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Short-term Garlic Supplementation and Highly Active Antiretroviral Treatment Adherence, CD4+ Cell Counts, and Human Immunodeficiency Virus Viral Load

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Abstract

Context—Human immunodeficiency virus (HIV)–infected individuals frequently have consumed garlic, a popular complementary supplement. Researchers rarely have studied garlic’s association with antiretroviral therapies, however, even though that association is very relevant clinically.

Objective—To examine associations of supplemental use of garlic with highly active antiretroviral treatment (HAART) adherence level and HAART effectiveness (HIV viral load and CD4+ cell counts) in HIV-infected women.

Design—The research team carried out a self-controlled, longitudinal study nested within the Women’s Interagency HIV Study (WIHS). The team used a paired study design that allowed participants to serve as their own controls. The team first identified all of the study’s visits in which the participant self-reported the use of a garlic supplement since her last visit (index visit). Then for each index visit, the team identified a matching visit (a control visit) using the following criteria: (a) the visit must be one for the same participant in which that participant reported no garlic supplementation; (b) the visit must immediately precede the index visit (less than 1 year

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apart); and (c) at the time of the control visit, the participant must have been using antiretroviral therapy identical to that used at the time of the index visit.

Participants—Participants were persons using garlic supplementation who already were participants in the WIHS.

Outcome Measures—The research team used a logistic regression model to examine the association between garlic supplementation and HAART adherence level. The team used a mixed linear model to examine the association of garlic supplementation with HIV viral load and CD4+ cell counts.

Results—From October 1994 to April 2009, 390 HIV-infected women in the WIHS made 1112 visits at which they reported using garlic supplements. Seventy-seven HIV-infected women using HAART met the research team's selection criteria and contributed 99 pairs of visits for the study. Among the women who used garlic supplements, 22% were 50 years and older; 58% were black and non-Hispanic; and 23% had less than a high-school education. Neither use of garlic supplementation nor reasons for using garlic supplements were significantly associated with the HAART adherence level, HIV viral load, or CD4+ cell counts; however, "use garlic as needed," a potential marker of a disease state, was significantly associated with higher viral load ($P = .0003$).

Conclusion—Short-term garlic supplementation did not impact HAART adherence level, HIV viral load, and CD4+ cell counts.

In the era of highly active antiretroviral therapy (HAART), human immunodeficiency virus (HIV)-infected individuals still use complementary and alternative medicine (CAM) widely.¹ Studies have shown that individuals mainly use CAM as a complementary rather than an alternative treatment to HAART to alleviate symptoms associated with HIV disease and its treatment or to improve quality of life.^{2,3}

It is well documented that many CAM supplements interact with allopathic medications.⁴⁻⁷ Some CAM supplements share the same metabolic pathways as HAART regimens, such as P450 (CYP450), CYP3A4, and CYP2B6.⁶ Unfortunately, many HIV-infected individuals are still using these CAM supplements without knowledge of their potential risks. A survey in London found that 20% of HIV patients were using herbs that could compromise the effectiveness of HAART.⁸ Furthermore, many HIV patients did not communicate CAM usage to their physicians or other health professionals.⁹

Garlic is a very popular dietary supplement as it is believed to lower the risk of many diseases such as cardiovascular diseases and cancers,^{10,11} but researchers have not studied its potential interaction with antiretroviral therapy in clinical settings extensively. In vitro, garlic is known to impact both P450 and P-gp pathways associated with metabolism of drugs for HIV/acquired immune deficiency syndrome.¹² For instance, allicin, a biologically active constituent of crushed or damaged garlic, exhibited a concentration-dependent inhibition of ritonavir efflux,¹³ while garlic extract significantly inhibited efflux level of saquinavir but increased levels of darunavir.¹⁴ In vivo studies with small sample size, however, showed different results.^{4,15} In healthy volunteers, administration of garlic extract or garlic oil had no significant effect on CYP2D6 or CYP3A4 metabolism.^{4,15,16} One pharmacokinetic study found garlic had no impact on the plasma concentration of ritonavir.^{12,17} Another study, however, showed that mean saquinavir area under the curve decreased by 51% for patients using garlic caplets.¹⁸

The objective of this study was to evaluate whether garlic supplementation impacted HAART's adherence level and HAART's effectiveness (HIV viral load and CD4+ cell counts) in HIV-infected women from the Women's Interagency HIV Study (WIHS). This

study is clinically relevant because of increasing use of CAM, such as garlic, in conjunction with antiretroviral therapies among HIV-infected individuals.

METHODS

Women's Interagency HIV Study

The WIHS is an ongoing longitudinal study designed to investigate the natural and treated history of HIV disease among women. Barkan et al¹⁹ and Bacon et al²⁰ have detailed its design previously. Briefly, the researchers enrolled 2056 HIV-infected and 569 HIV-uninfected women between October 1, 1994, and November 30, 1995, and recruited another 740 HIV-infected and 407 HIV-uninfected women from 2000 to 2001 from 6 study sites in Chicago, Illinois; Los Angeles and San Francisco, California; Washington, DC; and Brooklyn and the Bronx, New York. The researchers conducted standardized face-to-face interviews semiannually to collect data on participants' sociodemographic characteristics, behaviors, health-care utilization, and medication use. Additionally, the researchers performed physical and obstetric/gynecologic examinations and collected biological specimens. An institutional review board at each site approved the study's protocol, and all participants gave informed consent.

In the WIHS, the researchers asked questions about use of oral, vaginal, rectal, or skin CAM supplements, including garlic supplements, from the study's enrollment of participants (October 1994) until visit 30 (April 2009). At each visit, the researchers asked the participant whether she had used garlic supplements since her last visit, how frequently she had used them (either "every or almost every day" or "only as needed"), and the main reasons for taking garlic supplements ("to boost immune system," "for general health," "to treat or reduce side effects from standard medications," "to prevent opportunistic and general infections," "to treat HIV infection," "beneficial without causing side effects," "standard HIV medications don't work," or "others").

Current Study's Design

The current research team conducted a self-controlled, longitudinal study nested within the WIHS to examine whether garlic supplementation impacts HAART adherence and HAART effectiveness. The team used a paired study design that allowed participants to serve as their own controls. The team first identified all of the study's visits in which the participant self-reported the use of a garlic supplement since her last visit (index visit). Then for each index visit, the team identified a matching visit (control visit) using the following criteria: (a) the visit must be one for the same participant in which that participant reported no garlic supplementation; (b) the visit must immediately precede the index visit (less than 1 year apart); and (c) at the time of the control visit, the participant must have been using antiretroviral therapy identical to that used at the time of the index visit. Due to the short half-life of garlic, a washout period was not necessary when using a study design with a control visit (ie, participant did not use a garlic supplement during the period since the last visit) followed by an index visit (ie, participant used a garlic supplement during the period since last visit).

Exposure Variables and Study Outcomes

The primary exposure variable was a dichotomous variable indicating whether the participants had used a garlic supplement or not since the last visit. The secondary exposure variables included frequency of and reasons for garlic supplementation. Because of sparse data, the research team recoded the reasons for garlic supplementation into three categories: (a) "to boost immune system," (b) "for general health," and (c) "others." The research team followed the 2008 US Department of Health and Human Services/Kaiser Panel guidelines²¹

in defining HAART. The team assessed the interactions between garlic supplementation and antiretroviral regimens using the following outcome variables: (1) HAART adherence level and (2) HAART treatment effectiveness as defined by HIV viral load and CD4+ cell counts. The team examined HAART adherence level first as a binary variable based on reported HAART adherence level $\geq 95\%$, as research has associated this level with clinically significant outcomes.²² The team then also assessed HAART adherence level as a multicategorical measure (100%, 95–99%, 75–94%, and $<75\%$ of the time) because recent research has shown lower HAART adherence levels to be as effective due to the use of ritonavir.^{23,24}

Covariates

To examine the associations between garlic supplementation and HAART adherence level, the research team included age, education, race, income, depression, and drug use as covariates. To examine the impact of garlic supplementation on CD4+ cell counts and HIV viral load, the research team also included HAART adherence level as a covariate because it directly impacts those biologic markers of HIV disease.

Statistical Analysis

For analyses using binary (eg, $\geq 95\%$ or not) or categorical HAART adherence levels as the study's outcomes, the research team performed a logistic regression model, and due to repeated measurements, adjusted correlation using the general estimating equation method.²⁵ For the continuous study outcomes, such as HIV viral load and CD4+ cell counts, a random-effect mixed linear model was used. HIV viral load was transformed using natural log method to make sure its distribution was close to normal distribution. The research team conducted all analyses using SAS version 9.2 (SAS Inc, Cary, North Carolina).

RESULTS

Demographic Characteristics and Garlic Supplement Usage

From the study's period of enrollment (October 1994) to visit 30 (April 2009), 390 HIV-infected women in the WIHS made 1112 visits at which they reported use of garlic supplementation since the last visit. During this observation period, 182 used garlic supplementation once; 77 used garlic twice; and 131 used garlic more than 2 times. Seventy-seven HIV-infected women using HAART met the current study's selection criteria and contributed 99 pairs of visits for the study. Table 1 describes the characteristics of participants at the index visit. Among these women, 22% were 50 years and older, 58% were black and non-Hispanic, 23% had less than a high-school education, and 40% had a household-income level less than \$12 000 per year. At these visits, 65% of the participants reported using garlic supplements "every day," and 35% claimed using garlic supplement "only as needed." About 49% reported using garlic supplements "for general health," 27% "to boost the immune system," and 24% for other reasons. The five most frequently used antiretroviral drugs were lamivudine, stavudine, zidovudine, efavirenz, and abacavir.

Association Between Garlic Supplementation and HAART Adherence Level

According to univariate analysis, garlic supplementation, frequency of its use, and reasons for garlic supplementation were not significantly associated with the $\geq 95\%$ HAART adherence level (Table 2). After adjusting for age, education, race, income, drug use, and depression, these associations remained nonsignificant. The research team further modeled the HAART adherence level as a multcategory variable, but the results were almost the same (not shown).

Associations of Garlic Supplementation With CD4+ Cell Counts and HIV Viral Load

Garlic supplementation and reasons for its use were not associated with either CD4+ T cell counts or viral load in either univariate or multivariate analyses (Table 3). Regarding frequency of garlic supplementation, “using garlic supplement every day” was not significantly associated with either CD4+ cell counts or HIV viral load; however, “using garlic supplement as needed” was significantly associated with higher viral load (coefficient of log-transformed HIV viral load: 0.96; 95% confidence interval: 0.34–1.58; $P = .003$), even after adjusting for age, education level, race, income, drug use, depression score, and HAART adherence level.

DISCUSSION

Studies have shown that use of CAM may affect HAART adherence.²⁶ The research teams’s previous studies in the WIHS found that use of any kind of CAM was associated with earlier HAART initiation and slightly higher HAART adherence.^{27,28} In this analysis, the research team did not observe significant associations of HAART adherence level with garlic supplementation, the frequency of or reasons for its use. Possible explanations for the team’s findings might be that most participants used garlic supplements to complement rather than replace their HAART use, which other studies have demonstrated.^{2,3}

Compared to women who did not supplement with garlic, “using garlic supplement daily” was not associated with either CD4+ cell counts or HIV viral load, which indicates that garlic supplementation has no impact on these markers. The research team’s results are consistent with previous *in vivo* studies with specific antiretroviral drugs that showed no effect of garlic on CYP2D6 or CYP3A4 metabolism.^{4,15,16} On the other hand, the team’s findings might reflect the combined interactions of garlic with different antiretroviral drugs because garlic extracts might have different directional impacts on different antiretroviral drugs.¹⁴ Interestingly, “using garlic supplement as needed” was significantly associated with a higher viral load even after adjusting for HAART adherence level. It seems unlikely that the higher HIV viral load was due to less frequent garlic supplementation. Rather, “use garlic supplement as needed” is likely an indicator of a disease state or onset of illness, which itself might increase HIV viral load.

The study has some strengths when compared to previous research on garlic and HIV disease. First, the team used a paired study design allowing participants to serve as their own controls. In this way, the research team dramatically reduced potential biases due to differences in personal characteristics and individual preferences, and the results better reflect true biological plausibility. Second, compared to previous *in vivo* studies, the study’s sample size was much larger and thus had more power to detect potential differences. Third, the research team examined interactions between garlic supplementation with a variety of HAART regimens at one time, rather than with a single antiretroviral therapy. Thus, the research team observed overall interactions between garlic supplement and antiretroviral drugs. Finally, unlike previous *in vivo* studies that researchers mostly conducted with healthy individuals, the research team carried out the current study among HIV-infected individuals, so the study’s results might have a greater clinical significance.

Some limitations exist with the current study. First, the research team did not quantify garlic use at each visit; however, the research team collected data on frequency of garlic supplementation, which could serve as a proxy for quantity of garlic supplementation. Second, the research team used self-reported HAART adherence data; however, evidence exists that the self-reported adherence data in the WIHS is reliable.²⁹ Third, though the sample size of the study was much bigger than previous similar studies, it might still be

relatively small given subtle differences in the outcomes of studies occurring within a short period of time.

CONCLUSION

The current study showed garlic supplementation was not associated with HAART adherence level, CD4+ cell counts, or HIV viral load. Future research should explore possible long-term effects of garlic supplementation by type, quantity, and duration on important HIV-management outcomes.

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Table 1

Characteristics of Paired Garlic Using Participants at the Index Visit

Characteristics	Participants (N = 77)
	n (%)
Age	
<35 y	10 (12.99)
35–50 y	50 (64.94)
50+ y	17 (22.08)
Race	
White, non-Hispanic	15 (19.48)
Black, non-Hispanic	45 (58.44)
Hispanic and others	17 (22.08)
Education	
Less than high school	18 (23.38)
Completed high school	28 (36.36)
Some college and above	31 (40.26)
Income	
\$12 000+	42 (54.55)
\$12 000	31 (40.26)
Garlic use frequency	
Use every day	49 (65.33)
Use as needed	26 (34.67)
Garlic use reason	
To boost immune system	21 (27.27)
For general health	38 (49.35)
Other reasons	18 (23.38)
5 most frequently used ARV	
Lamivudine	56 (72.73)
Stavudine	32 (41.56)
Zidovudine	26 (33.77)
Efavirenz	22 (28.57)
Abacavir	17 (22.08)

Abbreviation: ARV, antiretroviral medication

Table 2
Association Between Highly Active Antiretroviral Treatment Adherence and Garlic Use

Outcome Variable	Exposure Variable	Univariate			Multivariate ^a		
		OR	95% CI	P-value	OR	95% CI	P-value
Adherence 95% or not	Garlic use or not	0.95	[0.57,1.58]	0.85	0.84	[0.48,1.47]	.54
	Garlic use frequency						
	Use every day	1.35	[0.72,2.54]	0.34	1.20	[0.62,2.32]	.59
	Use as needed	0.54	[0.26,1.10]	0.09	0.49	[0.22,1.09]	.08
	No use (ref)	1.00	[1.00,1.00]		1.00	[1.00,1.00]	
	Reasons for garlic use						
	To boost immune system	0.69	[0.29,1.65]	0.41	0.63	[0.22,1.76]	.38
	For general health	1.02	[0.53,1.94]	0.96	0.87	[0.44,1.72]	.68
	Other reasons	1.25	[0.48,3.28]	0.65	1.13	[0.44,2.90]	.80
	No use (ref)	1.00	[1.00,1.00]		1.00	[1.00,1.00]	

^a Adjusting for age, education, race, income, drug use, and depression.

Abbreviations: CI, confidence interval; OR, odds ratio.

Table 3
Association Between Garlic Use and CD4+ T Cell Counts and Human Immunodeficiency Virus RNA Level

Outcome Variable	Exposure Variable	Univariate			Multivariate ^a		
		Beta	95% CI	P-value	Beta	95% CI	P-value
CD4+ T cell counts	Garlic use or not	32.04	[-81.92,17.85]	.21	26.69	[-80.00,26.61]	.32
	Garlic use frequency:						
	Use every day	14.47	[-45.79,74.73]	.63	8.83	[-53.89,71.55]	.78
	Use as needed	75.85	[-4.34,156.04]	.06	61.57	[-22.39,145.53]	.15
	No use (ref)	0			0		
	Garlic use reasons:						
	To boost immune system	-58.7	[-45.71,28.33]	.18	-62.9	[-153.43,27.71]	.17
	For general health	69.03	[1.93,136.12]	.04	53.85	[-16.66,124.37]	.13
	Other reasons	64.91	[-33.46,163.28]	.19	83.53	[-21.69,188.76]	.12
	No use (ref)	0			0		
Log (viral load)	Garlic use or not	0.16	[-0.55,0.23]	.42	0.19	[-0.60,0.22]	.36
	Garlic use frequency:						
	Use every day	-0.26	[-0.71,0.20]	.26	-0.23	[-0.69,0.24]	.34
	Use as needed	0.96	[0.37,1.54]	.002	0.96	[0.34,1.58]	.003
	No use (ref)	0			0		
	Garlic use reasons:						
	To boost immune system	0.42	[-0.25,1.08]	.22	0.5	[-0.20,1.20]	.16
	For general health	-0.11	[-0.62,0.41]	.68	-0.13	[-0.67,0.42]	.65
	Other reasons	0.43	[-0.31,1.18]	.25	0.49	[-0.30,1.29]	.22
	No use (ref)	0			0		

^a Adjusting for age, race, education, income, drug use, depression, and highly active antiretroviral treatment adherence

Abbreviations: CI, confidence interval; OR, odds ratio.