Mechanical Heart Valve Surgery Patients' Experience with Warfarin: A Qualitative Study

Eda Ayten Kankaya, Özlem Bilik

1Department of Surgical Nursing, Dokuz Eylül University Faculty of Nursing, İzmir, Turkey

Abstract

BACKGROUND/AIMS: This study examined mechanical heart valve surgery (HVS) patients' experiences with warfarin. Although warfarin therapy is of vital importance for heart valve patients, the lack of therapeutic international normalized ratio (INR) levels in long-term anticoagulant therapy can cause various complications.

MATERIALS AND METHODS: This qualitative study was carried out as phenomenological. The sample included 12 first time HVS patients who received anticoagulant treatment for at least three months after discharge. Codes were put together for the purpose of this study and classified. Themes were created.

RESULTS: The mean age of the patients was 50.83±12.91 years, and 66.7% (n=8) of them were male. Their mean exposure time to warfarin was 70.50±49.93 months. Content analysis identified four main themes: "difficulties, facilitators, dependence and the impact of side effects from warfarin". Even those patients who had been using warfarin for many years still suffered from different problems. A lack of knowledge and information about warfarin use still exists. Some patients considered using warfarin as a part of their life, considering it to be more manageable when they agreed to use warfarin, and some said that they continue using warfarin with the support of their relatives and health professionals. Since this study was carried out in the Aegean region, patients had difficulties in limiting greens. The patients mentioned their dependence on the hospital because they had no INR measuring instruments. Some patients explained that they feared the side effects of the drugs, and avoided using other medications.

CONCLUSION: HVS patients had problems adhering to warfarin after discharge. They need follow-up and guidance from nurses.

Keywords: Heart valve diseases, adherence, outpatients, surgical procedures, warfarin

INTRODUCTION

The prevalence of heart valve diseases (HVD) is high both in Turkey and in the world. The prevalence of moderate or severe HVD, corrected by age, was found to be 2.5% in a U.S. study (n=11,911).[1] HVD caused by rheumatic or calcific causes may develop into multiple valvular diseases. HVD are generally progressive and surgical treatment is required in cases of severe insufficiency or stenosis.[2,3] It is important for patients to cope with further difficulties despite successful surgery. One of these difficulties in care after mechanical heart valve replacement surgery (MHVRS) is the patients' temporary or permanent use of anticoagulant medication. The age limitation range was increased from 50 to 50-65 years in 2017, which will increase the number of patients who undergo heart valve surgery (HVS) and receive anticoagulant treatment.[3]

Anticoagulation is very important to prevent valve-related complications in patients with mechanical prosthetic valves. It is assessed using the international normalized ratio (INR) test.[3,4] Although the target INR

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value varies according to the valve type, it is between 2.5-3.5 in the mitral valve, and 2.0-3.5 in the aortic valve. If the therapeutic INR level is high in the patient, while the risk of thrombosis is high, the high INR value may cause various bleeding in the patient. Warfarin is used as an anticoagulant after heart valve prosthesis surgery in Turkey. Therefore, one of the most important points after MHVRS is warfarin adherence. Adherence can be defined as a positive reaction to stimulation.[5,6] Factors that increase the patient's adherence to warfarin are: knowing the reason and importance of using this drug, taking the drug at the same time every day, taking the drug at the recommended dose, continuing their check-ups at least once every four weeks, continuing their check-ups in the same hospital/polyclinic, considering food-drug interactions when eating, checking the INR level within 3-7 days after using a new drug, being aware of the symptoms of complications, and being aware of the methods to avoid complications. The effectiveness of the education given to patients about warfarin at discharge should be evaluated.[7,8]

There are some deficiencies in evaluating warfarin adherence in the healthcare system in Turkey. There is no training program for warfarin and the health records of patients cannot be collected on a single system and records may vary from hospital to hospital. This situation also causes difficulties in INR monitoring. When the literature was analyzed, it was seen that the warfarin-related experiences of those patients with HVS were mostly examined by quantitative research. In one study (n=200), it was determined that 56% of the patients were unaware of potential drug interactions, 58% were not informed about side effects, and 12% were hospitalized due to side effects.[9] In another study conducted in Kenya (n=147), the warfarin adherence of the patients was evaluated via the Morisky Medication Adherence Scale, and it was found that adherence was better in women, older age groups and those patients who had undergone HVS.[10] In the Warfarin TR study conducted by Çelik et al.[12], it was determined that the awareness of the Turkish society about warfarin was low, the therapeutic range varied according to the region and the most bleeding was seen in the Aegean region. In other studies conducted in our country, it was seen that the level of awareness and the knowledge levels of the patients about the use of warfarin was low.[11-14] In these studies, patients using warfarin for reasons such as atrial fibrillation and thromboembolism constitute the sample of patients with valvular diseases. With the study we conducted on the warfarin use of MHVRS patients, we thought that understanding the perspectives, opinions and experiences of the patients would be useful in patient education, preventing warfarin-related complications and increasing their adherence to treatment. For these reasons, in our qualitative study, we examined the experiences of those patients with mechanical valve prosthesis regarding warfarin after discharge.

MATERIALS AND METHODS

This study was written using the Consolidated Criteria for Reporting Qualitative Research, which provides guidance in reporting qualitative research.[15] This qualitative and phenomenological study used purposeful sampling. The data were collected in the cardiovascular surgery outpatient unit in a university hospital between June and October, 2017. In the hospital outpatient unit where the study was carried out, no nurses worked. During discharge, education about warfarin therapy was provided by nurses. When they come to the polyclinic, their information needs about warfarin are provided by physicians.

The sampling criteria were as followed:

- Undergoing HVS for the first time,

- Receiving a mechanical heart valve prosthesis,

- At least three months having passed since surgery,

- Over 18 years old,

- Having no psychiatric diagnoses,

- Having no hearing loss.

These patients came to their polyclinic check-ups to have INR tests done. After giving blood for INR, the patients wait in the outpatient clinic until the test result are ready. Patients meeting the sampling criteria were interviewed while waiting. A total of 15 patients were approached: one declined to participate in the study, two patients left, saying that they had to go 15-20 minutes after the start of the interview, and the study was completed with 12 participants. The sample size was determined following the repetition and saturation of the data.[16,17]

Data Collection

The data were collected using a socio-demographic characteristics form, a semi-structured interview form and a tape recorder. The researcher asked the main interview question, "What is it like to use warfarin?" and these sub-questions in the semi-structured interviews:

- How does warfarin use affect your life?

- What are your difficulties with using warfarin?

- What are the factors that ease the use of warfarin?

This study was conducted by two female academic researchers, E.A.K. and Ö.B. (Ph.D. candidate and associate professor). The researchers had participated in courses related to qualitative research and had qualitative research experience. They also had conducted studies on cardiovascular surgery nursing. In this study, the interviews were conducted by E.A.K. Two academic nurses gave their expert opinions regarding the questions on the semi-structured interview. The data were collected during face-to-face and in-depth interviews which were conducted in a quiet, comfortable room, in the same outpatient clinic of the hospital. The interviews lasted for 35 to 45 minutes. During the interviews, the researcher took notes of her observations and the patients' statements. The notes taken during the interview were confirmed by the patients. The tape recording was transcribed. There was no relationship established prior to the study commencement. Repeated interviews were not conducted with the same patient.

Statistical Analysis

The data were analyzed using content analysis. All the expressions were written by listening to the audio records of the patients. The expressions associated with the patients' experience with warfarin use were combined to create codes. Similar codes were combined and categorized. The codes were put together for the purpose of the study and classified by the authors. Themes were created.[16] Data saturation was discussed and analyzed by two researchers. Their differences were discussed, and the data were organized and finalized. Transcripts were not returned to the participants for comment or correction. No software was used to manage the data. The participants did not provide feedback on the data.

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Validity and Reliability

The principles of plausibility, transmissibility, consistency and verifiability were used to confirm the validity and reliability of the study.[16,17] Expert review and long-term interaction ensured plausibility. The findings were presented without generalizing to ensure transmissibility. The same researcher collected the data using the collection forms and a tape recorder for consistency. The researchers reviewed all the data collection tools, voice recordings, raw data, and codes and themes generated during the analysis, which were all preserved to be further examined if necessary.[18,19]

Ethical Considerations

Permission was taken from the hospital where the study was conducted (Dokuz Eylül University Hospital) and the Dokuz Eylül University Ethics Committee for Non-invasive Clinical Studies (approval number: 2016/24-03, date: 08.09.2016). Before the interview, the researcher introduced herself and the purpose of the research was explained and written and verbal informed consent was obtained from the patients. The study data and the notes taken were kept by the researchers.

RESULTS

The mean age of the patients (n=12) was 50.83±12.91 years, and 66.7% (n=8) of them were male. Their mean time being on warfarin treatment was 70.50±49.93 months.

Four main themes and twelve sub-themes were identified in the interviews (Table 1). The socio-demographic characteristics of the patients and the duration of warfarin use are given at the end of the examples of the patients' expressions.

Theme 1: Difficulties

Patients have difficulties in using warfarin. Five sub-themes of this theme were determined.

Subtheme 1.1. Irregular INR Levels

The patients said that they had irregular INR levels, difficulties in organizing the therapeutic range of warfarin.

Table 1. Themes and sub-themes regarding warfarin use	
Main Theme	**Subthemes**
1. Difficulties	Irregular INR levels
	Forgetting to take warfarin
	Limitations on greenery consumption
	Self-reducing warfarin dosage
	Avoidance of using other medications
2. Facilitators	Acceptance
	Support of family and health professionals
3. Dependence	Requirement of frequent follow-ups
	Problems of measuring INR levels in different hospitals
4. Impact of side effects from warfarin	Bleeding and prevention behaviors
	Itchiness
	Fear
INR: international normalized ratio.	

"My INR level increased to over 5 about five months ago. I nearly had a brain hemorrhage. I felt nauseous and dizzy. My warfarin dosage was reduced" (24, male, 42 months).

"We realized just as it was about to clot. I ate plenty of vegetables since my INR level was high, and this caused it to fall. Only Allah and I know what I have been going through for almost 7 or 8 months" (47, male, 108 months).

Subtheme 1.2. Forgetting to Take Warfarin

Some of the patients said that they forgot whether they had taken their warfarin daily or doubted whether they had taken it.

"It took a while to get used to warfarin. I would forget to take warfarin. I had some difficulties with taking warfarin every day. But I got used to it after a while" (24, male, 42 months).

"I take a full dose of warfarin for two days, and a half for one day. I forget which day I took a full or a half dose. I wonder what I took this day. With age you get memory problems. What if I took my warfarin, forgot that I did and take it again?" (56, female, 60 months).

Subtheme 1.3. Limitations on Greenery Consumption

Among patients who restrict what they eat because of drug-nutrient interactions, some said they never consume green vegetables.

"When you eat greens, the effect of the blood thinner is reduced. More warfarin was needed. I thought that even though we didn't drink blood thinners, when we ate greens, our blood was diluted. But it wasn't so" (56, female, 60 months).

"We should not consume much greenery. There's too much vitamin K in parsley. Harmful to us. A month after my blood was taken. I can eat them a little bit for more than 15 days. I reduce the greens. I've put myself in such an order" (52, female, 96 months).

"I eat a small bowl of salad and vegetables, but not every day. If a pastry has vegetables in it, I do not eat that either" (41, female, 18 months).

"I did not change anything. They explained that certain foods are not allowed, but I did not pay attention" (24, male, 42 months).

Subtheme 1.4. Self-reducing Warfarin Dose

The patients said that they had reduced the dosage of the warfarin on their own or did not take it from time to time.

"I have not taken my warfarin since last week. I experienced tingling. I stop taking warfarin when I feel like my INR level has increased. You can tell when your INR level is high" (47, male, 108 months).

"If I have gingival bleeding or bleeding elsewhere, I take half of my blood thinner" (56, female, 60 months)

"I reduced the dosage of my warfarin myself. I did not realize its importance. I had a brain embolism, and I really suffered from it" (52, male, 240 months).

Subtheme 1.5. Avoided Using Other Medications

"Since we cannot use medications, I do not kiss anybody in winter because I fear it will be quite difficult for me to heal. I do not use

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medication when I get the flu. Doctors do not give antibiotics" (52, male, 96 months).

"I take painkillers when I have too much pain. I do not consult the doctor. I take them when I am quite sick" (45, male, 38 months).

"I do not take medications by myself. I do not even take painkillers" (66, male, 24 months).

Theme 2: Facilitators

Some patients considered using warfarin as a part of their life. They found it more manageable when they agreed to use warfarin, and some said that they continue using warfarin with the support of their relatives and health professionals.

Subtheme 2.1. Acceptance

"They said I will use warfarin for the rest of my life. I have accepted it. It prevents blood clotting. If blood clotting occurs, blood does not flow to the heart and brain. That's why I must take my warfarin" (66, male, 24 months).

"Of course it affects my life, but I do not feel uncomfortable with it because it is good for me. I am obliged to take warfarin and go to check-ups. I am aware of that" (71, male, 72 months).

"Life becomes easier when you psychologically accept the disease. I do not question why or how I use it" (39, male, 180 months).

Subtheme 2.2. Support of Family and Health Professionals

"My husband and daughter helped me a lot. They showed me how much I can eat. They gave me a diet book that says we should not eat heavy food. The dietitian plans my diet in accordance with it" (52, female, 96 months).

"I use the brochure that the doctor gave me. I ask my doctor about things I wonder about at check-ups. My partner helps me" (45, male, 38 months).

Theme 3: Dependence

The patients mentioned their dependence at the hospital because they had no INR measuring instruments.

Subtheme 3.1. Requirement of Frequent Follow-ups

The patients emphasized that going to check-ups every month was time consuming and tiring.

"I will have a tooth removed. I came back to the cardiovascular surgeon. It takes quite a time for us to inject. You cannot have a tooth removed without antibiotics. Taking warfarin, check-ups. Going to the doctor's and coming back. You need check-ups" (71, male, 72 months).

"You have to come to the doctor's every month. Coming and going is a waste of time. I am getting tired. While waiting for the results, I get bored" (66, male, 24 months).

Subtheme 3.2. The Problem of Measuring the INR Level in Different Hospitals

The results of tests done at different health centers and differences with the hospital where they went for check-ups caused the patients to lose trust in the healthcare system.

"I go to my check-ups in another hospital. They did not let me leave the hospital a few times because my INR level was high. I realized that I have nothing wrong, nothing is high. My INR level was 12 or 13 at that time. A value of 12 causes me to have cerebral bleeding. I did not eat anything, and they did nothing. I do not trust them after that" (47, male, 108 months).

"Sometimes when I do not come here, I get check-ups at another hospital. My blood value was much better here. My bleeding returned to normal, but when I got check-ups there, and my warfarin dose was increased, I encountered problems" (41, female, 18 months).

Theme 4: Impact of the Side Effects from Warfarin

Patients explained that they experienced bleeding and itching associated with the use of warfarin. They said that physicians warned them about bleeding, and they feared the side effects of the drugs, and avoided using other medications.

Subtheme 4.1. Bleeding and Prevention Behaviors

Bleeding was the most common problem for patients. Patients stated that the bleeding was so severe that they sometimes referred to emergency services. The types of bleeding that the patients expressed were menstrual bleeding, nasal bleeding and ecchymosis. Patients stated that they were paying attention to the warnings of doctors to protect themselves from bumping into things and falling.

"I had so much nasal bleeding right after surgery, a total of 10 or 15 hours per day. I went to the emergency room lots of times. Sometimes, my arms were black and blue. I once cut my wrist while I was doing technical work, and the bleeding did not stop. I do not do any risky work" (39, male, 180 months).

"When I bump into something, my skin turns black and blue. I take care not to cut my hands while cooking. When I cut myself, the bleeding does not stop. I get bruises because warfarin dilutes the blood. I take care not to bump into sharp objects. We made no special arrangements at home" (41, female, 18 months).

"I use gloves when I work. I use steel-toed shoes, boots so as not to hurt my feet because warfarin dilutes the blood. It immediately causes bleeding when I brush my teeth a little bit too hard" (45, male, 38 months).

Subtheme 4.2. Itchiness

"If severe itching occurs on specific parts of the body while using warfarin, its use should immediately be stopped. If it is not discomforting and there is no itching, then it means that the INR level is quite low. When you estimate the itchiness, you keep your INR around 2.5. I do it like that" (62, male, 96 months).

"I do not know if the reason is my INR level being high or what, but one time I had itching on my body. I had it one week earlier, too. I still have itching. I had it a few times. My back and my entire body itch" (45, male, 38 months).

Subtheme 4.3. Fear

Some patients experienced fear from time to time due to the side effects of warfarin.

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"I know how important warfarin is. If I do not use warfarin, my heart valve may develop a clot and it may affect blood flow. I had surgery for gynecology. I had HVS before. I wasn't so scared before heart surgery. Warfarin was discontinued for surgery. What if a clot is formed or I can't wake up? What if my heart doesn't work? I was so scared. I was very affected by the discontinuation of the drug" (52, female, 96 months).

"It did not affect me in the first few months after surgery, but in the last three or four months of taking warfarin, I was hospitalized two or three times. My menstruation did not stop for a month. I lost consciousness the last time I went to the emergency room. After this event, I'm very afraid to go out alone. My husband is afraid for me. He keeps calling frequently. I'm worried something's gonna happen" (41, female, 18 months).

"In the beginning, I was afraid of the risk of paralysis. You adapt with time. You are obliged to" (39, male, 180 months).

"Warfarin may cause bleeding. Stomach bleeding, nosebleeds, gum bleeding... If you don't use it, that can cause clots. You're scared you're affected. If you take less or more, you die" (52, male, 96 months).

DISCUSSION

The investigation of the experience of warfarin use in patients with mechanical heart valves is very important to facilitate training and follow-up. Although warfarin has been used for many years, patients still lack information. We aimed to investigate patients' experiences with warfarin in our study. We thought that understanding what patients experience would enhance their care regarding their treatment process and drug use.

This study found that patients had difficulties with warfarin usage. Some patients had irregular INR levels or had forgotten to take their warfarin. One of the patients who participated in this study stated that he was trying to reduce his high level of INR by eating excessive greens. These problems were thought to be caused by a lack of knowledge about warfarin.[20] A relevant study conducted in Turkey found that 114 patients had low levels of knowledge about warfarin treatment and difficulties adjusting to their warfarin treatment.[14] Another study specified the rate of reaching the desired INR levels of patients (n=57) who came to an internal medicine polyclinic to be 52.6%.[21] A study conducted in Jordan found that 22% of patients (n=331) had knowledge about warfarin-medication interactions, and 37% had knowledge about warfarin-food interactions.[22] The patient in our study who forgot to take warfarin or pay attention to nutrition despite having received education may have failed to accept the disease because he was young. A systematic study of cardiac failure patients determined that medication maladjustment is a significant risk factor, especially for younger patients.[23]

Patients were thought to have knowledge about warfarin-related food selection. One patient stated that he did not pay sufficient attention to the limitations on nutrition, although he had been informed. A few patients were extremely attentive in choosing green foods. The literature indicates that vitamin K affects coagulation.[24,25] Therefore, patients must limit their consumption of foods containing vitamin K, and their daily rate of vitamin K should be constant.[26] There were differences in reaching the therapeutic range in our country according to regions.[11] The consumption of greenery has an important place in the nutrition in Aegean culture. Since this study was conducted in the Aegean region, it was thought that the participants in this study had difficulty in limiting their intake of greens.

It was found that two patients in this study occasionally reduced their own doses of warfarin, and one patient discontinued the use of warfarin without medical advice. It is very important to take warfarin at the dose recommended by the physician in order to maintain a therapeutic INR level. A similar study also found that the rate of patients who were aware of the interaction of medication and food was 55% and that the INR levels of those patients with more awareness were higher.[12] Self-dose reduction or skipping of the medication by the patients may be explained by their low awareness levels on this issue.

Another point that the patients emphasized was the interaction of warfarin and other medications. As warfarin interacts with other drugs, the patients were anxious about taking other drugs. One patient stated that he avoided hugging and kissing other people because of the fear of falling ill, while two other patients even refrained from taking painkillers. Patients should only take other medication after consulting a doctor.[7,8] This is not maintained by all patients and it may be due to their inability to reach a physician easily and the lack of a dedicated anticoagulant clinic or nurse for these patients. Also, the patients' unwillingness to interact with other people because they are afraid of drug use can affect their interpersonal relationships.

Some patients said acceptance of warfarin use was facilitated by the support of their family and health professionals. Acceptance is an indicator of adherence to treatment. As the patients said, individuals must accept the disease and its effects on their lives in order to manage their chronic disease.[27,28] Both the support of family members and the professional support of the medical staff ease patients' acceptance to the disease and help them manage it better.[29]

Another theme identified in this study was dependence. One patient stated that when their INR level was outside of the therapeutic range, it was necessary to go to the polyclinic more frequently and another patient stated that the frequency of follow-up before and after tooth extraction increased. One patient mentioned that it often took a lot of time to come and go to the hospital. Patients may feel uncomfortable with going for constant clinical check-ups. A similar study (n=183) conducted in China found that 40% of patients said that they felt uncomfortable with waiting in anticoagulant clinics.[30] Another sub-theme was the problem of measuring their INR levels in different hospitals. Two patients had problems with visiting different health centers. Patients did not have their own measurement instruments. As a consequence, patients had to go to a polyclinic at least once a month. Different doctors interpreting the results may result in changes in warfarin dosages. Therefore, patients may suffer unwanted side effects, including bleeding. At the same time, hospitals do not have a standard protocol for warfarin dosages. All these factors are thought to cause problems because of the dependency on hospitals.

The last theme detected in our study was the impact of the side effects from warfarin. This study found that patients had bleeding caused by warfarin and fears about it. A few patients mentioned precautions to prevent bleeding. A similar study examining warfarin complications found that the most common hemorrhagic complications were nasal bleeding (n=9, 31%), dermal complications (n=7, 24%) and re-hospitalizations (n=7, 24%).[31] Another relevant study stated that the increase in INR values was found to be associated with the risk of bleeding.[32] The patients' lack of knowledge about warfarin may have caused the occurrence of bleeding. Some patients reported itchiness as emphasized in the literature.[33]

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Some of the patients said that they feared paralysis and death because they were unable to determine warfarin dosages. One patient emphasized the fear of clot formation after warfarin discontinuation before gynecological surgery. A patient stated that she had applied to the emergency department because of non-stop menstruation and that she was worried about going out alone. Patients should be allowed to express their fears and express themselves. Precautions need to be taken so that the prevention of side effects is effective.

We think our study will guide other studies in the future. In this study, with or without chronic disease, we worked with patients of different ages. It was important to understand the drug use experiences of this patient group. We could make the sample of our study more specific in a later study. In future studies, the patient experiences can be examined by studying the experiences of a targeted group, with patients having chronic illnesses and using multiple drugs, or patients using only warfarin without chronic disease. In addition, based on our research results, experimental studies can be conducted with MHVRS patients in order to increase the level of awareness and drug adherence.

CONCLUSION

A lack of knowledge and information about warfarin usage still exists. Patients had problems with adherence to warfarin usage and their check-ups. This study was carried out in the Aegean region where the consumption of greenery has an important place in the local nutrition. Therefore, it was thought that the participants had difficulty in limiting their intake of greens. There are some deficiencies in evaluating anticoagulant treatment adherence in the healthcare system in Turkey. The use of personal INR measuring devices could help improve patient comfort while reducing fear and loss of time due to outpatient check-ups.

MAIN POINTS

- The investigation of the experience of warfarin use in patients with mechanical heart valves is very important in order to design training and follow-ups. In our study, it was seen that patients who have been using these drugs for a long time still have information needs.

- The importance that patients attach to drug usage may vary depending on situations such as their eating styles, habits and their perception of their disease. After discharge, patients should be allowed to express their feelings and personalized nursing interventions should be provided.

- There is a need for experimental studies in order to improve the usage of warfarin in patients.

ETHICS

Ethics Committee Approval: Permission was taken from the hospital where the study was conducted (Dokuz Eylül University Hospital) and the Dokuz Eylül University Ethics Committee for Non-invasive Clinical Studies (approval number: 2016/24-03, date: 08.09.2016).

Informed Consent: It was obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: E.A.K., Ö.B., Design: E.A.K., Ö.B., Data Collection and/or Processing: E.A.K., Ö.B., Analysis and/or Interpretation: E.A.K., Ö.B., Literature Search: E.A.K., Ö.B., Writing: E.A.K., Ö.B., Critical Review: E.A.K., Ö.B.

DISCLOSURES

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