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Research Article

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Garlic EBP Protocol for Hypertension

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Abstract

Background: *In the contemporary life, the widespread of chronic diseases increases dramatically. The prevalence of hypertension continues to increase and the majority of individuals with hypertension exceed approximately one billion worldwide. With the emergence of the new American Heart Association Guidelines, the prevalence of hypertension particularly among young adults is becoming even higher than before. Thus, developing an evidence-based protocol to contribute with enhancing the quality of health of hypertensive patients is proposed to address the problem.*

Objective: *The purpose of this research is to develop an effective protocol through using the garlic as an alternative natural medicine to reduce high blood pressure.*

Design*: A Stevens Star Model of Knowledge Transformation© is used as a framework for developing an EBP protocol aimed at decreasing high blood pressure by using garlic.*

Method*: We searched the following electronic database Cochrane library, PubMed, EBSCO, and Google Scholar from September through October 2017 to identify evidence that compared garlic to placebo in reducing blood pressure among hypertensive patients. We identified 2 systematic, 2 meta- analysis, 2 systematic review and meta, 6 RCT, 1 cohort, and 1 Cochrane review.*

Result: *Due to those active components in garlic such as Allicin, it has proven its effectiveness in decreasing high blood pressure for patients with hypertension.*

Conclusion: *Utilizing the suggested guidelines will help hypertensive patients to control their hypertension. In addition, hypertensive patients could have other benefit such as decreasing their cholesterol level and improving their immunity.*

Keywords: Hypertension, Blood Pressure, Garlic, Evidence-based, Nurses, Allicin, Placebo.

Introduction

In the contemporary life, the widespread of chronic diseases increases dramatically. Many risk factors contribute and increase the risk of chronic conditions such as hypertension, diabetes mellitus and asthma. The most common risk factors are associated with the lifestyle pattern beside genetic factors. Hypertension is one of the chronic diseases that influences approximately one billion individuals globally and around 30% of adults in Western countries [1]. In addition, it leads to nearly 9.4 million deaths worldwide, of which 45% and 51% respectively attributed to stroke and heart disease [2]. With the emergence of the new American Heart Association Guidelines, the prevalence of hypertension among young and adults is becoming even higher [3]. Many researchers disclose that the prevalence of individuals who are diagnosed with essential hypertension is about 90 to 95%, whereas the remaining 5 to 10 % are non-essential hypertension, and the percentage might increase with the new changes in the hypertension classification guidelines [2].

Hypertension defined as a persistent elevation of systolic and diastolic blood pressure reading more than 140/ 90 mmHg whereas the normal blood pressure is 120/80 mmHg. However, now, patients who have a SBP reading between 130-139 mmHg and a DBP between 80-89 mmHg on two or more occasions are considered hypertensive, which makes hypertension one of the most if not the most prevalent chronic disease worldwide [3]. Hypertension is called the silent killer because it is asymptomatic in its early stages, which can immensely affect the quality of life. It is classified into two categories: essential (primary) and non-essential hypertension (secondary). The primary hypertension is the most common type among patients as it is idiopathic. In other words, the main cause of essential hypertension is unknown. In contrast, non-essential hypertension has specific causes that are associated with other health problems like cushion's syndrome, hyperthyroidism, chronic renal diseases and many more conditions.

About 3 million hypertensive patients have uncontrolled hypertension due to the ineffective antihypertensive medications [4]. This has lead scientist to search for other treatments that could be more effective in treating high blood pressure with minimal risks. In addition, according to Amoh-Mensah et al. (2017), the cost of medications that are used to treat patients with hypertension in 2006 was estimated as one billion pounds in the United Kingdom. Since the regular treatment of hypertension is ineffective and costly, the purpose of this paper is to develop an effective Evidence Based Practice (EBP) protocol through using the garlic as a complementary natural medicine to reduce high blood pressure.

Nursing significance

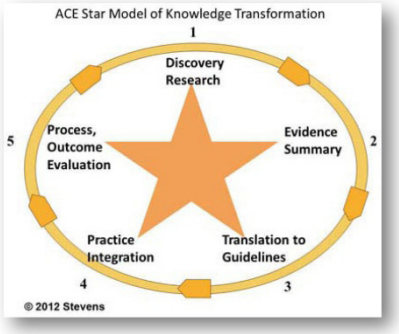
Using garlic has shown significant implications in the clinical, administrative and educational nursing practice. The research findings indicated that natural interventions may just be as effective as other chemical based medications. Therefore, utilizing such a natural intervention in the clinical sittings help to avoid the associated side effects of chemical based medications. In addition, the findings on the impact of natural interventions on the treatment of hypertension will have educational implications in the nursing practice. For instance, the nurses are accountable to educate and instruct their hypertensive patients about the consumption of the garlic supplementations. Nurses must become aware with the action, side effective, of several complementary alternative medicine products [5]. Hence, the instructional curriculum will have to be reconfigured to include the findings as an alternative mode of treating hypertension alongside the other conventional treatments [6]. Consequently, students may be encouraged to conduct more insightful research studies to uncover new and innovative ways of managing hypertension.

Similarly, the findings are likely to have implications in the nursing administrative sittings. In future, the administrative practices of managing patients or hospital units that deal with hypertension will have to adapt and include mechanisms to accommodate the new findings as means of managing hypertension. When aspiring administrative nurses are being well versed with the natural based interventions and promoting their use, the patients' well-being will be improved [7]. The reduced cost of treatment, which does not have to come at the expense of effectiveness, will have administrative implications for the treatment of hypertension [5].

PICOT Question

Among hypertensive patients, what is the effect of garlic in compare to placebo in reducing high blood pressure over a period of three months?

Model ACE STAR



Stevens Star Model of Knowledge Transformation© [Ref.No-8].

The ACE Star Model is used as a framework for developing an EBP protocol aimed at decreasing high blood pressure by using garlic. The ACE STAR Model of Knowledge Transformation consisted five stages that helped to organize the process of developing this protocol. This model is used for both translation and implementation of the EBP protocol. The first stage is discovery of new knowledge, and the second stage is evidence summary, which will assist nurses in critiquing the evidence. The third stage is translating evidence into guidelines, which can be applied into practice through the fourth stage, which is practice integration. Finally, the impact of the new guidelines will be evaluated in the process and outcome evaluation stage. However, the implementation and the evaluation stages for this protocol were not conducted [8].

Method

We searched the following electronic database Cochrane library, PubMed, EBSCO, and Google Scholar from September through October 2017 to identify evidence that compared garlic with placebo in reducing blood pressure among hypertensive patients. Keywords for databases searching were "garlic", "hypertension", "blood pressure", "clinical trials", "randomized clinical trials", "systematic review", and "evidence-based". We identified 2 systematic review, 2 meta- analysis, 2 systematic review and meta-analysis, 6 RCT, 1 cohort, and 1 Cochrane review articles.

Literature Review

For over 5,000 years garlic has been used for different purposes as it is considered one of the ancient herbs that proved its effectiveness for the health preservation and illnesses treatment. For instance, in ancient Greek, the father of medicine Hippocrates documented that garlic was utilized as a diuretic. Besides its profits on the cardiovascular system, ordinarily garlic has been used to bolster the immune system as well as improve the health of gastrointestinal system [1].

Most studies showed that garlic has several mechanisms. It consists of various bioactive substances including allicin, which has antioxidant action. Several studies explained that allicin could lower BP by inhibiting the angiotensin-converting enzymes

(ACEs) [10]. Moreover, the garlic's ability to reduce blood pressure has been associated with its hydrogen sulphide production and allicin component, which is announced to have angiotensin II inhibiting and vasodilating effects [11].

Due to those active components, garlic has proven its effectiveness in decreasing high blood pressure for patients with hypertension. In a randomized clinical trial (RCT) examining the effect of daily intake of 2 capsules of aged garlic extract (1.2 g containing 1.2 mg *S*-allylcysteine) on blood pressure and other cardiovascular risk factors over a period of 12 weeks, the researchers determined that garlic decreased the blood pressure for patients with SBP of $\geq$ 140 mmHg and DBP of $\geq$ 90 mmHg by 11.5 $\pm$ 1.9 mmHg systolic and 6.3 $\pm$ 1.1 mmHg diastolic (P<0.001) [4].

According to Ried and Fakler (2014) report, a meta-analysis including 20 clinical trials on hypertensive patients, proposed that garlic was better in compared to placebo in reducing the BP [1]. The average of the decrease in SBP was about 8–9 mmHg and 6–7 mmHg in DBP, $P < 0.0001$. The literature revealed that even though garlic supplementation played an essential role in lowering BP significantly in patients who are diagnosed with hypertensive, it did not considerably influence patients with normal BP [1].

Another Meta-analysis displayed that 4.4 mmHg was the mean decline in SBP in hypertensive patients after using garlic (95% CI, 7.37 to 1.42, I2=0.0%; P=.004) while there was no significant decrease in DBP. However, the heterogeneity existed in some trials; hence, these trials were removed after sensitivity analysis. As a result, the DBP was decreased by 2.68 mm Hg (95% CI, 4.93 to 0.42, I2=0.0%; P=.020). Overall, meta-analysis illustrated that using garlic supplementation resulted in significant decrease in both SBP and DBP in hypertensive patients while there was no effect on normotensive group [10].

Not only for hypertensive patients, but also for pre-hypertensive to mildly hypertensive patients, garlic has proven its effectiveness in decreasing SBP and DBP. Nakasone, Nakamura, Yamamoto, and Yamaguchi (2013) compared the use of GH diet, including two capsules each contained 500 mg of 'Dentouninnikuranwo™' with placebo on pre-hypertensive and mildly hypertensive patients over a period of 12 weeks [9]. The researchers concluded that the GH diet showed a significant effect on decreasing the blood pressure for mildly hypertensive patients.

Another meta-analysis that examined the use of different garlic preparation concluded that SBP and DBP were reduced more effectively with patients treated with different garlic preparation, which means that different forms of garlic can be effective in decreasing blood pressure [12]. However, Qidwai and Ashfaq (2013) reported that those different forms should contain a large amount of allicin in order to be effective [13].

Different studies that used garlic to decrease blood pressure reported other benefits of garlic, such as decreasing high cholesterol level and regulation other hemodynamic measures [14]. For example, Varshney and Budoff (2016) gathered eight meta-analyses that examined the effect of garlic in lowering cholesterol level [15]. The result shows that different garlic preparation reduced the level of total cholesterol (TC) by 7.4–29.8 mg/dL.

Stimulating immunity is another benefit of garlic. According to Ried (2016), in a clinical trial consisted of 120 participants, it was found that using 2.56 g of AGE over 3 months increased T cells significantly and reduced the inflammatory markers, including C-reactive protein and TNF-a [14]. Therefore, garlic can be utilized to improve the patient's immunity.

In this paper, we reviewed 15 articles that examined the effect of garlic on blood pressure. Appendix A includes the table of literature synthesis and a summary of the evidence gathered.

Target Population:

1. Stage 1 hypertensive patients who have a systolic BP reading of 130139 mmHg and a diastolic BP of 8089 mmHg [9].
2. Stage 2 hypertensive patients who have a BP reading of $\geq$ 140/90 mmHg [9].
3. High Cholesterol patients who have total cholesterol levels of 240 mg/dl or higher [16].

Assessment

1. Assess the patient's past and current medical history for any chronic diseases, the use of antihypertensive medications, and other medications.
2. Use the appropriate method in assessing the patient's' BP. The patients should be placed in sitting position with the arm supported at the heart level. The patients should be rested for at least five minutes and should abstain from food, caffeinated beverage, and smoking before the assessment (Ried, Travica, & Sali, 2016).
3. Measuring the BP by using an accurate sphygmomanometer and appropriate cuff size.
4. Assess the patient for garlic allergy.

Guidelines for using Garlic to decrease high blood pressure

1. For *uncontrolled* stage 2 hypertensive patients, take 2 capsules of (1.2g Aged Garlic Extract (AGE) + 1.2 mg *S*-allylcysteine (SAC)) in the evening daily for 12 weeks with regular medications and exercise 3 times a week [4].
2. For stage 1 hypertensive or mildly hypertensive patients, follow GH Diet: 2 capsules of 'Dentouninnikuranwo™' (each capsule is 500 mg containing 188 powdery mixture of garlic with egg yolk) daily at any time for 12 weeks without any medications [9].
3. For hypertensive patients with high cholesterol, take 3 gm of fresh garlic (1 Clove yields from 5-9 mg of allicin) for > 2 months without low fat diet or high cholesterol medications [12, 13].

4. For hypertensive patients with high platelet aggregation who are taking warfarin, take aged garlic extract (10 mL/day, containing 14.7 mg S-allylcysteine. Using a high concentration of AGE has shown no increase in the incidence of hemorrhage for patients on warfarin therapy [1, 11, 13, 14].
5. Avoid exposing garlic to heat because it could affect the active compound of garlic that reduces blood pressure, which is allicin [12].
6. Garlic powder, fresh garlic, and aged garlic extract are the most effective preparation for lowering high blood pressure. Most of the reviewed articles showed that garlic powder, fresh garlic, and aged garlic extract are the commonly used preparations for lowering high BP.
7. Besides using the garlic, the patients should modify their lifestyle such as low sodium intake, regular exercise, smoking cessation and limit alcohol intake.
8. Instruct the patient to consult the physician before discounting any medications. Even though there are evidence showing that garlic should be used with standard antihypertensive medication, the patient should discuss the dose with their doctors to avoid developing hypotension.
9. Patient's value and cultural beliefs should be considered while developing the patients' treatment plan especially discussing the use of garlic as a complementary medicine with standard antihypertensive medication (Lane, 2015).

Safety and Tolerability:

Generally, the use of garlic is very safe. However, consuming it daily might result in minor adverse effects. According to the literature, most of the side effects were minor and related to gastrointestinal system such as bloating, discomfort, flatulence and reflux [12]. The most statistically significant side effect associated with raw garlic are body odor and halitosis. In addition, some patients can develop allergic reaction like anaphylaxis reaction [15]. One of the side effects of GH diet is diarrhea.

Implementation

The implementation of this protocol would be appropriate in outpatient clinics or the chronic disease clinics in the primary health center. Before implementing the process, an approval should be obtained from the administration department, the supervisors, the doctors, and nurses who work in these clinics. Doctors, nurses, and dietitian should collaborate to develop a treatment plan for each patient according to his/her condition and involve this protocol in the plan. After that, nurses should provide educational sessions to inform the patient about the impact of garlic on their high blood pressure. Nurses and educators should also explain the use of garlic and its side effects with or without medication based on the patients' conditions and treatment plans. Nurses should provide the patients with a checklist form to help measuring the progress and compliance to the garlic use.

Resistance

The stakeholders should put into consideration the resistance that they might encounter. For example, the nurses might refuse to implement this protocol due to the increase in the work load because having educational sessions and collecting data will further increase the load. In addition, the patients might refuse or resist taking garlic especially in a raw form due to bad odor or abdominal discomfort. However, this resistance will be resolved when the nurses and the patients recognize the effectiveness of the intervention.

Cost Effectiveness

Based on the studies that showed the significant effectiveness of using garlic for lowering the BP among hypertensive patients and the safety demonstration with no side effects, most of the developing countries use the garlic as a supplementary medicine for hypertension [15] They have been using different types for their pharmaceutical benefits and cost effectiveness. Garlic supplementation is non-costly. It is estimated that garlic costs approximately between $1- $16 depending on the brand of the supplementary product [17]. In addition, upon exploring Amazon, it appears that the total cost of a bottle containing between 120-300 capsules of aged garlic extract ranges between $12- $24, which is about one cent per capsule. In addition, the cost of one pound fresh garlic is about $8.99. In 2008, the cost that was spent on adults with hypertension for the health care services was $47.3 billion. The amount of the expense for prescribed antihypertensive medications only cost $21.3 billion. This shows that garlic is much cheaper than the regular antihypertensive medications.

Timeline

After implementation, garlic has shown its effectiveness in decreasing high blood pressure over a period of 12 weeks. However, for long-term clinics, the implementation should be for a longer period of time to determine the outcomes on a wider range. Therefore, the plan for implementation will be over a period of 24 weeks. The outcomes will be measured during the first follow up after 2 weeks, then, after 12 weeks, and 24 weeks of application.

Outcomes Assessment Plan

According to the literature, garlic has resulted in many benefits for hypertensive patients besides reducing blood pressure. The expected outcomes for consuming garlic over 24 weeks are lowering high BP, lowering high cholesterol level, improving the immunity, and cost saving.

Lowering High BP

Most of studies have shown that the consumption of garlic reduces the systolic high BP. The high BP can be measured routinely by using an accurate sphygmomanometer. Patients should be placed in setting position and the BP will be measured after 10 minutes to allow patients to rest. In addition, Nurses and educators should

instruct patients to avoid caffeine, alcohol, smoking and vigorous exercises before the visit which may affect the reading. The reading will be recorded in each visit to evaluate the effectiveness and tolerability to garlic. The readings before starting the intervention should be documented in a line chart to compare it later at the end of the trial. Participants should report any side effects that they experience to nurses or educators in each visit to prevent any further complications. By the end of 24 weeks treatment with using the garlic the nurses compare the reading of BP and report the significance difference pre-and post-intervention.

High Cholesterol Level

Garlic was proven to reduce the serum cholesterol level in patients with high blood pressure. To determine the effect of garlic on high cholesterol level, the patients' healthcare providers should assess the laboratory results of the patients' who have high cholesterol level every follow up to determine if the Total Cholesterol (TC) level was decreased. The nurses should obtain a baseline data at the first day of treatment. After that, they can develop chart where they enter the patients' lab results for cholesterol and the date when those results were obtained. The nurse then should compare the results from one follow up to another. At the end of the treatment, the nurse will report any significant difference pre-and post-intervention.

Stimulating Immunity

According to Ried (2016), garlic has shown antibacterial, antiviral, antifungal, and anti-parasitic properties. In addition, garlic stimulates the growth of friendly bacteria in the digestive tract and the macrophage, which contribute to 80% of the immune system [14]. Immunity can be measured through blood test. The patient's healthcare worker should check the patient's laboratory test every follow up to determine any increase in the T-cells and NK cells [14]. The nurses should enter the patients' lab value in a chart that they can refer to when they compare the values at the end of the 24 weeks period.

Cost Saving

The literature has shown that supplementary medicine is cost effective more than the regular medicine. Garlic is cheaper than the regular antihypertensive medications. To determine the cost effectiveness of garlic, the hypertensive patients will be divided into two groups. The first group will use garlic and the second group will use antihypertensive medications. After that, the Incremental Cost Effectiveness Ratio (ICER) will be used. It is calculated by the difference in the cost between garlic users and non-garlic users divided by the difference in effect of garlic users and non-users (Kutch, 2016).

The financial department of the hospital should determine a willingness to accept value. After that, they will compare the value of ICER with the willingness to pay value. If the ICER is lower than the willingness to pay value, then the treatment is cost effective.

ICER = the mean cost of garlic users – the mean cost of garlic non-users ÷ the mean effect of garlic users – the mean effect of non-garlic users.

Based on the results of the outcome assessment plan, the health care providers then can decide if they should continue with using garlic as a complementary medicine with antihypertensive medications.

Implications for practice and future research

The reviewed literature illustrated the effectiveness of garlic in reducing hypertension. Most of researchers agreed that garlic lowers SBP significantly. However. Most of the studies revealed the effect of garlic on hypertensive patients who used antihypertensive medications and only a few studies displayed the effects of garlic alone without any medications. In addition, most studies used different types of garlic preparations, such as aged garlic extract, garlic powder, raw garlic and several dosages were used. Therefore, conducting more studies with using one specific dose and type of garlic is essential to determine the most effective from ana dose. Due to the recent changes in the hypertension classification guidelines, there is a gap in determining the effect of garlic on stage 1 hypertension. Further research should be conducted to determine the effect of garlic on stage I hypertension. Only one study illustrated that garlic consumption did not affect BP in normal patients. There should be further research to examine the effect of using garlic as a prophylactic intervention on normotensive people.

Conclusion

Garlic is one of the medicine that has been used in the developing countries as a complementary medicine for hypertension due to its low cost and high effect. This protocol was designed to aid hypertensive patient in controlling their hypertension. The effective utilization of this protocol should be the responsibility of healthcare providers. They should implement this protocol for their patients and educate them more about its effectiveness.

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