Evaluation of a Designed Warfarin Educational Program on Patients’ Knowledge and Incidence of Side Effects

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Abstract: Warfarin is one of the high alert medications, therefore, it is vitally to provide patients with enough knowledge about warfarin therapy in order to ensure patients’ safety and reduce the incidence of warfarin side effects. This study aimed to evaluate the effectiveness of a designed warfarin educational program on patients’ knowledge and incidence of side effects. Research hypothesis were H₁: patients who would receive a designed warfarin educational program will have higher knowledge scores related to warfarin therapy than patients who would not have received it. H₂: patients who would receive a designed warfarin educational program will have lower incidence of warfarin side effects than patients who would not have received it. Research design: One group pre/post- test quasi-experimental design was utilized. Setting: The study was conducted at the two cardiovascular surgical wards at Cairo University Hospitals. Subjects: A sample of convenience of 46 adult patients with the following inclusion criteria: a) hospital inpatients that had undergone cardiovascular surgeries and on warfarin therapy, b) intended duration of warfarin is more than three months and c) patients able to read and write. Tools for Data Collection: Two tools were utilized to collect data pertinent to the study; 1- Personal data sheet, it consists of two parts: a) demographic data and b) selected medical variables pertinent to the study and 2- Pre/post knowledge assessment questionnaire related to warfarin therapy: It is divided into two main sections, the first section concerned with evaluation of patients’ knowledge related to warfarin therapy. The second section concerned with sign and symptoms of side effects of warfarin therapy. Results revealed a high statistical significant difference was found in total knowledge scores of the studied subjects as well as lowering incidence of warfarin side effects. In conclusion, provision of an educational program about warfarin therapy may be considered as one of effective risk reduction strategies that promote patients’ safety and reduce life threatening situations. Recommendation: warfarin educational program should be provided to patients on warfarin therapy to maintain health and prevent complications.

Key words: A Designed Warfarin Educational Program · Incidence Of Side Effects · Patients’ Knowledge · And High Alert Medications

INTRODUCTION

Warfarin is one of the most widely prescribed drugs in the world. Every year, an estimated 2 million Americans with certain heart conditions or other risk factors start taking warfarin [1]. warfarin is used to prevent dangerous blood clots that can lead to heart attacks, strokes or even death. Warfarin is a major contributor to drug-related morbidity and mortality. Many of the clinical and healthcare system-related problems encountered during routine warfarin management are amplified in the period following a patient’s discharge from hospital, further increasing the risk of adverse outcomes [2].
Warfarin has remained the most commonly prescribed vitamin K antagonist (VKA) since its introduction into clinical practice approximately 60 years ago [3]. Warfarin produces its anticoagulant effect by inhibiting the synthesis of the vitamin K dependent clotting factors (factors II, VII, IX and X) as well as the coagulation proteins C and S. by acting in the liver to inhibit vitamin K production and decrease the production of the vitamin K–dependent clotting factors, warfarin affects the extrinsic coagulation pathway and prolongs the prothrombin time [4]. Warfarin is indicated for the primary and secondary prevention of venous thromboembolism, prevention of embolism in patients with atrial fibrillation and prosthetic heart valves and reduction of the risk of recurrent MI [5].

Warfarin (Coumadin) indicated for Prophylaxis and treatment of venous thrombosis and its extension, pulmonary embolism (PE), prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation (AF) and/or cardiac valve replacement, reduction in the risk of death, recurrent myocardial infarction (MI) and thromboembolic events such as stroke or systemic embolization after myocardial infarction [6, 7]. In addition, warfarin may be used to prevent an existing clot from growing larger [5, 6]. The goal of warfarin therapy is to decrease the clotting tendency of blood, but not to prevent clotting completely. Therefore, the blood's ability to clot must be carefully monitored while a person takes warfarin. The dose of warfarin is adjusted, based on the results of periodic blood tests of prothrombin time (PT) and International Normalized Ratio (INR) to maintain the clotting time within a target range [5].

The most common side effect of warfarin is bleeding. This is most likely to occur if INR is too high. The risk of bleeding is greatly reduced by managing warfarin therapy well and keeping INR inside target range [8, 9]. The major complications associated with warfarin are clotting due to under-dosing or bleeding due to excessive anticoagulation. The most serious bleeding is gastrointestinal or intracerebral. Excessive bleeding can occur in any area of the body and patients taking warfarin should report any falls or accidents, as well as signs or symptoms of bleeding or unusual bruising, to their healthcare provider [10]. Signs of unusual bleeding include bleeding from the gums, blood in the urine, bloody or dark stool, a nosebleed, or vomiting blood. An unusual headache or a headache that is more severe than usual may signal intracerebral bleeding [11]. It is important that patients follow precautions when taking warfarin to reduce the risk of side effects and improve the effectiveness of warfarin therapy [12].

Moreover, warfarin side effects can include interactions with some foods, prescription medicines and over-the-counter supplements [13]. Drug and food interactions can interfere with the anticoagulant effect of warfarin. It is imperative to pay close attention to the other medications, supplements and dietary habits of patients on this agent [4, 14]. Warfarin is a dangerous outpatient medication, by anyone’s estimation. It is the second most common cause of adverse drug events in emergency rooms and the overall risk of major bleeding averages 7–8% per year [15]. Warfarin is a common cause of emergency hospitalization in elderly patients and of serious, disabling, or fatal injury from bleeding in patients of all ages [16, 17].

Warfarin is one of the high-risk drugs. Patient education topics for the patient on warfarin include medication adherence, INR target, importance of laboratory monitoring and necessity of communicating changes in their medication regime to health-care provider. Diet education is critical, particularly for foods that contain vitamin K. The patient does not need to avoid foods rich in vitamin K, but the patient must be consistent with consumption habits. Warfarin drug can be life-saving. Nurses must carefully assess, closely monitor and comprehensively educate the patient receiving anticoagulation drugs to ensure the full benefit of anticoagulation therapy and to minimize potential harm [18].

Published reports of patient education related to warfarin anticoagulation vary greatly in strategy, content and patient testing. Prioritizing the educational domains, standardizing the educational content and delivering the content more efficiently will be necessary to improve the quality of anticoagulation with warfarin. Patient education is an essential component in quality management of the anticoagulated patient. Because it is time consuming for clinicians and overwhelming for patients, education of the anticoagulated patient is often neglected. To improve both efficacy and safety of oral anticoagulant treatment, several strategies have been developed including educational intervention. However the exact impact of an oral anticoagulant treatment patient education program remains debatable [19].

Effective patient education is a central part of the practice of nurses among all health professionals because it helps to ensure safe and effective warfarin management. With recent increase in warfarin prescribing and warfarin-related adverse drug events the need for an effective patient warfarin education program is more apparent. Nurses have a unique role in caring of patients who had taken warfarin therapy. Nurses’ roles include the
following: screening for known allergies to warfarin drug, conditions that could be exacerbated by increased bleeding tendencies, baseline status before beginning warfarin therapy and any potential adverse effects, monitor patient response and adverse effects, evaluate the effectiveness of the teaching plan as well as monitor the effectiveness of comfort measures and compliance to regimen [20]. Therefore the purpose of this study is to evaluate the effect of a designed warfarin educational program on patients’ knowledge and incidence of side effects.

Significance of the Study: Over period of 15 years of experience as a clinical nurse instructor in cardiovascular wards, it can be observed that a high number of patients readmitted to El-Manial University hospital as a result of warfarin related errors which cause serious side effects and potential morbidity. Leading support to this observation is granted from previous research results which estimated that, there may be as many as 34,000 fatal, life threatening, or serious adverse warfarin –related adverse events annually and that the majority of the most serious events are preventable [21]. Moreover Field, et al. [22] reported that, Warfarin is among the medication most frequently associated with emergency department visits, hospitalization and death. Unfortunately the quality of warfarin management in the long term oral anticoagulant setting has been shown to be suboptimal. Institute for Healthcare Improvement [23] reported that, it is important that patients receive education about the drug while they are in the hospital so they can manage their therapy properly at home. Patients who are knowledgeable about their medication therapy can help to reduce the risk of adverse drug events. However, patients didn’t receive any teaching about warfarin after physician prescription. Insufficient patient education is linked to poorly controlled anticoagulation. Therefore, this study aims to provide a designed warfarin education program for patients who undergone cardiovascular surgeries in simple, easy to read warfarin information, improved warfarin compliance, improved continuity of care between hospital and community setting; and improved patient follow up. Which in turn help to optimize their warfarin-related therapeutic outcomes and minimize warfarin-related side effects.

Aim of the Study: To evaluate the effectiveness of a designed warfarin educational program on patients’ knowledge and incidence of side effects.

Research Hypothesis:

H₁: Patients who would receive a designed warfarin educational program will have higher knowledge scores related to warfarin therapy than patients who would not have received it.

H₂: Patients who would receive a designed warfarin educational program will have lower incidence of warfarin side effects than patients who would not have received it.

MATERIALS AND METHODS

Research Design: Pre/post- test one group quasi-experimental design was used to fulfill the aim of the study. According to this design the researcher has a new intervention, randomization is absent. This type of design and these series of tests on different occasions will give an accurate picture of changes over time [24].

Setting: The study was conducted at the two cardiovascular surgical wards at Cairo University Hospitals. Data were collected during the period from January to June 2013.

Subjects: A sample of convenience of 46 patients in middle adulthood with mean age 41.04 ±12.22 years patients who were willing to participate and fulfilled the following inclusion criteria a) hospital in-patients who had undergone cardiovascular surgeries and on warfarin therapy, b) intended duration of warfarin is more than three month and c) patients able to read and write were recruited for this study. The participant’s characteristics were homogeneous in terms of their age group, marital status, monthly income and level of education…etc.

Tools for Data Collection: Two tools were utilized to collect data pertinent to the study. Tools and the designed warfarin educational program were constructed after extensive literature review of updated research journals and text books. The researchers translated the designed warfarin educational program DWEP into Arabic language for all study subjects. Content validity of utilized tools as well as the DWEP were examined by panel of experts consisted of five experts; two of them are professors of pharmacology and three medical –surgical nursing professors. The necessary modifications were done.
A pilot study was carried out on (10%) of the sample to examine its applicability, clarity, reliability and feasibility and to identify obstacles, problems that may be encountered during data collection.

**These Tools Are:**

A- Personal data sheet. It classified into a) demographic data which included age, gender, level of education, marital status, occupation, income, number of children, place of residence and b) selected medical variables including diagnosis/operation, other debilitating illness and used over-counter medications,….etc.

B- Pre/post knowledge assessment questionnaire related to warfarin therapy. It is divided into two main sections: the first section is concerned with evaluation of patients’ knowledge related to warfarin therapy. It consists of questions about action, indications, side effects, laboratory tests that should be monitored and evaluated frequently, pharmacokinetic and patients’ measures to avoid side effects. The second section concerned with sign and symptoms of side effects of warfarin therapy.

Total knowledge scores were calculated in response to 20 questions, each question is rated (1)=correct answer, (0)=incorrect answer, the highest score was (20) and the lowest is (0). Scores below 12 are considered to be unsatisfactory and above 12 is satisfactory knowledge. Data were analyzed using SPSS windows statistical package for social science version 20 and probability (p-value) less than 0.05 was considered significant and less than 0.001 is considered as highly significant.

**Ethical Consideration:** Permission to conduct the proposed study was obtained from the appropriate research committee. At the initial interview each potential subject was informed of the purpose, nature and benefits of the study. The investigators emphasized that participation in the study is voluntary, confidentiality and anonymity of the subjects will be assured through coding of all data. A written consent form was collected from each subject who agreed to participate in this study.

**Procedure:** Once permission was granted from the concerned hospital authority to proceed with the proposed study, the researchers initiated data collection. Names of the potential subjects who met the criteria for possible inclusion was obtained from the head nurse of the wards. During their hospital stay, each potential subject was contacted by the researchers at that time the researchers emphasized each subject that participation in the study is entirely voluntary and the anonymity and confidentiality of their responses will be assured. The purpose, nature and significant of the study were explained, patients who agreed to participate in the study were interviewed by the researcher to fulfill the personal data sheet and pre knowledge assessment questionnaire. After pretesting each subject was contacted by researchers and provided with three consecutive sessions about warfarin therapy preoperatively. Each session lasted from 30 to 45 minutes. It takes the form of a tutorial that provides information whilst continually ensuring that the patient has understood.

The contents are adapted to the needs of the patients, to their lifestyle, level of education and expectations. The first session was considered as introductory one concerned with providing information about warfarin such as what is warfarin, its action, indications, dosage, laboratory tests that should be monitored and evaluated frequently. The second section focused on pharmacokinetics of warfarin (drug-nutrition interactions, drug-drug interactions, various disease states that can interfere with the patients’ response to warfarin). The third session focused on warfarin side effects, precautions and patients’ measures to deal with these side effects and importance of follow up. In the last session; warfarin instructional handout was supplied to the study subjects and discussion was opened for any questions or concern. Postoperatively each subject was contacted individually to enforce all previously covered contents. After one week postoperatively the researchers interviewed patients and assessed their knowledge and incidence of side effects by using post test questionnaire about warfarin. After discharge each subject was called weekly for four weeks by telephone in order to reinforce the content of the program and follow up. After one month (when the next laboratory blood test is done and patients came to outpatient clinics) the researchers interviewed patients to fulfill the post–post knowledge assessment questionnaire related to warfarin therapy.

**N.B:** The rationale behind the researchers’ decision of collecting post-post data (after one month) based on Stafford, et al. [2] evidence based research finding which revealed that, the risk for major bleeding during the first month of therapy is approximately 10 times higher than the risk after the first year.

**Limitations of the Study:** The study was done at a single hospital and on a small number of patients therefore, its results might be lacking the generalizability.
Table 1: Frequency distribution of the baseline pre-program assessment regarding Patients’ information about warfarin therapy (N=46)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Patients received information about warfarin therapy</td>
<td>22</td>
<td>46.7</td>
</tr>
<tr>
<td>Sources of Patients’ information</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Nurse</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Physician</td>
<td>21</td>
<td>44.5</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>_</td>
<td>_</td>
</tr>
<tr>
<td>Others</td>
<td>_</td>
<td>_</td>
</tr>
</tbody>
</table>

Table 2: Mean Scores and F-ratio of the studied subjects’ total knowledge scores in pre, one week after and one month after receiving DEPWT (N=46)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Satisfactory</th>
<th>Unsatisfactory</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Pre</td>
<td>11</td>
<td>23.9</td>
<td>35</td>
</tr>
<tr>
<td>Total mean ± SD one week after</td>
<td>8.869±3.215</td>
<td></td>
<td>35</td>
</tr>
<tr>
<td>Total mean ± SD one month after</td>
<td>16.739±2.351</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Total mean ± SD</td>
<td>15.869±2.569</td>
<td></td>
<td>7</td>
</tr>
</tbody>
</table>

*** Significant at p ≤ 0.000

RESULTS

The analysis of data is presented in two main sections: the first section is devoted to description of the studied subjects’ demographic characteristics and some of selected medical variables. The statistical analyses testing the research hypothesis are presented in second section.

Section I: Description of the studied subjects’ demographic characteristics and selected medical variables: More than half of the studied sample were males in middle adulthood (52.2%, 60.8% respectively) while more than two thirds of them had a primary education and monthly income less than 500 Egyptian pound (69.7%, 69.6% respectively). Almost two thirds (60.9%) of the study sample were urban residence. The majority of the studied sample was married and had less than five children (80.4%, 97.4% respectively). As regards the selected medical variables, the entire studied sample was suffering from cardiovascular health problems. 43.4% of the studied group had other co-morbid diseases such as diabetes, respiratory problems and chronic renal diseases…etc, (21%, 6.5%, 6.5% respectively). As regards medication used by the studied sample, all of the sample were taking other drugs beside warfarin as follow; corticosteroids, anti-diabetic medications, lasix, antibiotics, aspirin and paracetamol.

Section II: results related to hypotheses testing:

As can be seen from Table (1), baseline pre-program assessment findings regarding Patients’ information about warfarin therapy and source of their information revealed that, more than half of the studied subjects (53.3%) didn’t get any information about warfarin, while (46.7%) of them received some sort of unstructured information. The main source of such information was the physicians (44.5%), while one patient only (2.2%) got the information through the nurse.

Hypotheses Testing:

H1: Patients who would receive a designed warfarin educational program will have higher knowledge scores related to warfarin therapy than patients who would not have received it.

It’s clear from Table (2) the existence of a high statistical significance difference among the pre, one week and one month after provision of the educational program as regard the total knowledge scores (F =114.303, P =0.000). Evidently, the majority of the studied subjects (76.1%) had unsatisfactory knowledge scores before the program compared to (89.1%) who had satisfactory knowledge scores after one week of the program and (84.8%) one month after of the educational program.

H2: Patients who would receive a designed warfarin educational program will have lower incidence of warfarin side effects than patients who would not have received it.
It is clear from Tables (3 & 4) that, there were high statistically significant difference as regards incidence of warfarin side effects (minor and major) among pre, one week and one month after receiving DEPWT (F = 23.18, \( P = 0.000 \) and F = 6.33, \( P = 0.000 \) respectively. It’s apparent from Table (3) that, the most common minor side effects of warfarin therapy experienced by the patients before receiving DEPWT were nausea/stomachache, easy bruising, gum bleeding, occasional nose bleeding and menstrual bleeding (52.2%, 39.1%, 34.8%, 28.3% and 28.3%) respectively compared to (43.5%, 15.2%, 10.5%, 10.5% and 17.4%) respectively after one week of the program, a relatively consistent results showed after one month assessment (13%, 17.4%,10.9%, 6.5.9% and 15.2 ) respectively. As well as table (4) revealed that the most common major side effects of warfarin therapy occurred among the studied subjects are hematuria, dark bloody stool, vaginal bleeding and bleeding from a cut that not stopped (32.6%, 23.9%, 0 and 2.2%) respectively before educational program compared to (13%, 10.9%, 0 and 0) respectively after one week of the program and (8.7, 6.5, 2.2 and 0) respectively after one month. These results statistically supported hypothesis 2.

**DISCUSSION**

The purpose of this study was to evaluate the effectiveness of a designed warfarin educational program on patients’ knowledge and incidence of side effects. The following discussion will focus upon the findings related to the two stated research hypotheses. The discussion of findings is presented in the following sequences: a) patients’ knowledge and DWEP and b) incidence of warfarin side effects and DWEP.

**A-Effectiveness of Implementing a Designed Warfarin Educational Program on Patients’ Knowledge:** Patient’s lack of knowledge surrounding their treatment and condition, coupled with the potential burden of a complex regime may be barriers to treatment uptake and adherence [25]. There is a general consensus in the literature that improved patient knowledge about warfarin therapy improves therapeutic outcomes [26-29]. Therefore it was hypothesized that H \(_{1}\); patients who would receive a designed warfarin educational program will have higher knowledge scores related to warfarin therapy than patients who would not have received it. The statistical analysis indicated that, there was a statistical significant difference in patients’ knowledge mean scores among three different assessment times. The hypothesis was supported as the mean knowledge score in both one week and one month after provision of DWEP were higher than the baseline pre-program patients’ knowledge mean scores. This result may be attributed to the exposure of the study sample to DWEP. This finding is consistent with Clarkesmith, *et al.* [25] who studied anticoagulation control in arterial fibrillation patients. They found that knowledge increased significantly across time. Lending support to this speculation was obtained from a
quasi-systematic review of the literature carried by Nasser, Mullan & Bajorek [27] via electronic data base searches from 1990-to May 2011 and revealed that the 62 reviewed articles indicated that the provision of warfarin educational program improved patient knowledge results in decrease incidence of side effects (better anticoagulation control).

B-Effectiveness of Implementing a Designed Warfarin Educational Program on Incidence of Warfarin Side Effects: There is tremendous range in the perceived impact of warfarin therapy on the lives of patients on long life warfarin therapy. Studies have confirmed that insufficient adherence and a low level of patient knowledge about oral anticoagulant therapy (OAT) are the primary causes for warfarin complications [24, 31, 32]. In the current study, it is important to note that the incidence of minor as well as major side effects was lowered after one month compared to pre and one week after receiving DEPW. As a high statistically significant difference existed as regards incidence of warfarin side effects (minor and major) in pre, one week and one month after receiving DEPWT. These findings supported the second hypothesis which stated that, H: patients who would receive a designed warfarin educational program will have lower incidence of warfarin side effects than patients who would not have received it. As the present study documented that, the most common minor side effects pre, after one week and one month of warfarin therapy experienced by the patients were nausea/stomachache (52.2%, 43.5% and 13%) respectively. While the most common major side effects are red urine (hematuria) 32.6%, 13% and 8.7%) respectively the most common minor side effects of warfarin therapy experienced by the patients pre, after one week and one month were nausea/stomachache (52.2%, 43.5% and 13%) respectively. While the most common major side effects are red urine (hematuria) 32.6%, 13% and 8.7%) respectively.

The study results go inconsistent with a similar study carried out by Pernod et al. [30] to evaluate the effect of patient education program in reducing VKA-related adverse event rates. During the 3-month follow-up, reported that 15 hemorrhagic incidents (5%) occurred including two major bleeding events were recorded. Three (1.9%) hemorrhages occurred in the experimental group (1 major and 2 non major) versus 12 (8.5%) in the control group (one major and 11 non major), the cumulative risk reduction in the experimental group was statistically significant.

This results go on the same vein with a retrospective survey study entitled “A pre- post-evaluation of implementing an inpatient warfarin monitoring and education program” carried by Armstrong, Chemodurow, Christensen and Johnson [31] on 112 patients in the pre- and 115 patients in the post-program group reported that there were 8 patients in the pre-group that developed minor bleeding complications versus 3 in the post-group; this difference was not statistically significant. Of the 8 minor bleeding complications in the pre-group, 4 experienced hematuria and the other 4 experienced epistaxis. The 4 minor bleeding complications experienced in the post-group were all documented as hematuria. Major bleeding complications occurred in 3 patients in the pre-group and 0 patients in the post-group; however, this difference was not statistically significant. Also, Armstrong, et al. and Biscup-Horn, et al. [31, 32] performed a randomized controlled trial and found that an inpatient anticoagulation guideline-based consultation service was associated with reduction in the frequency of anticoagulant-related bleeding in patients at increased risk for major in- hospital bleeding.

More recently, Clarkesmith et al. [25] who carried out study entitled “Educational Intervention Improves Anticoagulation Control in Atrial Fibrillation Patients: The Treat Randomised Trial” and their results revealed that only eight adverse events occurred during the 12 month follow-up; seven in the usual care group (three ischaemic non-fatal strokes, two minor bleeding episodes, one major bleeding episode and one non-cardiac related death) and one event in the intervention group (peripheral embolism). Warfarin is a less-than-ideal anticoagulant because of its narrow therapeutic range, interactions with numerous drugs and foods and need for routine laboratory monitoring [33]. It is therefore important for the patient to be educated fully regarding warfarin to prevent thromboembolism or serious bleeding with potential fatal complications may occur [29, 34].

CONCLUSION

The provision of an integrated and multidisciplinary warfarin instructional program may improve the patients’ knowledge as well as reduce incidence of warfarin side effects among patients on long life warfarin therapy. This might lead to a better anticoagulation control.

Recommendation: Based on the finding of this study, warfarin education should be routinely and consistently provided to all patients on warfarin treatment prior to their
discharge from the hospital. Patients’ education should focus on pharmacokinetics of drug, side effects, precautions and patients’ measures to avoid or reduce the untoward effects of warfarin. These areas were found to be of highest knowledge deficit. Nurses working at the cardiovascular care units should be provided by in-service educational program regarding warfarin therapy. Replication of the study by using a larger probability sample from different setting is recommended.

REFERENCES


