Warfarin and dietary vitamin K:
A multidisciplinary patient tool to improve INR maintenance

Krista Lee
A Project presented to the faculty of
The University of North Carolina at Chapel Hill
in fulfillment of the requirements for
Undergraduate Honors

Date Completed: April 10, 2014

Honors Advisor Approval: ____________________________________________

Christina Leonard, MSN, RN, FNP-bc, CNL
Abstract

Warfarin is a vitamin K antagonist that is the most commonly prescribed anticoagulant and continued use is anticipated even with the new anticoagulants. It is well known that warfarin has a narrow therapeutic range, potential life-threatening side effects and is known for multiple drug-drug, drug-disease, and drug-food interactions. Despite these known interactions, there is very little consistency regarding the patient education, which is integral to any medication, especially in regards to warfarin which has such life-threatening side effects. While many interactions are unavoidable, drug-food interactions can be controlled by the patient if they have received education. Research has shown that by improving diet education regarding vitamin K content of foods, patients can have more stable INR values (Dennis, Ripley, Planas and Beach, 2008). With adequate education, a patient is capable of maintaining a consistent daily vitamin K intake which will aid in his/her ability to maintain a therapeutic INR. A review of the nursing literature from the last ten years has revealed an extreme deficit of information regarding specific vitamin K content of food items. Since nurses are frequently in the position to offer formal and informal patient education, it is important that they possess essential knowledge about high-risk medications. This enables nurses to educate their patients accurately about these medications. There is some highly detailed patient information available about food items and vitamin K content, but they are long, cumbersome lists. In response, a clear, concise patient tool has been created that sorts foods into categories of low, moderate, high, and extremely high and also groups some food items for simplicity to keep the tool to a single page. It is the aim of this tool to improve patient and nursing education as well as increase patient diet choices regarding vitamin K content of foods which should lead to improvement in maintenance of therapeutic INR.
Introduction

Warfarin is a well-known blood thinner commonly prescribed to prevent blood clots. Even though it is being used by about 2 million people (Agency for HealthCare Research and Quality, 2010), it is not a popular drug with patients because of the many lifestyle changes that are required while on the drug. Specifically, warfarin is an oral vitamin K antagonist used primarily in approximately four million U.S. patients for the prevention of primary and secondary venous thromboembolisms (Ansell, Hirsh, Poller, Bussey, Jacobson, & Hylek, 2004; Nutescu, Wittkowsky, Burnett, Merli, Ansell, & Garcia, 2013). It is the most commonly used vitamin K antagonist (VKA) worldwide, but its use with inpatient and outpatient settings can be problematic. It has a very narrow therapeutic range, there is considerable variability in patient dosage, it has numerous drug-drug, drug-disease, and drug-food interactions, and physicians have numerous problems maintaining therapeutic levels in patients due to non-adherence and miscommunication (Ansell et al., 2004).

While three new oral anticoagulants have been approved by the U.S. Food and Drug Administration, dabigatran (Pradaxa®) in 2010, rivaroxaban (Xarelto®) in 2011, and apixaban (Eliquis®) in 2012, there are some drawbacks to using them. While studies have shown that even though these new medications have fewer drug and food interactions, a lower bleeding risk, and no laboratory monitoring, they have significant disadvantages. There is no antidote or testing for effectiveness and toxicity which can be problematic especially if a patient needs emergency surgery. This inability to determine if the dosage is therapeutic increases the risk of hemorrhaging. The long-term safety and effectiveness of these new medications is also missing along with limited usage by the FDA (Wigle, Bloomfield, Tubb, & Doherty, 2013; Wanat, 2013.)
In addition to these limited uses, another disadvantage to consider is their short half-life. If a dosage is missed or held, this will increase the patient’s risk of a thromboembolic event compared to warfarin (Wanat, 2013). Considering these short-comings and the cost-effectiveness of warfarin at this time, it is assumed that warfarin will continue to remain the more commonly used oral anticoagulant world-wide for a variety of reasons (Cook-Campbell & Sefton, 2010). Warfarin is the only oral anticoagulant currently recommended for valvular heart disease and coronary heart disease (Wigle et al., 2013). Studies have also shown that in 79% of older patients with a chronic condition that maintain therapeutic INR levels on warfarin, they have a 79% reduced stroke risk without increasing their risk of complications from hemorrhaging (Venkatachalam, D'Attilio, Lewis, & Acevedo, 2007).

In a review of anticoagulation education and patient understanding, Moreland, Kravitz, Paterniti, Li, Lin, and White (2013) discuss how the Joint Commission’s National Patient Safety Goal and the Joint Commission Venous Thromboembolism (VTE) National Hospital Inpatient Quality Measure now require that providers educate patients and families who are prescribed any anticoagulant before they are discharged. These two Joint Commission statements require that patient education include information on “follow-up monitoring, compliance, dietary restrictions, and the potential for adverse drug reactions and interactions” (Moreland et al., 2013.) Even though patient education is now mandated and some studies have shown that pharmacist led education appears to have a more effective impact on patients over physician led (Moreland et al., 2013), warfarin continues to be implicated in multiple adverse drug events. Current data indicate that VKA’s are associated with “approximately 7% of all medication errors” in hospitalized patients (Nutescu et al., 2013). Other studies (Davis, Billet, Cohen, & Arnsten, 2005) have shown that patients are in therapeutic range only about one-third of the time. In an
evaluation of the effectiveness of patient education, “the questions most often missed related to medication dosing or dietary interactions (Moreland et al., 2013).

This is emphasized in a study of oral anticoagulation patient education done by Winans, Rudd, and Triller (2010). They assessed patient knowledge of warfarin using the Oral Anticoagulation Knowledge Test (OAK) developed by Zeolla, Brodeur, Dominelli, Haines, & Allie (2006). They split their patients up into two groups 1) the “usual care” group which consisted of any new warfarin patient who had been educated in the usual way, typically a nurse with no standardized protocol and 2) the “intervention” group which consisted of new warfarin patients that were educated by a pharmacist in a more structured and standardized protocol that included “brand/generic name; indication; dosing and administration; missed doses; drug and dietary interactions; therapeutic, subtherapeutic, and supratherapeutic ; international normalized ratios (INR); monitoring; reversal of warfarin effects; adverse events; and emergency care.” Their results indicate that the “usual” group had a mean OAK score of 55% and their “structured” group had an average score of 74%, which surpassed their predetermined goal of 72% based on patients taking the OAK test who were long-time warfarin users. However, when the OAK test is examined in detail, out of twenty questions, only three are diet specific. (Zoella et al., 2006).

Another recent study by Dennis, Ripley, Planas and Beach (2008) specifically examines the role of vitamin K in oral VKA patients and clinician knowledge. Their review of the literature indicates that “a change in vitamin K intake was the largest interacting factor for accounting for sub-therapeutic INR levels.” The primary goal of their survey was to examine clinician practices for determining diet history and the characteristics of dietary education materials that they provided to their patients. They found that all participants reported providing
education to their patients to maintain consistent vitamin K levels. Some participants reported that they advised their patients to avoid foods high in vitamin K and the main factors affecting this decision were a low literacy in their patient or a high risk for a thromboembolism. The information provided to patients was typically printed information, with 91% of the material being supplied by the manufacturer. The reading level of this material is not reported. Their overall conclusion is that all clinicians placed an emphasis on diet and obtaining a diet history from new VKA patients, however there needs to be improvements in maintaining the emphasis on diet in subsequent visits.

In the published guidelines for the use of anticoagulants (Ansell, Buttaro, Thomas, Knowlton, 1997) a high value is placed on the importance of providing dietary education to all patients on VKA’s. Even though some studies have shown an improved patient adherence with a pharmacist led education plan (Moreland et al., 2013), nurses continue to provide patient education more often and in a more informal setting because they have the greatest access to the patient and the patient’s family (Marcum, Ridenour, Shaff, Hammons, & Taylor, 2002). The question becomes, what information is available to nurses to increase their knowledge regarding the vitamin K content of foods and how best to provide this information to their patients in a format that will be effective? Dennis et al., (2008) included in their study an assessment of the vitamin K knowledge of the clinicians. They were asked to classify 20 vegetables by vitamin K content and had a mean of “64.6 ± 10.9 correct out of 100”, so this evidence supports the lack of dietary knowledge amongst health care providers.

Method for Identifying the Literature

Four literature searches were done using CINAHL to identify articles written for a general nursing audience that provided education on warfarin and vitamin K foods. The
following limitations were established aprior: publication date 2003-2014, English language, Human, Geographic subset: USA, and Age group: All Adult. Boolean phrase searches were conducted using the words “patient education and warfarin”, “patient education and warfarin and diet”, “warfarin and vitamin K and patient education” and “nursing role and patient education and warfarin.” These searches yielded only seven articles in nursing journals.

Four articles were essentially based on the results of a telephone survey of patients post-discharge to assess their knowledge of warfarin (Cheah and Martens 2003; Hu Chow, Dao, Errett and Keith, 2006; Cook-Campbell and Sefton, 2010; Polek and Hardie, 2012). These surveys either had very basic information regarding vitamin K content of foods or none at all.

McCarron (2010) provided a strong background to nurses in clot formation, coagulation factors and pathways, parenteral anticoagulants, oral anticoagulants and teaching tips. It in this last section that she provides some specific information about vitamin K rich foods, listing the following: broccoli, spinach, collard greens, cabbage, chard, parsley, mayonnaise, canola oil, and soybean oil. She also mentions the necessity of informing patients that they do not need to eliminate these foods from their diet only that they are consistent in what they eat.

Eisenstein (2012) provided a general education article and with continuing education credits to its readers. It contained very little information that is specific to warfarin and patient education by two sentences at the bottom of one page regarding vitamin K. “You should avoid eating large amounts of vitamin K-rich foods at a single meal. These include green, leafy, vegetables, such as kale, collard greens, spinach and turnip greens.” Michaels and Regan (2013) focus on patient education regarding self-testing and management, making no specific mention of vitamin K or vitamin K-rich foods, only that patients need information about nutrition and foods that can affect warfarin’s action.
Out of a total of seven articles found specifically in nursing journals that span a period of ten years, only three provide specific food items that patients need to know are high in vitamin K. This clearly seems to indicate that assumptions are made regarding a nurse’s knowledge base regarding vitamin K-rich foods. These assumptions can have profound impacts on how effectively education is provided and patients are able to maintain a therapeutic INR. Cook-Campbell and Sefton (2010) recommend based on their results that “patients need education about vitamin K foods and the association with clot formation….and nurses provide more patient education during the first 24 months of therapy and have an opportunity to improve patient education of warfarin during this time.”

Patient Education

In their consensus guidelines for anticoagulation management Ansell, et al. (1997) found that patient education initiatives that promoted self-care were the most successful in maintaining therapeutic INR levels. Their guidelines also include a list of what information the patient should be able to state, which includes the ability to “identify diet, drug, and alcohol use that might cause problems with therapy” without going into specific information on what aspect of diet can impact warfarin effectiveness. In their review of inpatient anticoagulation therapy, Nutescu et al., (2013) have stated that “to achieve better patient outcomes, patient education is a vital component of an anticoagulation therapy program.” Diamantouros, Bartle, and Geerts (2013) have shown that a majority of the information that patients do receive contains about 63% of the content that experts consider to be necessary to maintain patient safety, with the only dietary reference being made to alcohol consumption.
While there are many aspects regarding patient safety when it comes to taking warfarin, there seems to be very little information in the literature regarding vitamin K and foods high in vitamin K, other than the general statement of “dark leafy greens” or “green leafy vegetables.” Knowledge about vitamin K and its effects on anticoagulation does not carry the urgency that patient knowledge of the symptoms of life-threatening events such as stroke or pulmonary embolism. However, it is an element of patient education that could improve adherence and therapeutic INR values because of the potential for increased knowledge of the clotting process. Wittkwosky and Devine (2004) have shown that for 5% of the patients that are over or under anticoagulated, it is due to changes in dietary Vitamin K. Therefore it seems necessary to provide patients with specific information on the vitamin K content of foods and their need to maintain consistency in their daily intake.

What is surprising to find is that there is still no “gold standard” for educational material that is provided to patients on warfarin. In the candidate handbook for Certified Anticoagulation Care Providers there is no mention of any patient education regarding Vitamin K content of foods (NCBAP, 2013). Cook-Campbell and Sefton (2010) have also noted that patient education on the Vitamin K content of foods and their interaction with warfarin is significantly lacking.

General improvement of patient education needs multiple approaches as suggested by Nutescu et al., (2013) and Cené and DeWalt (2013) and Wilson, Mood, Risk, & Kershaw (2003). Their recommendations include professionally trained educators leading a face-to-face interaction with the patient, groups training sessions for several patients at once, the use of written and/or audiovisual materials, and use of knowledge assessment tools to verify understanding of the material. Nurses are ideal candidates for this role because they have the most interaction with patients on a daily basis and are often able to use “teachable moments” to
reinforce patient education. In a study of patient preferences for communicating the benefits of medicine, Goodyear-Smith, Kenealy, Wells, Arroll, & Horsburgh (2011) found that over half of their study sample preferred pictorial presentations to numbers. They also showed that clinicians need to use multiple methods to communicate risks to patients.

One significant barrier to patient education is the contrast between the literacy level of the patient and the material that they are provided (Cené and DeWalt, 2013; Eisenstein, 2012; Ryan et al., 2008). One way to address literacy levels would be to provide simple cue cards (Cook-Campbell and Sefton, 2010). In addressing dietary issues for any type of patient, keeping a daily journal has often been the recommendation. However regarding vitamin K content, Couris, Tatoron, Booth, Dallal, Blumberg, & Dwyer, (2000) found that having patients maintain a complete diet record to be cumbersome and time consuming not only for the patient but for the health care provider to code and subsequently analyze record entries. They developed a “K-card” for patients to use to determine their weekly vitamin K intake however; it was not tested on actual patients.

Dennis et al. (2008) classified vegetables into three basic categories, low (<10mcg), medium (10-99mcg) and high (>100mcg) when they assessed care-giver and patient knowledge about the vitamin K content of certain foods. The category most often missed was “medium” level food items. Rather than have patients try to determine what their average daily intake is, it may be more effective to have them determine what ranking they are: low, medium, or high so they are better able to maintain their diet consistency and maintain a therapeutic INR level. In developing this ranking level, Dennis et al, (2008) stressed the importance of focusing not only on serving size, but more on the actual amount of food item typically eaten.
Development of the Patient Dietary Tool

I developed a patient tool (see Appendices A, B, and C) that combines a ranking system for vitamin K content of foods into low, medium, high, and extremely high. These levels were chosen based on the current USDA recommended daily allowance of 90micrograms (mcg) of vitamin K for women and 120mcg for men (Vitamin K Foods, 2014). Patients on warfarin should not be discouraged from consuming certain healthy vegetables. The latest USDA (2011) dietary guidelines from their Choosemyplate website suggest not only increasing our daily servings of vegetables but to “choose vegetables rich in color and to brighten our plate with vegetables that are red, orange, or dark green” (USDA, 2011). Vitamin K has also been linked to reducing atherosclerosis and boosting bone health (Barclay, 2007). This tool will enable patients to incorporate these vegetables into their diet on a consistent basis, which is the key to maintaining therapeutic INR levels.

The patient tool has been designed to be simple to read so rather than list vitamin K content of each food item; four different levels of vitamin K content have been used. These levels are low (<10mcg), moderate (10-50mcg), high (51-100mcg), and extremely high (>100mcg). These categories were chosen based on varying assumptions of the average person’s diet and the recommended daily allowance of vitamin K. For example, if a patient consumed daily, on average, three items from the low category, s/he would still be consuming less than the recommended daily allowance. Serving sizes were standardized into 1cup amounts consistent with the USDA recommended servings. Food categories were also grouped to keep the list short and confined to a single sheet for simplicity. The tool is also designed to reduce patient dietary restrictions, giving them more options in their daily diet. By having more options, patients should feel more in control of their daily activities and more likely to adhere to the diet.
In order to begin to demonstrate cultural competence and cultural awareness, certain food items were included to account for varying cultures in the U.S. and also for age, since a majority of warfarin users are over 65 (Cook-Campbell & Sefton, 2010.) According to Campinha-Bacote, (2003) it is the long-standing disparities in the health status of people from culturally diverse backgrounds that has challenged health care providers and they must begin to address these differences and make them a priority. Since the demographics of the U.S. are changing, it is important to acknowledge these cultural changes in the dietary preferences of warfarin patients. In addition to an English Version (Appendix A), the tool was translated into Spanish (Appendix B) and Mandarin Chinese (Appendix C) to aid these patients in their INR maintenance and to begin to increase the cultural knowledge of nurses that will be using this tool.

Options for Administering Patient Tool

It is recommended to have a multidisciplinary approach to patient education regarding warfarin and adherence to INR levels. Anticoagulation treatment is typically initiated with inpatients (Dennis et al., 2008) and most hospitals now use pharmacists when providing education to first time patients (Nutescu et al., 2013, Zeolla et al., 2006). However, Marcum et al., (2002) and Cook-Campbell & Sefton, (2010) have shown that a majority of informal patient education is done by registered nurses. Dennis et al. (2008) found that vitamin K content of food item knowledge among health care providers was minimal. Therefore, it is important for nurses to be educated on the vitamin K content of foods since they are most likely the ones to witness what food items the patients will eat at the bedside. This also presents them with the opportunity to reinforce accurate information and use of the tool. This tool can also improve their knowledge and scope of practice since nurses are the ones to review medication information with patients.
upon discharge and answer patients’ questions. This also improves their ability to evaluate the
patient’s understanding of the use of the tool prior to discharge and maintain the nursing process.

One way to achieve this would be an in-service on how to use the tool. The nurses should
complete the tool themselves, as if they were the patient to gain a full understanding on how to
use it. The improvement in a nurses’ knowledge of vitamin K content of foods can only enhance
bedside care because of the frequency of informal educational opportunities and teachable
moments. As Habel (2005) and Wingard (2005) have suggested, it is nurses who spend more
time with patients than any other team member and are instinctively assessing the patient, which
provides them with the opportunity to develop a trusting relationship, determine learning needs
and abilities, and provide continuity. It becomes clear that nurses are at the forefront of
improving patient understanding of dietary consistency, as long as they have the knowledge
themselves. This impact of nursing care and education is supported in a study by González, B.,
that nurse-guided education changed the self-care behavior of patients with heart failure in
several important aspects, such as weight and blood controls, and increased patient knowledge
and understanding of the disease and treatment.

Once the in-service has been completed, a nurse will present the tool to a patient prior to
discharge but after s/he has been provided general warfarin education by a pharmacist. The
patient is requested to look over the lists of food items and highlight what s/he eats, on average,
over a week. This will then determine which overall category the patient falls into, being low,
moderate, high, or extremely high. If the patient falls into the low category, it could be
suggested that they alter their diet to meet the minimum daily requirements. Enabling a patient
to be more actively involved in their health care decisions can only result in healthier behavior,
greater improvement in their adherence to their INR levels, and will be better at self-monitoring their diet (Sisneros, 2013). It is the goal of modern patient education for nurses to empower their patients to be able to make appropriate decisions regarding their health care and become more autonomous in the daily maintenance of their illness (Wingard, 2005).

If additional questions still arise after this exercise, then a hospital registered nutritionist/dietician could be included on a consult. This patient tool can also be used in the outpatient setting with home health care nurses or rehabilitation nurses due to their potential impact on patient care and education as shown by Cook-Campbell & Sefton (2010) and Polek & Hardie (2012).

Conclusion

Warfarin is an anticoagulant that will probably be continued to be prescribed even though there are several new anticoagulants available. It is disappointing to discover that after more than fifty years, there is still no gold standard when it comes to patient education on warfarin. The tool developed during this review has the potential to increase patient understanding of the importance of consistency in dietary vitamin K which can only improve patient adherence to a therapeutic range for their INR values. This tool will function to expand a patient’s dietary choices and dispel prior inaccurate education that limited their intake of vitamin K rich foods. It emphasizes the importance of consistency by placing the patient in a category of low, medium, high, or extremely high which should likely lead to a stabilizing of INR values. This tool removes dietary control as one of the many variables that contributes to INR levels and addresses some of the lack of patient education in the past.

One key to the proper use of this tool is an in-service training for nurses to understand the tool and an inclusion of a full health care team, including the primary care physician, pharmacist,
nutritionist/dietician, and the HCP supervising the patient post discharge. Nurses are the most trusted profession and are essential to opening and maintaining the channels of communication between the patient and the health care team. This creates a partnership between the patient and the nurse, allowing the nurse to act as a facilitator in aiding the patient’s ability to have more control over their healthcare and creating a sense of shared governance between the nurse and the health care team.
References


United States Department of Agriculture-USDA. (June 2011) *Add more vegetables to your day, DG Tip Sheet No 2*. Retrieved from http://www.choosemyplate.gov


Note: Serving Sizes are essentially 1 cup of each item unless otherwise indicated. Vitamin K sources are PTINR.com and inrtracker.com
Recommended daily allowance of Vitamin K for women is 90mcg and men is 120mcg
NOTA: tamaño de las porciones son esencialmente 1 taza de cada artículo, a menos que se indique lo contrario.

Fuentes de vitamina K es PTINR.com y inrtracker.com

Cantidades recomendadas de vitamina K para las mujeres es 90mcg y los hombres es 120mcg
注意：每份为1勺，除非有特殊注明

Sources are PTINR.com and inrtracker.com

女性每日的摄入钾量：90MCG；男性：120MCG