

## **Effect of Using Apple Cider Vinegar on Foot Ulcer Healing in Patients with Type II Diabetes**

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### **Abstract**

*Background: Foot ulcers are one of the usual and dangerous complication that occurs in patients with diabetes. In severe cases, diabetic foot lesions cause amputation of the lower extremities. Apple vinegar have an antimicrobial properties and other clinical therapeutic consequences. Objective: This study was performed to examine the apple cider vinegar's impact on foot ulcer healing in diabetes mellitus patients. Method: A quasi-experimental study was conducted at the Imam Al-Hassan Center for Endocrinology and Diabetes from September 26, 2022, to June 12, 2023. A purposive sample include of sixty patients with diabetic foot ulceration who they were separated randomly into intervention and control group. Patients in the intervention group were instructed to perform foot ulcer irrigation once a day for 30 days, while only routine care was provided to the control group. The study instrument included socio-demographic and clinical data of participants, and the DMIST for observing the process of healing from a diabetic foot ulcer. The instruments were validated by a panel of experts, and its reliability was verified through a pilot study. Both a descriptive analysis procedure and an inferential analysis procedure (independent sample T-test, repeated measures ANOVA and Chi-square) were used to examine and measure the study findings; a p-value of <0.05 was determined to be statistically relevant. Results: Most (70% and 66.7%) of patients in the control and experimental groups, respectively, had a moderate level of healing at pre-test assessment. Conversely, at the post-test assessment, 80% of patients in the intervention group had good foot ulcer healing, while 16.7% of patients in the control group had good foot ulceration healing. Furthermore, a significant difference at p-value 0.001 noticed among the control and apple cider vinegar irrigation groups. after using apple cider vinegar on foot ulcers. Conclusions: Using apple cider vinegar as foot ulcer irrigation is an effective method for promoting foot ulcer healing among diabetic patients.*

**Keywords:** *Diabetes mellitus, Foot Ulcers, Apple Cider Vinegar.*

### **Introduction**

One of the most prevalent long-term consequences for diabetic individuals is diabetic foot ulceration (DFU). The common reasons for poor peripheral perfusion, diabetic neuropathy, and inadequate diabetic management, especially inadequate foot care, Additionally, DFU has been determined to be among the frequent reasons for lower extremity amputations and foot osteomyelitis. This kind of ulcer usually appears where the foot experiences pressure and repetitive damage. Between 9.1 and 26.1 million DFU

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occur each year worldwide. In their lifetime, diabetic foot ulcers will develop in 15% to 25% of people with diabetes. The frequency of diabetic foot ulcers is expected to rise along with the annual a rise in those getting new diagnoses for diabetes [1]. According to recent studies, every 30 seconds, a lower extremity is amputated as a result of diabetes, and the average annual price of treating a diabetic foot for each patient is 8659 dollars. In the United States, diabetes involves extra expenditures that vary from 9 to 13 billion dollars for medical treatment related to diabetic foot diseases. In diabetic patients, foot ulcerations that progress to severe gangrene or infection are the cause of 85% of amputations [2].

Patients with DFU and peripheral arterial disease (PAD) have a lower chance of healing and a higher chance of needing an amputation [3]. Care of people with DFU necessitates a coordinated, multidisciplinary approach from healthcare providers considering the disease load and its detrimental long-term impact on health [4]. Medical intervention for diabetic foot infections can range from mild (debridement, antibiotics, etc.) to major (resection, and amputation) [5].

The infection of DFU or chronic wounds is frequently brought on by a combination of aerobic and anaerobic bacteria. This combination of infections led to the rise of bacterial antibiotic resistance, so the need for new antibiotics has resulted in the resurgence of therapies that have been used for centuries but fell out of favor during the age of antibiotics but are safe, widely effective, and possess a low tendency to produce resistance. To reveal healthy tissue and promote healing, debridement entails removing devitalized and polluted tissue from the wounds [6]. An apple fruit fermentation that is either alcoholic or acetic results in apple vinegar (AV) [7]. The use of apple vinegar for removing and treating warts, head lice, and nail fungus is only one example of how its many antimicrobial properties have clinical therapeutic consequences. Apple vinegar is also well recognized for its effectiveness as a fruit and vegetable surface cleaner, to limit the development of foodborne harmful bacteria in food as a type of natural preservative, or both. [8]. Several studies have demonstrated the high levels of phenolic substances, tannins, flavonoids, carotenoids, and organic acids in apple vinegar, giving it the ability to be both an antioxidant and an antibacterial versus a range of pathogenic agents [9]. This study will provide new proof for apple cider vinegar's effectiveness as an antibacterial agent and healing aid in the management of DFU.

## Methods:

### Objectives:

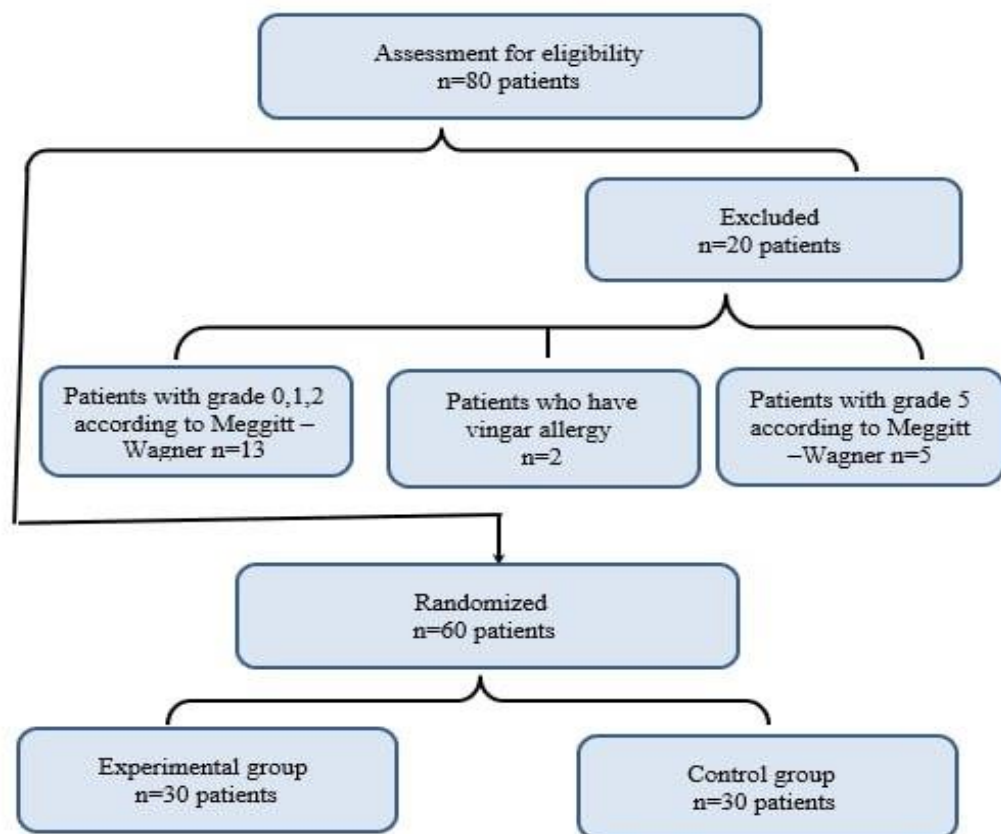
The purpose of the study is to determine how using apple cider vinegar improves diabetic patients' ability to cure foot ulcers.

### Study design and participants:

A quasi-experimental study conducted at the Imam Al-Hassan Center for Endocrinology and Diabetes. The study was initiated from September 26, 2022, to June 12, 2023. A non-probability purposive sampling sixty individuals with diabetic foot ulcers were include, the participants were assigned randomly using a simple randomization process into two groups: the intervention group and the control group. Each of the control and intervention groups had 30 participant (Figure 1).

Data collection instruments: The data collection instrument consists of three parts: First part: Socio-demographic features and clinical data that include age, gender, marital status, educational attainment, place of residence, occupation, type of treatment, chronic illnesses, the length of time a patient has had diabetic foot ulcer disease, the ankle-brachial pressure index ratio, and the cumulative sugar test (HbA1c); Second part: diabetic foot ulcer healing scale. This part uses a DMIST for monitoring the healing of

diabetic foot ulcers. It was designed by Oe et al., (2020) and consists of seven domains: depth, maceration, inflammation or infection, size, tissue type of the wound bed, type of wound edge, and tunneling or undermining. This scale was named "DMIST" as an acronym from the initials of these seven domains: if the total points of this scale are from 0 to 11, the healing rate is good; if the total points are from 12 to 23, the healing rate is medium; and if the total points are  $> 23$ , the healing rate is weak or late [10]. The third part, the Meggitt-Wagner classification system for diabetic foot ulcers, was used to determine the degree of diabetic foot ulcers. It was designed by Meggitt and Wagner (1976–1979) [11]. This scale includes six grades that can measure the degree of foot ulcers (from 0 to 5 grades) according to the severity of the ulcer. Degree 0 refers to intact skin; degree I refers to a superficial ulcer; degree II refers to an ulcer penetrating to a tendon or joint capsule; degree III refers to a lesion involving deeper tissues; degree IV refers to forefoot gangrene; and degree V refers to whole foot gangrene involving more than two thirds of the foot. The validity of the study instruments was determined by a panel of seventeen experts, and a pilot study was used to assess its reliability. by using Cronbach's alpha of 0.79, and 0.71 for the DMIST and Meggitt-Wagner scales, respectively.



**Figure (1): Flowchart of the eligibility and excluded criteria.**

#### Intervention:

Patients in the treatment group were instructed to perform foot ulcer irrigation once a day for 30 days, while only routine care was provided to the control group. This intervention its objective is to discover approaches to lessen the severity and speed up the healing process. of DFU by using apple cider vinegar, In this group, every patient received instructions to perform ulcer cleansing with normal saline, irrigation with apple cider vinegar, and dressing. We start by evaluating diabetic foot ulcer healing by using the DMIST scale and classification according to the Meggitt-Wagner classification system for DFU as a pre-test evaluation procedure before the application of the intervention. The

ulcer is then cleaned and irrigated with normal saline. After that, the ulcer was irrigated with 1-5% apple cider vinegar, and then the wound was cover with sterile dressings. Apple cider vinegar was examined to ensure the appropriate concentration for dressing diabetic foot ulcers. The examination process was carried out by an assistant professor of organic chemistry at the College of Nursing, Al-Ameed University, and examined by specialists in the laboratories of the Iraqi Biotechnology Company in Basra Governorate to ensure the toxicity rate on human cells. The results of the examination showed that apple cider vinegar was safe for human cells at this concentration.

The researchers once daily check-ins with the patients to ensure the patient perform ulcer cleansing with normal saline, irrigation with apple cider vinegar and dressing. The follow-up method was completed through the phone by establishing communication groups on social media sites (WhatsApp and Telegram) and by communicating with patients through telephones (SIM-card). During this follow-up, the researchers monitored the patient's adherence and responses to the treatment. Patients in the control group just obtain the conventional care provided to all patients in the study setting. The data collection process was carried out from January 12th to April 19th, 2023. The ulcer in both groups was evaluated every week for 30 days to identify the degree of healing.

Statistical analysis: The data were examined using the IBM program Statistical Package for Social Sciences Version 26. A descriptive statistical method, e.g., frequency, percentage, standard deviation and mean of score, was used to summarize the study result, and an inferential analysis method, independent t-test for comparisons between-group, repeated measure ANOVA was used to compare between four measures within intervention group and the Chi-square test was used to investigate the difference between groups. At p-value of <0.05 was determined to be statistically significant.

Ethical considerations: an ethical authorization was attained from the Ethical Committee at the College of Nursing/University of Kerbala (code: IQUOKCON. 1507.82) on November 13, 2022. An informed agreement was made from each patient and each person who enrolls in this study is also presumed to have the right to withdraw at any moment.

## Result:

Table (1): Distribution of participants according to their socio-demographic characteristics in study and control groups:

Socio-demographic characteristics		Control group n=30		Intervention group n=30		p-value <sup>a</sup>
		F	%	f	%	
Age groups	20-39 years	6	20.0	3	10.0	0.354
	40 - 59 years	20	66.7	22	73.3	
	≥ 60 years	4	13.3	5	16.7	
	M±SD	48.66±11.66		51.33±10.41		
Gender	Male	23	76.7	22	73.3	0.770
	Female	7	23.3	8	26.7	
Marital status	Single	2	6.7	1	3.3	0.647
	Married	23	76.7	23	76.7	
	Widower	4	13.3	5	16.7	
	Divorced	1	3.3	1	3.3	
Educational	Does not read or write	5	16.7	3	10.0	0.680
	Reads and writes	6	20.0	4	13.3	
	Elementary school	10	33.3	13	43.3	
	Middle school	6	20.0	9	30.0	
	Preparatory school	2	6.7	1	3.3	
	Collage or above	1	3.3	3	10.0	
Residency	Urban	26	86.7	26	86.7	1.00

	<b>Rural</b>	<b>4</b>	<b>13.3</b>	<b>4</b>	<b>13.3</b>	
<b>Occupation</b>	<b>Earners</b>	<b>15</b>	<b>50.0</b>	<b>14</b>	<b>46.7</b>	<b>0.839</b>
	<b>Government employee</b>	<b>5</b>	<b>16.7</b>	<b>6</b>	<b>20.0</b>	
	<b>Retired</b>	<b>3</b>	<b>10.0</b>	<b>2</b>	<b>6.7</b>	
	<b>House wife</b>	<b>7</b>	<b>23.3</b>	<b>8</b>	<b>26.7</b>	

f. (frequency); % (percentage); a = (Chi-square test)

The results table (1) indicates that 66.7%, and 73.3% of participants in the control and study groups, respectively, are within the aged of 40-59 years, the mean age of patients in the control group is  $48.6 \pm 11.6$  and intervention group is  $51.3 \pm 10.4$ . Regarding gender of patients, 76.7% and 73.3% of them are male in control and study group respectively. A 76.7 % of patients are married in both groups. Moreover, 33.3% of patient in the control group and 43.3% in the intervention group had elementary school, and 86.7% of patient in the control and study group are from urban residency.

Table (2): Distribution of participants according to their clinical data in study and control groups:

<i>Clinical data</i>		<i>Control group n=30</i>		<i>Study group n=30</i>		<b>p-value<sup>a</sup></b>
		<i>F</i>	<i>%</i>	<i>F</i>	<i>%</i>	
<b>Duration of DM</b>	<b>&lt;5 years</b>	0	0	3	10.0	0.050
	<b>5-9 years</b>	9	30.0	6	20.0	
	<b>10- 14 years</b>	14	46.7	8	26.7	
	<b>≥15 years</b>	7	23.3	13	43.3	
<b>Type of treatment used</b>	<b>Diet</b>	0	0	2	6.7	1.00
	<b>Hypoglycemic tablets</b>	14	46.7	14	46.7	
	<b>Insulin</b>	16	53.3	16	53.3	
<b>Chronic diseases</b>	<b>Heart disease</b>	7	23.3	9	30.0	0.266
	<b>kidney failure</b>	1	3.3	2	6.7	
	<b>None</b>	22	73.3	19	63.3	
<b>Ankle-brachial pressure index ratio</b>	<b>&gt; 1.4</b>	0	0	1	3.3	0.072
	<b>1.0-1.4</b>	13	43.3	12	40.0	
	<b>0.9-1.0</b>	8	26.7	7	23.3	
	<b>0.8-0.9</b>	7	23.3	5	16.7	
	<b>0.5-0.8</b>	1	3.3	5	16.7	
	<b>&lt; 0.5</b>	1	3.3	0	0	
<b>HbA1c</b>	<b>&lt; 5.7</b>	1	3.3	0	0	0.066
	<b>5.7 to 6.4</b>	23	76.7	19	63.3	
	<b>≥ 6.5</b>	6	20.0	11	36.7	

f. (frequency); % (percentage); a = (Chi-square test)

Regarding the clinical data, as shown in table (2) the result exposed that 46.7% of patients in control group had DM for 10- 14 years ago, while 43.3% of patients in intervention group had DM for 15 years and above. 73.3% and 63.3% of patients in control and intervention group respectively did not have any chronic diseases other than DM. Regarding ankle-brachial pressure index ratio, 43.3% and 40.0% of patients in control and intervention group respectively, had 1.0-1.4mmhg. A 76.7% of patients in control group 63.3% of study group had reading of HbA1c is (5.7 to 6.4).

Table (3): Comparison the level of diabetic foot ulcer healing within groups at both the pre- and post-test period:

Level of diabetic foot ulcer healing	Control group				Intervention group			
	Pre-test		Post-test		Pre-test		Post-test	
	f.	%	f.	%	f.	%	f.	%
Good	0	0	5	16.7	0	0	24	80.0
Moderate	21	70.0	20	66.6	20	66.7	6	20.0
Bad or late	9	30.0	5	16.7	10	33.3	0	0
Total	30	100.0	30	100.0	30	100.0	30	100.0
MS $\pm$ SD	2.3 $\pm$ 0.46		2.2 $\pm$ 0.43		2.3 $\pm$ 0.47		1.7 $\pm$ 0.39	

Table 3 shows that at pre-test period, 70%, 30% of patients in the control group had a moderate and late level of diabetic foot ulcer healing, on the other hand, approximately the same percent (66.7%, and 33.3%) of patients in the intervention group had a moderate and late level of diabetic foot ulcer healing. In the post test period, 16.7%, 66.6%, and 16.7% of participant in the control group had a good, moderate, and late level of diabetic foot ulcer healing. Conversely, 80%, and 20% of patients in the intervention group had good, and moderate level of diabetic foot ulcer healing.

Table (4): Comparison the level of healing between groups in two-time period:

Groups	Level of healing	Pre-test (First assessment)						Post-test (Fourth assessment)					
		f	%	MS	SD	t	p-value <sup>a</sup>	f	%	MS	SD	T	p-value <sup>a</sup>
Control group	Good	0	0	2.3	0.46	0.27	0.58 NS	5	16.7	2.2	0.43	4.11	0.001 S
	Moderate	21	70.0					20	66.6				
	Bad or late	9	30.0					5	16.7				
Intervention group	Good	0	0	2.3	0.47			24	80.0	1.7	0.39		
	Moderate	20	66.7					6	20.0				
	Bad or late	10	33.3					0	0				

f=frequencies; %=Percentage; a independent-sample t-test; NS=Non significant; S=Significant (P-value  $\leq$  0.05).

Table 4 demonstrates that before the interventional protocol, there were no significant statistical differences at a p value of 0.58 in the rate of diabetic foot ulcer healing between the intervention and control groups. However, after the intervention was in place for 30 days, there were significant statistical differences at a p value of 0.001 between the two groups.

Table (5): Pairwise comparisons of the diabetic foot ulceration healing readings under the effect of using apple cider vinegar on wounds healing among the intervention group between the four assessment periods:

(I) time	(J) time	Mean Difference (I-J)	Std. Error	p-value*	Significant level
1	2	.241	.081	0.006	HS
	3	.862	.065	0.000	HS
	4	1.138	.082	0.000	HS
2	1	-.241	.081	0.006	HS
	3	.621	.092	0.000	HS
	4	.897	.058	0.000	HS
3	1	-.862	.065	0.000	HS



4	2	-.621	.092	0.000	HS
	4	.276	.084	0.003	HS
	1	-1.138	.082	0.000	HS
	2	-.897	.058	0.000	HS
	3	-.276	.084	0.003	HS

\* repeated measures ANOVA. NS: Non-Significant (P value >0.05); S: Significant (P value ≤0.05- > 0.01); HS: Highly Significant (P value ≤0.01). (I) time = The measurement to which it is compared. (J) time = Measurements that compare to the main measurement.

Table 5 represented a highly significant difference, as shown by the pairwise comparisons table between the four-time assessment.

## Discussion:

Our study findings as shown in table 3 exposed that at pre-test assessment, the majority (70%) of participant in the control group had a moderate level of diabetic foot ulcer healing, while, 30% of patients in the same group had a late level of diabetic foot ulcer healing. On the other hand, about two-third (66.7%), and one-third (33.3%) of patients in the intervention group had a moderate and late level of diabetic foot ulcer healing at pre-test assessment. In the post test period, 16.7%, 66.6%, and 16.7% of participant in the control group had a good, moderate, and late level of diabetic foot ulcer healing. Conversely, 80% of patients in the intervention group had good level of diabetic foot ulcer healing.

It is clear from the study results, the mean of diabetic foot ulcer healing levels within control group is higher than the mean of diabetic foot ulcer healing levels within intervention group after 30 days of intervention. Also, the independent sample T-test value shows a non- significant difference in the diabetic foot ulcer healing score at p-value 0.58 between intervention and control groups at pre-test time, conversely, a significant difference in the diabetic foot ulcer healing score at p-value 0.001 between intervention and control groups at post-test time. This indicates the beneficial effect of apple cider vinegar on wounds healing that was applied on within the intervention group patients. In a randomized control trial conducted to examine the effects of honey and olive oil on the recovery of diabetic foot in Iran, researchers came to the conclusion that honey is just as helpful in curing diabetic foot as olive oil. [12].

The current study's findings showed an extremely significant variance between the first measure and the second measure in the percentage of diabetic foot ulcerations that were successfully treated. (before the application of irrigation with apple cider vinegar solution) and the fourth measure (30 days after the application of the ulcer irrigation with apple cider vinegar solution). This result is consistent with the outcomes of the research being conducted at the College of Veterinary Medicine at the University of Mosul, Iraq, is examining the effects of apple cider vinegar on the recovery of artificially produced wounds contaminated with *Pseudomonas aeruginosa*. They discovered that applying quantities of apple cider vinegar led to quicker and better healing of ulcers caused by diabetes [13]. The result of experimental study to evaluate the treatment of diabetic foot by natural honey in Jamshoro, Pakistan. They concluded that natural honey decreased the frequency of foot or leg amputations and enhanced the healing process [14].

When comparing the four assessment times of the diabetic foot ulceration healing readings under the effect of using apple cider vinegar, the findings in Table (5) indicate a significant difference between these four measures, it shows a significant difference between the first measure (before using apple cider vinegar) and the second measure (one week after using apple cider vinegar) at a P-value of 0.006. Additionally, there was a very big variation in diabetic foot ulcer healing readings between the periods of the first measure and the third measure (two weeks after using apple cider vinegar) at a P-value of

0.000. Prospective observational research was conducted to determine whether honey is beneficial at treating diabetic foot ulcers. at Al-Noor Specialist Hospital in Saudi Arabia. They concluded that using honey significantly reduces the rate of amputation and improves wound healing in chronic diabetic foot ulcers. The researcher suggests that the application of apple cider vinegar to wounds affected healing progress through the four measurement periods, with the fourth measurement period being much better than the first period [15]. Shukrimi, et al., (2008) conducted control trial research at Hospital University Sains Malaysia to examine the effectiveness of honey and povidone iodine as dressing solutions for Wagner type II diabetic foot ulcers. They discovered that applying honey to wounds can help manage diabetic foot ulcers, speed up wound healing, and more effectively reduce edema and odor. [16].

Study limitations: The core limitation of this study was that the patients should self-administer diabetic foot ulcer cleansing with normal saline, irrigation with apple cider vinegar and then dressing one time a day at home; thus, they researchers might followed the patients electronically. Additionally, the researchers were suffered from lack of related references.

### **Conclusion:**

Using apple cider vinegar as foot ulcer irrigation one time a day for 30 days is an effective method for promoting foot ulcer healing among diabetic patients. Nursing and patient implications: the most significant consequences of diabetes are those that pertain to diabetic foot issues. It is still regarded as the biggest risk factor for non-traumatic foot amputation and continues to remain as a health problem. As a result, the nurse must participate actively in providing patients with diabetic foot ulcers with holistic care through the use of complementary and alternative therapies for wound healing. Therefore, the application of apple cider vinegar dressing Providing a practical nursing role for such patients in common hospital care is crucial, and this intervention may help to raise the standard of nursing care. Apple cider vinegar dressing can be applied easily without complications by the nurse on the diabetic foot, and the dressing method can also be taught to the patient or a family member to do at home, to improve patients' and their careers' quality of life, lifestyle, and social and physical activities. Additionally, it may lead to lower healthcare expenses.

### **Acknowledgments:**

The authors would like to express their deepest appreciation to all patients with diabetes who are taking follow-up appointments at the Imam Al-Hassan Center for Endocrinology and Diabetes in Kerbala City. Thank you very much to everyone who took part in the study for being cooperative, and a special thank you to the members of the Karbala University/College of Nursing Research Ethics Committee for their help and counsel. Additionally, we would like to express our appreciation to the Holy Kerbala Health Directorate and Imam Al-Hassan Center for Endocrinology and Diabetes for their great efforts and vital assistance.

Financial Disclosure: There is no financial disclosure.

Conflict of Interest: Nothing will happen to harm anyone.

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