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The Effect of Topical Apple Cider Vinegar Application on Symptoms Associated with Varicosities: A Randomized Controlled Trial

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Abstract

Background: Apple cider vinegar contains polyphenolic compounds that have beneficial health effects. Varicosity negatively affects patients' quality of life and causes significant workforce losses. Conservative treatment in varicosity patients aims to reduce the condition's symptoms, try to prevent its progress, and prevent the development of complications.

Aim: This study aimed to determine the effect of topical apple cider vinegar application on the symptoms of varicosities.

Methods: A total of 74 patients who have varicosities, 37 patients in the intervention and 37 in the control. Two patients from the intervention dropped out, three from the control group, and 69 patients were analyzed in this randomized controlled trial: 35 patients in the intervention group and 34 patients in the control group. The study outcomes were assessed at the beginning of the study and after one month. The varicosities symptoms were assessed using the Varicosities symptoms questionnaire and visual Analogue Scale.

Results: The sociodemographic and clinical characteristics of both groups were found to be similar. The patients were evaluated concerning cramps, pain, leg fatigue perception, edema, itching, pigmentation, and weight feelings in the leg, and VAS in the second evaluation; the decrease in the intervention group was higher and statistically meaningful ($p < 0.05$).

Conclusion. We determined that the external application of apple vinegar on varicosity patients, which is an effortless application, increased the positive effects of conservative treatment.

What is already known about the topic? Topical apple cider vinegar (ACV) is commonly used in alternative medicine for varicose veins, with claims that it can reduce symptoms such as swelling and discomfort. Anecdotal evidence suggests that ACV may improve circulation and reduce inflammation, but scientific research on its effectiveness is limited. Existing studies are often small-scale or lack rigorous controls, making it difficult to draw definitive conclusions about its benefits for varicosities.

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Introduction:

The term “varicose veins” or varicosities refers to the condition in which the leg veins are tortuous, twisted, or extended. Varicose veins represent superficial veins located in the subcutaneous tissue (Das et al., 2023). The overall population commonly has varicose veins. Varicose vein prevalence varies significantly (Beebe-Dimmer et al., 2005). In the US, it has been valued that 23% of adults suffer from varicose veins. In Egypt, according to Aly et al., 2020 study, about 118 childbearing women from a total sample of 200 suffered from varicose veins.

Trunk varicose veins, reticular varicose veins, and telangiectasia varicose veins are the three types of varicose veins (Parihar et al., 2022) . The symptoms of varicose veins, which might include hurting, throbbing, weariness, pruritus, ankle swelling, Muscle cramps, heaviness, venous ulceration and discomfort, are what drive the majority of patients to seek treatment rather than aesthetic concerns (Gloviczki et al., 2011). Additionally, varicose veins are a symptom of chronic venous insufficiency, which can lead to leg discomfort, edema, long-lasting skin abnormalities, and non-healing ulcers (Das et al., 2023).

Serious health hazards are hardly ever associated with varicose veins. Pulmonary embolism (PE), Deep vein thrombosis (DVT), and peripheral artery disease (PAD) are vascular conditions that can result in significant systemic consequences. Inflammatory and pro-thrombotic indicators are present at higher levels in patients with varicose veins (Das et al., 2023; Poredos et al., 2015).

Complementary and alternative medicine (CAM) is a cost-effective alternative therapy used for the prevention and treatment of various communicable and non-communicable disorders (Das et al., 2023). A wide assortment of therapeutic plants can be found all over the world. Many weeds in our environment are highly operative medicinal plants that can help with a diversity of major health issues (Gloviczki et al., 2011; Parihar et al., 2022). Apple cider vinegar is one of them that can be used in treatment of varicose veins (Parihar et al., 2022).

The apple cider vinegar advances the blood flow and blood circulation. The assembled toxins of body are cleaned by apple cider vinegar. In the varicosities, the undiluted apple cider vinegar is applied on that body part and massage into the skin twice a day. Apple cider vinegar has antioxidant properties which can fight with free radicals to damaging the molecules which mainly affect the body cells. It also contains mainly acetic acid. Pectin, polyphenols and carotenoids are the other components of the apple cider vinegar (Eshghizadeh et al., 2018; Mulla & Pai, 2017).

An experiment conducted on a certain group of patients suffering from varicose veins revealed that the application of apple cider vinegar helped in providing the relief from symptoms associated with it as pain, edema, irritation, pigmentation, ulceration, fatigue, and others. In this study, the patients were asked to apply the apple cider vinegar on the affected region and keep it covered using a cloth for about 30 minutes twice a day for a month along with the physician’s treatment. On the completion of the experiment, the results showed that there was decrease in the pain, fatigue, edema, itching, pigmentation,

and cramps as compared to the patients who were not asked to apply the vinegar. This results are supported by the effectiveness of ACV components as acetic acid. Other components include pectin, polyphenols, carotenoids. These constituents have the prebiotic and antibacterial activity which results in the health benefits (Chaudhary et al., 2021). Thus, it was concluded that the harmonizing function of apple cider vinegar increases the effect of other routine treatments (Atik et al., 2016a; Girish D Dahikar et al., 2022).

Moreover, apple vinegar is effective in cleansing the wound and preventing its swelling. Many traditional medicine books have cited properties of apple vinegar in the treatment of dandruff and itching, eliminating facial brown spots, reducing facial acne and freckles, and skin rash. Apple vinegar is also highly useful in the treatment of warts, corns, skin moles, and skin irritations. With its acidic properties, apple vinegar maintains skin health and vitality (Eshghizadeh et al., 2018).

Considering apple vinegar's useful compounds, availability, low costs, and simplicity of use, and lack of studies similar to what is intended in the present study; this study was conducted to determine the effect of topical application of apple cider vinegar on discomfort and symptoms associated with varicosities. The aim of this study was to investigate the effects of a topical application of apple cider vinegar on symptoms associated with varicosities

Hypothesis

Patients who apply topical apple Cider vinegar on varicosities exhibit decrease in Symptoms than those who don't apply it.

Method

Study design: This study was designed as experimental, randomized and controlled

Setting: The study conducted at cardiovascular clinics at Sohag university hospital

Sample Selection

This study sample selection by simple blind random sampling method. Patients with varicosities were randomly assigned to the apple cider vinegar application (intervention) group or control group. We distributed participants to two comparable groups in terms of their characteristics and background, to ensure that any difference in the outcomes is attributed to our intervention. Sample size was 74 patients. It calculated by G power version 3.1.9.7. we used mean and stander deviation of previous study (Atik et al., 2016a), type 1 error was 0.05 and a power of 90%, sample size was 68 and we increased 6 participants for anticipated drop out cases. We used power analysis as it more accurate for our study sample size determination. Participants were divided into 2 equal groups, 37 in the intervention and 37 in the control.

The participants were had the following inclusion criteria: a C.E.A.P. ,"stands for: Clinical, Etiologic, Anatomic and Pathophysiologic", class 1: Telangiectasies or Reticular and spider veins and no need to refer for medical treatment, cosmetic problem only, class 2: Varicose veins and refer routinely to vein specialist for duplex color doppler assessment, Class 3: varicose veins and edema and Refer early to Vein Specialist for duplex color doppler assessment & management (Mulita et al., 2024). Patients planned only for conservative treatment, able to communicate verbally, aged from 18 years and above. Patients who had open wound near or over varicose vein, used

any cream for varicose vein that not prescribed, allergy or any skin reaction were excluded.

Outcome measures

The data collection tools were comprised of three tools: Tool 1: Sociodemographic and clinical data questionnaire: included data related to age, gender, educational status, occupation, BMI, smoking, and previous associated disease. Tool 2: Varicosities symptoms questionnaire: it was constructed and translated by the researchers after review of relevant literatures to collect data related to varicosities symptoms includes edema, itching, irritation, pigmentation, ulceration, fatigue, and cramps. In addition to Tool 3: visual Analogue Scale (VAS) to assess pain severity. a traditional 10-cm visual analog scale (VAS) (0= no pain; 10= worst pain), which has demonstrated good reliability and validity (Atik et al., 2016a; Mulita et al., 2024) . The patients mark the point on the line that corresponds best to their symptom severity or control status.

Content validity of tool 2 was revised by panel of five experts in the field of Medical-Surgical Nursing, to test its contents validity, clarity and completeness, of its items, and appropriateness of translations. The reliability of tool 2 was acceptable reliability (0.7) using Cronbach's Alpha.

Data collection and procedure

An official letter was sent from our college to responsible authorities of the selected setting and approval to collect the data was obtained after explaining the aim of the study. The study setting was visited, and participants were selected according to systematic random sampling method. First, study aim was explained to study's participants and informed written consents were obtained. participants who meet the study's inclusion criteria were selected. Before the intervention, Sociodemographic and clinical data questionnaire, Varicosities symptoms questionnaire were completed through self-report and interview, and patients' records. VAS was explained and taught to every study's participant separately and then measure pain severity.

- The proper intervention method was taught by the researchers to patients in the intervention group in the first session. The patients in the intervention group were instructed to first: clean the area of the leg with varicosity using cotton soaked in pure water without soap. Second: elevate the affected leg/s by 45 degrees. Third: apply cotton soaked in ACV that was composed of one teaspoon of natural ACV with 4% acidity and one teaspoon of pure water to the area of the leg with varicosity (Eshghizadeh et al., 2018). Fourth: clean the area of the leg/s using cotton soaked in pure water after 20 minutes. To test patient's allergy to ACV before starting the application every study participant was asked to apply ACV to an area of the hand or leg and wait for 15 minutes if itching, irritation, redness or any others signs of allergies occur don't apply it and call the researcher/s. There wasn't any allergic reaction reported by any of the study participants. Every patient in the intervention group was apply ACV twice daily, on the morning and in the evening, for 1 month. The intervention group applied vinegar alongside the treatment suggested by the doctor. The control group took the treatment suggested by the doctor without any other intervention. All study participants were asked to come after one month to assess our study outcome (Atik et al., 2016a). The researchers called or messaged the participants in the intervention group on daily base to emphasis the application of

ACV. Five patients dropped out from our study, two patients from intervention group, and three patients from control. 69 patients were analyzed in this randomized controlled trial, 35 patients in the intervention and 34 patients in the control group. Data collection took 4 months.

Ethical Considerations:

Written informed patients' consent were obtained before data collection after explanation of the study aim. Autonomy, secrecy, and the protection of secrecy, fairness, and no harm were asserted. Patients' right to withdraw at any time of research participation was considered and respected. written permission and approval of the ethics committee was received.

Statistical analysis of the data

Data was evaluated using the SPSS 21.0 (SPSS, Inc., Chicago, IL, USA) statistics program. Continuous variables are used mean ± standard deviation and numbers (percentages). Efficacy outcomes were presented as percentages, and P values were from Mann-Whitney test; For categorical variables between the two groups in the evaluation chi-square test, independent samples t-test were used.

RESULTS

Table 1 shown the sociodemographic characteristics of the patients in the intervention and control groups. The characteristics of both groups were similar ($p > 0.05$). Most of the patients were married, housewives, or laborers. Mean age was more than 40 years and more than three fifths of the study participants were females and had secondary education. The majority of the patients were married.

Table 2 shown the clinical characteristics of the study participants. There was no difference between both groups regarding clinical characteristics ($p > 0.05$). Around two thirds were had comorbid diseases mainly hypertension. Nearly one third was obese, the majority of the patients had one affected limb and more than half had Class 1 CEAP varicosities.

Table 3 illustrated varicosities symptoms in the intervention group and control group. No difference was found between both groups regarding varicosities symptoms ($p > 0.05$) in base line assessment. In the 2nd assessment, there were statically significance differences between both groups, in favor of the study group, regarding varicosities symptoms ($p < 0.05$) including: nighttime leg cramp, edema in the leg/s, pigmentation or Skin color changes around the veins, feeling of heaviness in the legs and feet, leg fatigue and throbbing.

Table 4 shown pain severity in the intervention group and control group. In base line assessment, no difference was found between both groups regarding pain severity ($p > 0.05$). In the 2nd assessment, there was statically significance difference between both groups, in favor of the study group, regarding pain severity ($p < 0.05$).

Table 1: Distribution of the study participants according to their Socio-demographic characteristics

Socio-demographic characteristics	Groups				Test of Significance
	Intervention (n=35)		Control (n=34)		
	No.	%	No.	%	
Age (years)					
Mean (SD)	45.20 (10.07)		44.09 (9.01)		t= 0 .483 (0 .631)
Gender					
Male	16	45.7	11	33.3	X^2= 0 1.293 (0.256)
Female	19	54.3	23	67.6	
Level of education					
Basic education	10	28.6	11	32.4	X^2= 2.285 (0.319)
Secondary education	14	40.0	8	23.5	
University or higher	11	31.4	15	44.1	
Marital status					
Single	7	20.0	8	23.5	X^2 = 0.126 (0.722)
Married	28	80.0	26	76.5	
Occupation					
Housewife	11	31.4	14	41.2	X^2 = 3.166 (0.367)
Manual work	9	25.7	5	14.7	
Official	10	28.6	13	38.2	
Not work	5	14.3	2	5.9	
Smoking					
Yes	15	42.9	11	32.4	X^2 = 0.810 (0.368)
No	20	57.1	23	67.6	

χ^2: Chi-Square test, *level of significance p = ≤0.05, t= independent t-test.

Table 2: Distribution of the study participants according to their clinical data

clinical data items	Groups				Test of Significance
	Intervention (n=35)		Control (n=34)		
	No.	%	No.	%	
Comorbidity Disease					X^2= 2.612 (0.271)
Yes	18	51.4	11	32.4	
No	17	48.6	23	67.6	
Type of the Comorbid Disease	**(n=18)**		**(n=11)**		X^2= 2.612 (0.271)
Diabetes mellitus	8	44.4	3	27.3	
Hypertension	6	33.3	7	63.6	
Cardiac disease	4	22.2	1	9.1	
BMI					X^2=1.383 (0.926)
<18.5	1	2.9	0	0.0	
18.5–24.9	4	11.4	3	8.8	
25–29.9	5	14.3	6	17.6	
30–34.9	11	31.4	11	32.4	
35–39.9	9	25.7	10	29.4	
>40	5	14.3	4	11.8	
Affected limb					X^2= 0 .369 (0.543)
Unilateral	26	74.3	23	67.6	
Bilateral	9	25.7	11	32.4	
Degree of varicosities according to CEAP classification:					X^2= 0.793 (0.673)
Class 1	21	60.0	17	50.0	
Class 2	9	25.7	10	29.4	
Class 3	5	14.3	7	20.6	

χ^2: Chi-Square test, *level of significance p = ≤0.05.

Table 3: Varicosities symptoms before and after topical apple cider vinegar application among the intervention and control group.

Varicosities symptoms	Intervention group (n=35)		Control group (n=34)		Test of Significance X^2 (P)	
	1st assessment	2nd assessment	1st assessment	2nd assessment		
	No. (%)	No. (%)	No. (%)	No. (%)		
Nighttime leg Cramp						
No	5 (14.3)	18 (51.4)	5 (14.7)	8 (23.5)	0.160	6.580
Sometimes	25 (71.4)	16 (45.7)	23 (67.6)	22 (64.7)	(0.923)	(0.037)*
Always	5 (14.3)	1 (2.9)	6 (17.6)	4 (11.8)		
Edema in the leg/s						
No	20 (57.1)	29 (82.9)	23 (67.6)	20 (58.8)	2.759	6.110
Grade 1	14 (40.0)	6 (17.1)	10 (29.4)	11 (32.4)	(0.737)	(0.047)*
Grade 2	1 (2.9)	0 (0.0)	1 (2.9)	3 (8.8)		
Itching or burning discomfort around the veins						
No	21 (60.0)	32 (91.4)	22(64.7)	25 (73.5)	0.163	3.846
Yes	14 (40.0)	3 (8.6)	12(35.3)	9 (26.5)	(0.687)	(0.050)
Pigmentation or Skin color changes around the veins						
No	3 (8.6)	24 (68.6)	0 (0.0)	11 (32.4)	3.334	9.941
Slight	29 (82.9)	11 (31.4)	32(94.1)	21 (61.8)	(0.189)	(0.007)*
Severe	3 (8.6)	0 (0.0)	2(5.9)	2 (5.9)		
Feeling of heaviness in the legs and feet						
Slight	9 (25.7)	21 (60.0)	5 (0.153)	13 (38.2)	1.947	6.159
Disturbing	22 (62.9)	14 (40.0)	22 (64.7)	17 (50.0)	(0.378)	(0.046)*
Severe	4 (11.4)	0 (0.0)	7 (20.6)	4 (11.8)		
Leg fatigue						
Slight	11 (31.4)	20 (57.1)	6 (17.6)	10 (29.4)	3.754	6.744
Disturbing	21 (60.0)	14 (40.0)	20 (58.8)	19 (55.9)	(0.153)	(0.034)*
Severe	3 (8.6)	1 (2.9)	8 (23.5)	5 (14.7)		
Throbbing						
No	13 (37.1)	19 (54.3)	8 (23.5)	11 (32.4)	(0.137)	6.377
Sometimes	20 (57.1)	16 (45.7)	19 (55.9)	19 (55.9)	3.980	(0.041)*
Always	2 (5.7)	0 (0.0)	7 (20.6)	4 (11.8)		

χ^2: Chi-Square test, *level of significance p = ≤0.05. 1st assessment= base line assessment, 2nd assessment= assessment after one month.

Table 4: Effect of topical apple cider vinegar application on varicosities pain severity among the intervention and control group. (n=69)

Pain severity	Intervention group (n=35)	Control group (n=34)	Significance between groups	(95% CI)
	No. (%)	No. (%)		
1st assessment				
No pain	13 (37.1)	10 (29.4)	X^2 = 0.741 (0.864)	
Mild pain	16 (45.7)	17 (50.0)		
Moderate pain	5 (14.3)	5 (14.7)		
Severe pain	1 (2.9)	2 (5.9)		
Mean (SD)	2.23± 2.12	2.85± 2.25	t= -1.182 (0.241)	(-1.679 to 0.430)
2nd assessment				
No pain	19 (54.3)	8 (23.5)	X^2 8.246 (0.041)*	
Mild pain	14 (40.0)	22 (64.7)		
Moderate pain	2 (5.7)	2 (5.9)		
Severe pain	0 (0.0)	2 (5.9)		
Mean (SD)	1.06±1.37	2.50±2.01	t= -3.482 (0.001)*	(-2.270 to -0.616)

χ^2: Chi-Square test, *level of significance p = ≤0.05, t= independent t-test, CI, Confidence Interval.

DISCUSSION:

The influence of apple cider vinegar has been investigated for hundreds of years. Use of apple cider vinegar is considered a tradition as in the year 400 B.C., Hippocrates, the father of modern medicine, prescribed the mixture of honey and apple cider vinegar for treatment of various diseases. It has been particularly used during the American Civil War for disinfecting the wounds of soldiers (Atik et al., 2016a).

Fruit juices like grape, apple, plum, coconut, tomato, rice, and potato are used to make vinegar. Apples are crushed and the liquid is squeezed out to make it. The liquid is mixed with yeast and bacteria to initiate the alcoholic fermentation process, which converts the carbohydrates into alcohol. Bacteria that generate acetic acid transform the alcohol into vinegar during a second fermentation step (Acetobacter) (Gopal et al., 2019)

Moreover, vinegar is a plant-based product that has been used and known for an undetermined amount of time. Many proven health benefits of vinegar include its ability to fight bacteria, lower blood pressure, reduce inflammation, act as an antioxidant, prevent diabetes, fight cancer, reduce and prevent obesity, lower cholesterol and blood pressure, heal wounds, and improve mental and cognitive functions. Recently, more

beneficial qualities of apple cider vinegar, its components, and their medicinal effects have been found (Boonstra et al., 2008; Budak et al., 2014; Carlsson, 1983; Gopal et al., 2019). Apple cider vinegar contains polyphenolic compounds that have beneficial health effects (VERZELLONI et al., 2007). Varicosity has negative effects on the quality of life of patients, and it causes important workforce losses (Palfreyman et al., 2004). The aim of conservative treatment in varicosity patients is to reduce the symptoms of the condition, try to prevent its progress, and prevent the development of complications (Aktas et al., 2015). CAM applications in integrative medicine can be defined as diagnosis, treatment, and protection systems that provide a holistic approach to medicine and meet the demands that cannot be met by conventional medicine. In this study, which was performed with the thought that the external application of apple vinegar as an addition to the routine conservative treatment would increase the betterment in symptoms and pain of patients with varicosity, in compliance with the holistic management tactic, the expected outcomes were touched.

It was noticed that the intervention group after application of topical apple cider vinegar has a great improvement explained in decreased pain level, night time leg cramp, leg edema, throbbing, itching, feeling of heaviness in leg, and leg fatigue. Only one study was integer with our study topic and support our study results (Aktas et al., 2015). Before 2016, no studies examining the effects of the external application of apple vinegar on varicosity could be found.

On the other hand, many studies support the positive impact of apple cider vinegar on various body systems and functions. As apple cider vinegar contains acetic acid, polyphenols, pectin, and carotenoids with antibacterial and prebiotic properties. Acetic acid is the main ingredient of apple cider vinegar. It is consumable at concentrations of 3–9% (Fushimi et al., 2006).

Its antioxidant flavonoid content can reduce the harmful effects of high cholesterol diets (Setorki et al., 2010). Furthermore, Setorki et al. detected the benefits of apple cider vinegar consumption on reducing the harmful effects of a high cholesterol diet, including atherosclerotic lesions in the aorta, among rabbits with hypercholesterolemia.

(Atik et al., 2016b) study showed that application of twelve weeks of aerobic exercise with apple vinegar makes a significant decrease in CRP, cholesterol, and LDL and significantly increased HDL levels. Within this context, (Setorki et al., 2010) showed that acute consumption of apple cider vinegar (as an antioxidant) causes significant reduction on some risk factors of atherosclerosis.

(Budak et al., 2014)found a significant reduction in steatosis in the rats treated with apple cider vinegars as oral for 7 weeks when compared to control group. Studies on the use of homeopathy, hydrotherapy, and hiruditherapy for varicosity patients have been identified in the literature; these studies have shown that CAM techniques have a good impact on symptoms (Atik et al., 2016b; Duncan-Cross et al., 2024; Suter et al., 2006; Wolf et al., 2003).

Further study showed that drinking apple vinegar was stated to decrease obesity (Wolf et al., 2003). Although only one similar article to our study, it can be seen in these studies that CAM methods provide optimistic effects. In our study, the external application of apple vinegar was initiated to increase the effect of conservative treatment and expressively decrease symptoms and pain levels without causing any side effects.

Conclusion and recommendations

We determined that the external application of apple vinegar on varicosity patients, which is a very easy application, increased the positive effects of conservative treatment. CAM methods are not definitive treatment methods, but when applied in compliance with scientific medical methods, they can support the quality of life of patients. Thus, CAM methods extensively used within the society should be tested in new scientific studies to prove their effectiveness and appraise the outcomes of their use alongside medical treatment, which would also provide foresight and contribution to integrative medicine practitioners.

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