, relative to the total number of patients in the group.

#### %Time in Therapeutic Range (%TTR)

This is calculated using Roosendaal's linear interpolation method. The calculation is performed as follows:

$\%TTR = (\text{Number of days the INR is within the target range} / \text{Total number of days}) \times 100$  Where: Number of days the INR is within the target range =  $(\text{Number of INR intervals within the target range} / \text{Total number of INR intervals}) \times \text{Number of days the patient was on warfarin}$ . The researcher calculates the %TTR using a formula in Microsoft Excel. For example, Patient 1 has a target INR range of 2.0 - 3.0. The patient's INR values for two measurements are: INR at measurement 1 = 1.50 and INR at measurement 2 = 2.30. The total INR interval is  $2.30 - 1.50 = 0.8$ . To make it countable, multiply by 10, meaning that from 1.5 to 2.3, there are 8 intervals in total. The INR values that fall within the

target range (2.0 - 2.3) constitute 3 intervals. The total duration the patient was on warfarin is 90 days. Therefore, the duration of time the INR was within the target range is  $(3/8) \times 90 = 33.75$  days. Converting this to a percentage:  $\%TTR = 37.5\%$ .<sup>20,21</sup>

The **secondary outcomes** consist of two main components:

#### Medication Adherence

Medication adherence was assessed using two methods:

**Method 1: Involves counting the remaining warfarin tablets.** Only warfarin tablets are counted. If the patient does not bring the remaining tablets, an interview is conducted to ask the patient how many warfarin tablets are left. To find out how many tablets are left, the researcher will give the patient a call after they get home. The adherence percentage is calculated using the following formula:

$\% \text{ Medication Adherence} = [(\text{Total number of tablets} - \text{Remaining tablets}) / \text{Total number of tablets}] \times 100$

**Method 2: Involves the use of the MAST questionnaire.** The patient independently completes the MAST questionnaire, and the scores are aggregated.<sup>22</sup>

#### Knowledge about Warfarin

Patients were asked to complete a self-administered quiz to assess their knowledge of warfarin. The total score from the knowledge test was then compiled.

In summary, the study assessed four outcomes in total: two primary outcomes (INR within the target range and %TTR) and two secondary outcomes (medication adherence and knowledge of warfarin).

#### Research Instruments and Quality Testing of the Instruments

##### Patient Data Record Form

This form was created by the researcher to record five sections of information: 1. General information: Gender, age, religion, education level. Data was collected from the HOSxP system, along with patient interviews. 2. Comorbidities and indications for warfarin use: Data was obtained from the HOSxP system. 3. INR Values: Data was obtained from the HOSxP system. 4. Adverse Drug Reactions (ADR) from warfarin: Information was gathered from the physician's notes in the HOSxP system and patient interviews were conducted by the clinic's pharmacist. 5.

Medication Adherence: Data was recorded from both the pill count method and the MAST questionnaire.

#### **Telephone Interview Data Record Form**

This form was created by the researcher to record answers to questions asked during telephone interviews. The seven questions are as follows: 1. Can you follow the treatment goals that were set? 2. How do you take warfarin? 3. Do you take warfarin consistently? How many times have you missed doses? If you missed a dose, what did you do? 4. Do you take any other medications, herbs, or dietary supplements? 5. Have you experienced any side effects from the medication, such as blood in the urine, stool, bruising on the skin, weakness on one side of your body, stiff tongue, or drooping mouth? 6. Do you engage in any behaviors that may increase the risk of adverse drug reactions, such as traditional Thai massage or intramuscular injections? 7. Reminder to schedule your next doctor's appointment.

#### **Medication Adherence Scale for Thai Patients (MAST)**

The MAST was developed by Jongwilakasem and Lerkiatbundit (2021). The scale has a Cronbach's alpha coefficient of 0.87 for test-retest reliability. It also demonstrates strong content validity, with an  $r$  value of 0.56 – 0.64 ( $P < 0.001$ ) between MAST scores and medication adherence (pill count) at months 0, 2, 4, and 6. The score range is 0 to 40, with 8 items covering: 1. Consistency of medication use (items 1, 5, 6). 2. Incorrect medication-taking behaviors, such as self-adjusting the dose, stopping the medication, or irregular dosing (items 2, 3, 4). 3. Adherence to appointments and missed doses (items 7, 8).<sup>22</sup> The researcher translated the MAST scale from Thai to Malay using the translation-back translation method with the help of two experts fluent in both languages.

#### **Knowledge Test on Warfarin Use**

The knowledge test on warfarin use was developed by Phornsiri Udomdechana and colleagues. It has item-level content validity indices (I-CVI) ranging from 0.83 to 1.00 and a Cronbach's alpha coefficient of 0.76 for reliability.<sup>23</sup> The original version contained 30 multiple-choice questions. However, due to time constraints and feedback from 10 patients (who found the original 30-item test too long), the researcher selected a 15-item version. The test covers 7 topics: 1. Warfarin 2. Warfarin administration 3. Laboratory

monitoring 4. Adverse drug reactions and behavior 5. Drug, herb, and supplement interactions 6. Dietary behavior related to warfarin 7. Daily lifestyle behaviors affecting warfarin. The researcher translated the test from Thai to Malay using the translation-back translation method with the help of two experts fluent in both languages. Content validity was assessed by three experts (one physician, one nurse, and one pharmacist from the warfarin clinic), resulting in an item-objective congruence (IOC) index of 0.67 – 1.00. The test's reliability was tested by administering it to 30 warfarin clinic patients who were not taking part. The results showed a Cronbach's alpha coefficient of 0.71, indicating the test was valid and reliable.

#### **Data Collection Process and Procedure**

The researcher assigned another pharmacist from the Thoracic Surgery Warfarin clinic to provide regular care to the patients. If a patient had an INR value outside the target range, the pharmacist would refer that patient to the researcher. The researcher would then select patients who met the eligibility criteria and randomly assign them to either the intervention group or control group using block randomization. Randomization Process: 1. The researcher created 8 slips: 4 labelled for the intervention group and 4 labelled for the control group. 2. The slips were placed in envelopes, with one slip in each envelope. The envelopes were sealed, and each envelope was numbered 1 to 8. 3. When the first patient entered the study, the researcher opened envelope 1, which determined the patient's group based on the slip inside. The researcher repeated this process for each patient, eventually enrolling 160 participants in the study. Data Collection Steps: The researcher first assessed medication adherence by counting the remaining pills. The researcher asked the patient to complete the MAST and a warfarin knowledge test. Then the researcher opened the randomization envelope to determine whether the patient was in the control or intervention group; if the patient was assigned to the control group, they were sent home with no further intervention. But if patients assigned to the intervention group were given an intervention, they watched a warfarin educational video in either Thai or Malay, depending on the patient's language preference. The researcher informed the patient that they would receive a follow-up phone call in 14 days. After 14 days, the researcher contacted the patient by phone to discuss their treatment and adherence. At 1 and 3

months, the patients attended regular follow-up appointments with the doctor for routine care. During these visits, they received standard care as usual practice. At the three-month point, the researcher did not meet with the patients in person but collected INR data from the HOSxP system. The researcher used this data to calculate the %TTR.

### Data analysis

Demographic and clinical characteristics of the participants were summarized by mean with standard deviation and frequency with percentage. Differences between the two groups were compared using chi-square test for categorial variables and independent t test or Mann-Witney test, as appropriate for continuous variables.

At 1 and 3 months after the intervention, outcomes between the two groups were compared, i.e., the percentage of patients with INR within the target range (using the chi-square test), %Time in Therapeutic Range (%TTR), warfarin knowledge, and medication adherence (both by pill count and the Medication Adherence Scale for Thais (using the independent t test or Mann-Whitney U test, as appropriate). MAST Scale was compared within each group using the Wilcoxon Signed-Rank Test. ทำ ำ ไม มี within group comparisons Statistical significance was set at a type I error of 5% (or P-value < 0.05). All statistical analyses were performed using the software program SPSS version 20.

## Results

Of the total of 160 participants (80 in each group), most participants in both groups were male, with the average age of the control group being  $52.94 \pm 11.56$  years and the intervention group  $51.18 \pm 11.12$  years (Table 1). The majority of participants in both groups adhered to the Islamic faith and had completed only primary school education. The comorbidities, indications for warfarin use, target INR levels, and factors affecting INR in both the control and intervention groups did not show any significant statistical differences. Most participants in both groups had two or more comorbidities. The primary indication for warfarin uses in both groups was to prevent thromboembolism in patients who underwent mechanical heart valve replacement. The target INR for both the control and intervention groups was 2.0 – 3.0. There were no significant differences between the

two groups when it came to things that could affect INR levels, such as changing the dose of warfarin or the percentage of milligrams of warfarin that were changed (Table 1).

**Table 1** Demographic and clinical characteristics of the participants (N = 160).

| Characteristic                                          | Control group<br>(n = 80) | Intervention group<br>(n = 80) | P-value            |
|---------------------------------------------------------|---------------------------|--------------------------------|--------------------|
| <b>Sex, n (%)</b>                                       |                           |                                | 0.227 <sup>†</sup> |
| Male                                                    | 44 (55.0)                 | 48 (60.0)                      |                    |
| Female                                                  | 36 (45.0)                 | 32 (40.0)                      |                    |
| <b>Age (mean <math>\pm</math> SD, years)</b>            | 52.94 $\pm$ 11.56         | 51.18 $\pm$ 11.12              | 0.639 <sup>§</sup> |
| <b>Religion, n (%)</b>                                  |                           |                                | 0.172 <sup>†</sup> |
| Buddhist                                                | 26 (32.5)                 | 22 (27.5)                      |                    |
| Muslim                                                  | 54 (67.5)                 | 58 (72.5)                      |                    |
| <b>Educational Level, n (%)</b>                         |                           |                                | 0.779 <sup>†</sup> |
| No formal education                                     | 18 (22.5)                 | 19 (23.8)                      |                    |
| Primary education                                       | 33 (41.3)                 | 27 (33.8)                      |                    |
| Lower secondary education                               | 18 (22.5)                 | 20 (25.0)                      |                    |
| Upper secondary education                               | 7 (8.8)                   | 11 (13.8)                      |                    |
| Bachelor's degree                                       | 4 (5.0)                   | 3 (3.8)                        |                    |
| <b>Comorbidities, n (%)</b>                             |                           |                                | 0.608 <sup>†</sup> |
| No comorbidities                                        | 20 (25.0)                 | 25 (31.3)                      |                    |
| Atrial fibrillation                                     | 15 (18.8)                 | 14 (17.5)                      |                    |
| Hypertension                                            | 12 (15.0)                 | 8 (10.0)                       |                    |
| Hyperlipidemia                                          | 9 (11.3)                  | 4 (5.0)                        |                    |
| Diabetes mellitus                                       | 1 (1.3)                   | 2 (2.5)                        |                    |
| Others                                                  | 2 (2.5)                   | 1 (1.3)                        |                    |
| $\geq 2$ comorbidities                                  | 21 (26.3)                 | 26 (32.5)                      |                    |
| <b>Indications for Warfarin Use, n (%)</b>              |                           |                                | 0.152 <sup>†</sup> |
| Tissue heart valves                                     | 8 (10.0)                  | 7 (8.75)                       |                    |
| Valvular heart disease                                  | 13 (16.25)                | 10 (12.5)                      |                    |
| Mechanical prosthetic valves                            | 57 (71.25)                | 62 (77.5)                      |                    |
| High-risk mechanical prosthetic valves                  | 2 (2.5)                   | 1 (1.25)                       |                    |
| <b>Target INR, n (%)</b>                                |                           |                                | 0.246 <sup>†</sup> |
| 2.0 - 3.0                                               | 78 (97.5)                 | 79 (98.75)                     |                    |
| 2.5 - 3.5                                               | 2 (2.5)                   | 1 (1.25)                       |                    |
| <b>Factors Influencing INR</b>                          |                           |                                | 0.239 <sup>†</sup> |
| Patients with physician-adjusted warfarin dosage, n (%) | 37 (46.25)                | 33 (41.25)                     |                    |
| Percentage of warfarin dose adjustment (mean $\pm$ SD)  | 8.48 $\pm$ 10.75          | 8.86 $\pm$ 13.31               | 0.381 <sup>§</sup> |

<sup>†</sup> Chi-square test, <sup>§</sup> Independent sample t-test.

### Clinical outcomes

The number of patients with INR levels within the therapeutic range in the first month for the intervention group was 50 patients (62.5%), and for the control group, it was 37 patients (46.25%). In the first month, the intervention group had a statistically significantly higher percentage of

patients with INR levels within the target range compared to the control group (P-value = 0.039). In the third month, the number of patients with INR levels within the therapeutic range in the intervention group was 55 patients (68.75%), while in the control group, it was 41 patients (51.52%). In the third month, the intervention group again showed a statistically significant higher percentage of patients with INR within the target range compared to the control group (P-value = 0.035) (Table 2).

%Time in therapeutic range (%TTR) in the first month for the intervention group was  $28.70 \pm 28.27$ , while for the control group, it was  $22.77 \pm 25.16$ . %TTR in the first month between the intervention and control groups was not significantly different (P-value = 0.122). In the third month, %TTR for the intervention group was  $68.70 \pm 41.82$ , and for the control group, it was  $54.72 \pm 40.97$ . %TTR in the third month was significantly higher in the intervention group compared to the control group (P-value = 0.041) (Table 2).

**Table 2** Comparisons of INR and %TTR between the intervention and control groups (N = 160).

| Clinical Outcomes                                                           | Control Group<br>(n = 80) | Intervention Group<br>(n = 80) | P-value            |
|-----------------------------------------------------------------------------|---------------------------|--------------------------------|--------------------|
| Number of patients with INR within the therapeutic range at 1 month, n (%)  | 37 (46.25)                | 50 (62.50)                     | 0.039 <sup>†</sup> |
| Number of patients with INR within the therapeutic range at 3 months, n (%) | 41 (51.25)                | 55 (68.75)                     | 0.035 <sup>†</sup> |
| %Time in therapeutic range (TTR) at 1 month, mean $\pm$ SD                  | $22.77 \pm 25.16$         | $28.70 \pm 28.27$              | 0.122 <sup>‡</sup> |
| %Time in therapeutic range (TTR) at 3 months, mean $\pm$ SD                 | $54.72 \pm 40.97$         | $68.12 \pm 41.82$              | 0.041 <sup>§</sup> |

<sup>†</sup> Chi-square test, <sup>§</sup> Independent sample t-test.

### Medication adherence and knowledge about warfarin

Medication adherence was assessed using the pill count method, with a maximum score of 100. The post-study comparison between the intervention and control groups showed that the intervention group had a higher score than the control group, with an average of  $88.40 \pm 9.80$  and  $78.97 \pm 9.89$ , respectively (P-value < 0.001). This is consistent with the results of medication adherence assessed using the MAST scale, where the maximum score was 40. The post-study comparison revealed that the intervention group scored higher than the control group, with an average of  $37.74 \pm 2.87$  and  $33.71 \pm 2.78$ , respectively (P-value < 0.001). Regarding the study on medication adherence as assessed using the pill count method, when comparing

within the control group before and after the study, it was found that the adherence score did not significantly differ (P-value = 0.146). Similarly, the control group showed no significant difference in the MAST adherence scores before and after the study (p = 0.166). As for the intervention group, the comparison of medication adherence before and after the study revealed that the pill count score significantly increased after the intervention (P-value < 0.001). Similarly, the MAST score also showed a significant increase in post-study (P-value < 0.001) (Table 3).

The average knowledge score on warfarin after the study was significantly higher in the intervention group than in the control group. The average scores for knowledge on warfarin in the intervention and control groups were  $9.71 \pm 1.54$  and  $8.75 \pm 1.18$ , respectively (P-value = 0.043). When comparing the knowledge scores on warfarin within each group before and after the study, both groups showed a significant increase in knowledge after the study (P-value < 0.001) (Table 3).

**Table 3** Comparisons of outcome scores before and after the intervention between the two groups (N = 160).

| Outcomes                                       | Control Group<br>(n = 80) |              | P-<br>value*         | Intervention Group<br>(n = 80) |              | P-<br>value*         | P-<br>value®         |
|------------------------------------------------|---------------------------|--------------|----------------------|--------------------------------|--------------|----------------------|----------------------|
|                                                | Before                    | After        |                      | Before                         | After        |                      |                      |
| 1. Medication Adherence                        |                           |              |                      |                                |              |                      |                      |
| - Pill count (mean ± SD)<br>(Total score: 100) | 8.06 ± 11.01              | 8.97 ± 9.81  | 0.146 <sup>†</sup>   | 77.08 ± 7.52                   | 88.40 ± 9.80 | < 0.001 <sup>†</sup> | < 0.001 <sup>§</sup> |
| - MAST (mean ± SD)<br>(Total score: 40)        | 33.45 ± 2.59              | 33.71 ± 2.71 | 0.166 <sup>#</sup>   | 33.85 ± 2.24                   | 37.74 ± 2.87 | < 0.001 <sup>#</sup> | < 0.001 <sup>†</sup> |
| 2. Knowledge of Warfarin                       |                           |              |                      |                                |              |                      |                      |
| (mean ± SD)<br>(Total score: 15)               | 7.78 ± 1.18               | 3.75 ± 1.18  | < 0.001 <sup>†</sup> | 7.63 ± 1.54                    | 9.71 ± 1.54  | < 0.001 <sup>†</sup> | 0.043 <sup>§</sup>   |

<sup>§</sup> Independent sample t-test; <sup>†</sup> Paired-sample t-test; <sup>‡</sup> Mann-Whitney U test; <sup>®</sup> Wilcoxon Signed-Rank tests.

<sup>\*</sup> Within-group comparison; <sup>®</sup> Between-group comparison.

### Medication-related issues identified during follow-up calls with patients

During the follow-up phone calls with patients, the researcher made a total of 80 calls, with an average duration of 10.5 minutes per call. Five patients called back for consultation. The issues raised were adverse drug reactions in 3 patients, insufficient medication until the next appointment in 1 patient, and a question about the safety of additional supplements in 1 patient. Among the patients, 52 were able to meet the treatment goals and follow all the prescribed instructions. A total of 30 medication-related problems were identified, which included 13 instances of



patients forgetting to take their medication, 2 instances of incorrect medication use, 9 instances of mild adverse drug reactions, such as gum bleeding or small bruises on the skin, 5 instances where patients took herbal medicines or supplements that interacted with warfarin, and 1 instance where a patient engaged in risky behavior (Thai massage), which could lead to adverse effects. In 28 of the 30 incidents, the pharmacist was able to provide immediate advice and resolve the issues. In 2 incidents, the patients were advised to visit a doctor at the hospital: 1 patient had blood in their urine, and another had blood in their stool. After treatment, both patients were allowed to return home, and no patients were required to stay in the hospital.

## Discussions and Conclusion

This study found that the use of educational video clips about warfarin, combined with follow-up phone calls by pharmacists, significantly increased the proportion of patients with INR values within the target therapeutic range ( $P$ -value = 0.035). Additionally, %TTR was significantly higher in the intervention group compared to the control group ( $P$ -value = 0.041). The intervention group also showed significantly better medication adherence, as measured by both the pill count method ( $P$ -value < 0.001) and the MAST ( $P$ -value < 0.001), as well as better knowledge about warfarin ( $P$ -value = 0.043) compared to the control group.

This study is consistent with the research by Sudas Na Ayutthaya et al., which found that pharmacist-led follow-up phone calls for warfarin patients significantly increased the proportion of patients with INR values within the target therapeutic range in the intervention group compared to the control group ( $P$ -value = 0.005)<sup>18</sup>. However, it differs from the study by Wittkowsky et al., which found no significant difference in the proportion of patients with INR within the target range between those who received pharmacist-led phone follow-up and those who were followed up at the warfarin clinic ( $P$ -value = 0.84)<sup>24</sup>. The discrepancy may arise because the study by Wittkowsky et al. used pharmacist-led phone follow-up as a substitute for clinic visits, which may not have been as comprehensive or detailed as in-person clinic follow-up. This difference in follow-up methods could have affected the INR results for patients. Moreover, the findings of this study align with the research by Al Ammari

et al., who tracked warfarin patients by having them send their INR results via WhatsApp, followed by pharmacist phone calls to explain the results and adjust their medication plan. This study reported that 59.39% of patients had their INR within the target range, and 30% had a TTR greater than 70%<sup>16</sup>. The results are also in line with the study by Wipha Thamthinnano, which found that pharmacist-led phone follow-up helped maintain patients' INR within the therapeutic range at 64.44% during subsequent visits<sup>17</sup>. Therefore, it can be concluded that pharmacist-led phone follow-up effectively helps keep INR values within the target therapeutic range.

The research findings showed that the %TTR at 1 month did not differ significantly between the intervention and control groups ( $P$ -value = 0.122). This is because the study sample was selected from patients whose INR values were outside the therapeutic range. In some cases, physicians would adjust the warfarin dosage, and it typically takes 7-10 days for the warfarin levels in the blood to stabilize (reach a steady state) before the full effects of the medication can be observed. The experiment resulted in relatively low %TTR values for both groups during the first month, with no significant statistical difference between the groups. However, when the %TTR at 3 months was measured, the intervention group showed a significantly higher %TTR than the control group ( $P$ -value = 0.041). The study by Sudas Na Ayutthaya et al., which looked at the %TTR after 3 months and found that it was significantly higher in the intervention group compared to the control group ( $P$ -value = 0.017)<sup>18</sup>, agrees with this result. Additionally, this study aligns with the research by Clarkesmith et al., which measured the %TTR at 6 months and found that the intervention group had a significantly higher %TTR than the control group ( $P$ -value = 0.035)<sup>9</sup>.

After the study, the intervention group showed significantly higher knowledge about warfarin compared to the control group, which is consistent with the research by Heinrich et al. In Heinrich's study, knowledge about warfarin was provided to patients through the use of iPads by the researchers, and it was found that patients' knowledge scores significantly increased ( $P$ -value < 0.001)<sup>7</sup>. Similarly, the study by Kim et al. found that after providing knowledge about warfarin through video clips, patients' knowledge scores significantly increased ( $P$ -value < 0.001)<sup>8</sup>. However, these studies used different knowledge tests than this study,

which may affect knowledge scores. When comparing patients' knowledge within the groups, both the intervention and control groups showed an increase in average knowledge scores after completing the study. This improvement could be due to the control group, who did not watch the video clip, seeking additional knowledge on their own. Motivated by the initial knowledge test, where they were unable to answer some questions, they may have sought more information, leading to higher scores on the second knowledge test. From the open-ended interviews with patients regarding their satisfaction with the video clips, it was found that patients were satisfied with the content, aesthetics, and the engaging nature of the video, as well as the Malay voiceover that helped those who were not comfortable using the Thai language better understand the information about warfarin. Patients also suggested that the researchers include more content in the video about foods and herbs to avoid, as the video only provided a few examples of these. Additionally, patients recommended including information on safe exercise methods for patients with heart disease.

The research findings revealed that medication adherence in the intervention group was significantly higher than in the control group, which aligns with the quasi-experimental study by Phiwpong et al. Their study found that after using a program designed to enhance the capabilities of elderly patients receiving warfarin (which included relationship-building, goal-setting, education, and follow-up via phone), patients showed increased adherence to medication ( $P$ -value  $< 0.001$ )<sup>5</sup>. Additionally, research in other disease areas has shown similar findings. For example, a study by Somphetch et al. evaluated the effect of phone reminders on medication adherence in patients with hypertension, finding that it significantly improved medication adherence compared to the control group ( $P$ -value = 0.024)<sup>6</sup>. However, both of these studies only assessed medication adherence using the pill count method, whereas the present study assessed medication adherence using two methods: pill counting and the MAST evaluation, which enhances the accuracy of the assessment.

The strengths of this study include its randomized controlled trial design with equal-sized experimental and control groups. Data collection was conducted by a single researcher, and multiple methods were used together to enhance clinical outcomes and medication adherence.

These methods included the use of a video clip to educate patients about warfarin and pharmacist-led follow-up calls. The use of video clips as an educational medium offers several advantages. They are engaging and can be viewed repeatedly at the patient's convenience, which helps increase the patient's knowledge about warfarin. On the other hand, telephone follow-ups provide the benefit of two-way communication, where the researcher can immediately assist or offer advice to the patients. Additionally, this study used two methods to assess medication adherence, further enhancing the accuracy of the evaluation. It also employed the MAST, an adherence assessment tool that is appropriate and culturally relevant for the Thai context.

The limitations of this study include the lack of blinding regarding which patients were assigned to the control or intervention group. However, the primary outcome of this study, INR values, is a laboratory test result, and the researcher had no influence on the results, nor could they interfere with the INR measurement process. Regarding standard care, the researcher had another pharmacist at the warfarin clinic provide pharmaceutical care according to clear guidelines and documentation. For the telephone follow-ups conducted by the researcher, a structured script was established to minimize bias in communication. A limitation of the telephone follow-up process is the need to find a convenient time for both the researcher and the patient. The researcher would schedule a phone call with the patient, but sometimes more than one attempt was needed to reach them. The researcher provided the intervention group with a video clip to educate them about warfarin, which they could watch multiple times as needed. However, the number of times the video was watched was not recorded, which could potentially impact the patients' knowledge scores. For the medication adherence assessment using the pill count method, some patients did not bring their remaining medication on the follow-up day, either due to forgetfulness or other reasons. The researcher used interviews to enquire about the remaining number of pills and, after the patient returned home, followed up with a call to verify the remaining pill count. Patients may or may not provide accurate information, which is a limitation of the study.

**Opportunities for Development:** An opportunity for improvement is the use of video calls for follow-up, which would allow for two-way communication and the ability to

observe the patient's facial expressions, body language, and symptoms. Such information could be helpful in assessing the patient's condition more thoroughly. If there was more time for the study, the frequency of follow-up calls should be increased, and at least six months of follow-up should be conducted to see a clearer effect on %TTR values. In addition to clinical outcomes, the safety aspect should be monitored, specifically the tracking of adverse drug reactions (ADRs), as they may take time to manifest. According to the results of the warfarin knowledge assessment, it was found that the three most common questions that patients answered incorrectly were: 1) What disease is warfarin used to prevent? 2) What is the correct target for blood coagulation? 3) Which vitamin affects the action of warfarin? As a result, the researcher focused more on educating patients about these points, which were beneficial for their understanding of warfarin use. Future research should combine the use of educational video clips about warfarin with pharmacist-led telephone follow-ups for patients using warfarin. This program could be implemented as an additional service to regular care in hospitals of varying levels or in patients attending other chronic disease clinics, such as diabetes or hypertension clinics. A cost-effectiveness study of this service would also be valuable. Hospitals should support services of this nature to help patients use their medications more effectively and safely.

In conclusion, after providing patients with educational video clips about warfarin, combined with pharmacist-led telephone follow-ups in addition to usual care, and monitoring for a period of 1 month, the intervention group showed statistically significant improvements compared to the control group in the following areas: the percentage of patients with their INR within the therapeutic range, medication adherence and knowledge of warfarin. Additionally, after a 3-month follow-up, the intervention group exhibited statistically significant improvements over the control group in the percentage of patients with INR within the therapeutic range and %TTR. Therefore, this approach should be applied to patients using warfarin with INR values outside the therapeutic range to improve clinical outcomes, medication adherence, and warfarin knowledge, which will contribute to more effective and safer patient management.

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