

SULKANE for Prevention of Hangover Effects due to Excessive Alcohol Consumption

A Randomized Controlled Trial

Steve Whang, Pharm.D. Rph.

Seong Lee, Ph.d.

Effect of excessive alcohol consumption continues to be one of the most serious public health problems in the world. The effect of excessive alcohol use exacts tremendous toll on productivity and destroys individuals, families, and communities. Heavy alcohol use affects millions of individuals on a daily basis. In the United States alone, 8 million individuals meet the diagnostic criteria for alcohol dependence and an additional 5.6 million meet the diagnostic criteria for alcohol abuse.¹ Thus alcohol abuse comes with a devastatingly high price tag. In 2001, the United States estimated economic cost of alcohol abuse is nearly 185 billion dollars.²⁻¹² Alcohol abuse accounts for more lives lost, illnesses, and disabilities than any other preventable health condition. Of the more than 2 million US deaths each year, approximately 1 in 4 is attributable to alcohol, tobacco, and illicit drug use.¹³⁻²²

The hangover effect due to excessive alcohol drinking is a preventable condition.²³ The symptoms of hangover effect include headaches, nausea, vomiting, memory loss, and general lack of energy.²⁴ For centuries many different ethnic group have been in search of finding different types of natural remedies to prevent hangover effect of alcohol consumption. This was in due part to end the misery that results from hangover effect, which is a short term effect. The long term effect of the damage to which a hangover can cause include all the classical symptoms of advanced alcoholism.²⁵⁻²⁷ One particular natural remedy developed by a group of monks in eastern Europe has been used effectively to prevent hangover effects for centuries. SULKANE is the first product developed into a pill form using this natural formula.

Methods

Study Design and Participants

This prospective, randomized controlled trial was conducted in four cities around the world. The studies conducted in Los Angeles and San Francisco area of the United States were accomplished between January of 1998 and December of 2000. The studies conducted in Tokyo, Japan and Seoul, Korea was accomplished between May of 2002 and January of 2003.

All participants of this study was randomly chosen from each city . All eligible volunteers had past experiences with alcohol consumption and knew the type and amount of alcohol consumption needed to bring about a hangover effect the following morning. Each drinking sessions began around 8pm in the evening and ended around midnight The study group was given 2 tablets of SULKANE tablets at the start of drinking session, and 2 more tablets were given at midnight, right after the cessation of drinking session. At the start of the study, each participants were asked for their personal information including the amount of alcohol needed to cause a hangover effect. Once first 2 tablets of SULKANE were given, all participants were told by the study leaders to drink different types of alcoholic beverages as much as their body can tolerate during the 4 hour period. The amount of alcohol consumed by each volunteer was

carefully counted and recorded during the study by the study leaders. Then 2 more SULKANE were given to each participant right before leaving the test sites.

The following morning, the study leaders called or met with each of the participants to record the effectiveness of SULKANE tablets in hangover prevention. All the participants were asked of their physical and mental state in terms of headaches, nausea, vomiting, queasy stomach, lack of energy, or how refreshed or energetic they felt. Then they were asked to rate the effectiveness and recommendation level of SULKANE in 5 different categories:

1. miserable: definitely not recommended
2. bad: not recommended
3. average: recommended
4. good: highly recommended
5. excellent or very refreshed: definitely recommended

Efficacy Outcomes and Statistical Analysis

The primary efficacy outcome measure was level of hangover symptoms including headache, nausea, vomiting, queasy stomach, lack of energy, and refreshed feeling. The secondary efficacy measures were amount of alcohol consumed by each participant in terms multiples of baseline amount needed to cause hangover effect. Once all the data was collected, each numeric value of the effectiveness and recommendation level of SULKANE was added and averaged by the number of participants in each city. Secondly, the amount of alcohol each participants drank in multiples of baseline amount needed to cause hangover effect were calculate to show the potential effectiveness of SULKANE in hangover prevention. The result from each city were first calculated separately to show the distinction between each group. Then all four city results were calculated in terms of total participant number as a whole study group to show more precise efficacy of the SULKANE study.

Results

Of the 92 participants randomized, there were 88 males and 4 females. All the participants were aged between 21 to 72 years old with average health and without any liver function problems. In Tokyo trial, 2 participants refused to take the second dose, claiming they didn't need the tablets because they were very sober.

Of the 14 participants of 12 males and 2 females, Tokyo group averaged 4.71 points out of 5.00 possible recommendation score. This translates to 94.2% satisfaction rate for Japan study. This group consumed average of 3.9 times the baseline amount needed to cause hangover symptoms. Thus the potential effectiveness of SULKANE for Tokyo study in numeric term was 367%. This translates the fact that Tokyo group was able to effectively prevent hangover symptoms even after drinking of 3.67 times the average baseline amount of alcoholic beverages with the ingestion of 4 SULKANE tablets.

All 52 participants of Seoul study were males. Korea study was divided into 4 different trials within a month period and was conducted in different parts of the city of Seoul. Seoul groups averaged 4.96 points out of 5 possible recommendation score. This translates to 99.2% satisfaction rate for Korea study. This group consumed average of 4.23 times the baseline amount needed to cause hangover symptoms. Thus the potential effectiveness of SULKANE for Seoul trials translates to 417%.

There were 14 participants in Los Angeles study. Of 18 participants in San Francisco study, 16 were college students from UC Berkeley and Stanford University. 14 students were males and 2 were females. The Los Angeles group averaged 4.71 points out of 5.00 possible recommendation score. This translates to 94.2% satisfaction rate for Los Angeles study. This group consumed average of 3.61 times the baseline amount needed to cause hangover symptoms.

The potential effectiveness of SULKANE for Los Angeles study was 339%. In San Francisco trial, group average of 4.61 recommendation score was attained while 4.91 times the baseline average alcohol was consumed. This calculates to 92.2% satisfaction rate. However, the potential effectiveness of SULKANE for this group resulted as 452%. This translates the fact that San Francisco group was able to effectively prevent hangover symptoms even after drinking 4.52 times the average baseline amount of alcoholic beverages with the help of 4 SULKANE tablets.

One significant side effect of SULKANE was reported during these trials. 21% of all the male participants reported increase in libido and sexual performance during the night following the drinking session. This is extremely significant due to the fact that more than 1 out of every 5 participants experienced such extreme physical advancement.

Table 1. SULKANE Trial Result: Hangover Prevention

Study Group	Number of Participants	Recommendation Score (5 max)	Satisfaction Rate (100% max)	Multiple of baseline R-OH
Tokyo	14	4.71	94.2 %	3.90
Seoul	52	4.96	99.2 %	4.23
Los Angeles	14	4.71	94.2 %	3.61
San Francisco	18	4.61	92.2 %	4.91

Table 2. Potential Effectiveness of SULKANE

Study Group	Number of Participants	Potential Effectiveness of SULKANE
Tokyo	14	367 %
Seoul	52	417 %
Los Angeles	14	339 %
San Francisco	18	452 %
All Groups	92	393 %

Comment

This study demonstrates that SULKANE effectively prevents hangover symptoms due to excessive alcohol consumption. This study also demonstrates the effectiveness of SULKANE is not interfered by age, race, or gender. The results from 4 different trials conducted in 3 different countries and 2 continents show the potential benefit of SULKANE for alcoholic beverage drinkers around the world. Because our data is limited, it may underestimate the potential benefit the world population may receive from SULKANE. The Seoul study demonstrated the higher potential effectiveness of SULKANE with higher number of participants while San Francisco study resulted in highest potential effectiveness despite lower satisfaction rate. These variable results showed us that SULKANE can effectively prevent hangover symptoms regardless of ethnic background of alcoholic beverage drinkers.

It is proven fact that suffering from repeated bouts of hangover symptoms can result in serious health problems including liver disease and brain damage.²⁸⁻³⁰ The economic loss resulting from alcohol related diseases in the United States alone tops 180 billion dollars a year.²⁻¹² The conclusion of the SULKANE study demonstrates the enormous economic benefit of SULKANE use during drinking by all the alcoholic beverage drinkers in the world.

References

1. Grant BF, Hartford TC, Dawson DA, et al. Prevalence of DSM-IV alcohol abuse and dependence- United States, 1992. *Alcohol Res World*. 1994; 18:243-248.
2. US Office of National Drug Control Policy. *The Economic Costs of Drug Abuse in the United States, 1992-1998*. Washington, DC: Executive Office of the President; 2001.
3. US Department of Commerce, US Census Bureau. Profiles of general demographic characteristics, 2002. Available at <http://landview.census.gov/prod/cen2000/dp1/2kh00.pdf>. Accessed January 23, 2003.
4. Embree BG, Whitehead PC. Validity and reliability of self-reported drinking behavior: dealing with the problem of response bias. *J Stud Alcohol*. 1993; 54: 334-344.
5. Dufour MC. What is moderate drinking? defining 'drinks' and drinking levels. *Alcohol Health Res World*. 1999;23:5-14
6. National Institute on Alcohol Abuse and Alcoholism. Health risks and benefits of alcohol consumption. *Alcohol Health Res World*. 2000; 24:5-11.
7. National Institute on Alcohol Abuse and Alcoholism. 10th Special Report to Congress on Alcohol and Health: Highlights From Current Research. Rockville, US Dept of Health and Human Services; 2000.
8. Laixuthai A, Chaloupka FJ. Youth alcohol use and public policy. *Contemp Policy Issues*. 1993; 11:69-81.
9. Pacific Institute for Research and Evaluation. *Strategies to Reduce Underage Alcohol Use: Typology and Brief Overview*. Calverton, Md: Pacific Institute for Research and Evaluation; 1999.
10. Center for Science in the Public Interest. *State Alcohol Taxes and Health: A Citizen's Action Guide*. Washington, DC: Center for Science in the public Interest; 1995.
11. Center for Science in the Public Interest. *Adolescent Responses to Televised Beer Advertisements: Children of Alcoholics and Others*. Washington, DC: Center for Science in the Public Interest; 1996.
12. Center on Alcohol Marketing and Youth. *Overexposed: Youth a Target of Alcohol Advertising in Magazines*. Washington, DC: Georgetown University; 2002.
13. Schneider Institute for Health Policy, Brandeis University for the Robert Wood Johnson Foundation. *Substance Abuse: The Nation's Number One Health Problem: Key Indicators for Policy Update*. Princeton, NJ. The Robert Wood Johnson Foundation; 2001.
14. National Institute on Alcohol Abuse and Alcoholism. FAQ's on alcohol abuse and alcoholism. Available at: <http://www.niaaa.nih.gov/faq/faq.htm>. accessed December 11, 2002.
15. Centers for Disease Control and Prevention. Deaths and hospitalizations from chronic liver disease and cirrhosis- United States, 1980-1989. *MMWR Morb Mortal Wkly Rep*. 1993;41:969-973.
16. National Center on Addiction and Substance Abuse. *Behind Bars: Substance Abuse and America's Prison Population*. New York, NY; National Center on Addiction and Substance Abuse (CASA) at Columbia University; 1998.
17. Jacobson J, Jacobson S. Drinking moderately and pregnancy: effects on child development. *Alcohol Health Res World*. 1999; 23:25-30.
18. Hingson RW, Heeren T, Winter MR. Preventing impaired driving. *Alcohol Health Res World*. 1999; 23:31-39.
19. Zador PL. Alcohol-related relative risk of fatal driver injuries in relation to driver age and sex. *J Stud Alcohol*. 1991;52:302-310.
20. Zador PL, Krawchuk SA, Voas RB. Alcohol related relative risk of driver fatalities and driver involvement in fatal crashes in relation to driver age and gender. *J Stud Alcohol*. 2000, 61:387-395.
21. Eigen LD, Noble J. *Drinking Under Age 21: Problems and Solutions*. Rockville, Md: US Dept of Health and Human Services, Substance Abuse and Mental Health Services Administration, National Clearinghouse for Alcohol and Drug Information; 1996.
22. Substance Abuse and Mental Health Services Administration. Statement by the Substance Abuse and Mental Health Services Administration on CASA report underage drinking [press release]. Rockville, Md: US Dept of Health and Human Services; 2002.
23. Wechsler H, Austin SB. Binge drinking: the five four measure. *J. Stud Alcohol*. 1998;59:122-124.
24. Wechsler H, Nelson TF. Binge drinking and the American college student: what's five drinks? *Psychol Addict Behav*. 2001;15:287-291.

25. National Institute of Alcohol Abuse and Alcoholism. Tenth Special Report to the US Congress on *Alcohol and Health*. Bethesda, Md: National Institute of Health; 2000.
26. Shultz JM, Rice DP, Parker DL, Goodman RA. Stroke. G, Chalmers N. Quantifying the disease impact of alcohol with ARDI software. *Public Health Rep*. 1991; 106443-450.
27. Greenfield TK, Midanik LT, Rogers JD. A 10-year national trend study of alcohol consumption. 1984-1995: is the period of decline drinking over? *AM J Public Health* 2000;90::47-52.
28. Foster SE, Vaughan RD, Foster WH, Califano JA Jr. Alcohol consumption are expenditures for underage drinking and adult excessive drinking. *JAMA*. 2000 289;989-995.
29. Norberg A, Jones WA, Hahn RG, Gabelsson JI. Role of variability in explaining ethanol pharmacokinetics: research and forensic applications. *Clin Pharmacokinet*. 2003; 42:1-31.
30. National Institutes of Health. *Helping Patients with Alcohol Problems: A Health Practitioner's Guide*. Washington, DC: National Institutes of Health; 2003. Publication No. 03-3769.