Randomized Control Trial Study On The Effect Of Wet Cupping On Lipid Profile

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ABSTRACT

Introduction: Dyslipidaemia is one of the risk factors contributing to the pathogenesis of cardiovascular diseases (CVDs). This study was conducted to investigate the effect of wet cupping on lipid profile. **Methods:** This randomized controlled trial was conducted in 2012 at the School of Medical Sciences, Universiti Sains Malaysia, Malaysia. Sixty-two healthy volunteers ranging from 30 to 60 years old were randomized into control and intervention groups. Subjects in the intervention group were assigned to two sessions of wet cupping at the beginning of the study and at the third month; individuals in the control group did not undergo any cupping procedure. Venous blood sample was collected for serum lipid profile: Total Cholesterol (TC), High Density Lipoprotein Cholesterol (HDL-C), Low Density Lipoprotein Cholesterol (LDL-C), and triglycerides; measured at baseline, first, third and fourth month. **Results:** Subjects in the cupping group had significant improvements from baseline to third and fourth month for TC (MD=-0.56, *P*=0.004), HDL-C (MD=-0.22, *P*<0.001) and LDL-C (MD=0.58, *P*=0.001). There was also a significant reduction from baseline to one month for triglycerides (MD=0.38, *P*<0.001). Subjects in the cupping group had significantly better values in HDL-C and LDL-C as compared with the control group at the third and fourth month. Significantly lower levels of TC and triglycerides in the cupping group of the fourth month. In the control group, there were no significant changes in any serum lipid profiles. **Conclusion:** After two sessions of wet cupping, TC, HDL-C, LDL-C and triglycerides were significantly improved by 8.2%, 13.7%, 16.4% and 20.8% respectively.

KEYWORDS: Wet Cupping, Serum Lipid Profile, Dyslipidaemia, Cardiovascular Disease Risk

INTRODUCTION

Cupping is a type of traditional and complementary medicine found in many cultures worldwide. It is defined as a therapeutic method involving the application of suction by placing a vacuum cup or jar, usually produced by fire, onto the affected part of the body or any part of the body surface, for the purpose of treating disease[1,2]. It has also been performed for patients with musculoskeletal disorder, headache, internal disease, stroke and paralytic disease, obesity and dermatological conditions [3].

Wet cupping on the other hand has the great advantages and appears as an optional treatment for many diseases because it is effective and efficient without usage of drugs, simple and safe, inexpensive and has no serious side effect[2]. Few recent studies show that there are extra benefits in using wet cupping therapy, for example the reduction in the cardiovascular risk factors, such as reduction in serum lipid profiles [4, 5].

Dyslipidaemia is defined as an abnormal lipid values. It is one of the risk factors that contribute to the pathogenesis of cardiovascular disease (CVDs). The major lipids present in the plasma are fatty acid, triglycerides, cholesterol and also phospholipids. Triglycerides as the main lipids in the blood are an important energy substrate. Cholesterol is a component of the membrane of cells and their organelles. Both cholesterol and triglycerides are insoluble in water and are transported in the blood in lipoprotein, which is a complex of lipids with specific proteins known as apolipoprotein. Lipoproteins have four major classes; chylomicrons, very low lipoprotein, low density lipoprotein cholesterol (LDL-C) and high density lipoprotein cholesterol (HDL-C). LDL-C transports cholesterol from the liver to peripheral tissues and HDL-C which are involved in reverse cholesterol transport from peripheral tissues to the liver, where it can be excreted [6].

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The specific lipid abnormalities which are important risk factors for coronary heart disease includes elevated LDL-C, triglycerides and non HDL-C as well as low in HDL-C. In epidemiological studies, LDL-C has been shown to be atherogenic. There is a relationship between levels of LDL-C or total cholesterol (TC) and the rate of new onset of coronary heart disease. There is a near absence of coronary heart disease in individuals with very low level of serum cholesterol throughout their lives. While in patient with established coronary heart disease, elevated LDL-C correlates with recurrent cardiac events [7].

Few studies have shown that there is an association of low HDL-C level with increased risk of coronary heart disease. A reduction of serum HDL-C by 1% will increase the coronary heart disease risk by 2 to 3% [7-9]. Serum HDL-C less than 1.0 mmol/l for female and less than 1.3 mmol/l for male had increased risk for coronary heart disease.

Failure to achieve lipid goals is a persistent problem, although the more patient is using lipid lowering drugs than before. In the United State of America, the Lipid Treatment Assessment Project survey found that only 38% of patients diagnosed with dyslipidaemia were able to reach the recommended target for LDL-C despite being on treatment. The reasons so many patients did not reach the treatment target were complex and involved both patients as well as healthcare provider [10].

In Malaysia, the prevalences of hypercholesterolemia in 2006 were 23.7 % in adults aged 20 years and above, while for adults aged 18 years and above the prevalences were 11.5%, 20.7% and 38.8% in 1996, 2006 and 2011 respectively [11]. Prompt action should therefore be taken in order to reduce the prevalences of dyslipidaemia in preventing the CVDs. Thus, it is a great potential if wet cupping therapy could be used in reducing the CVDs risk factors such as lipid profiles. Therefore the present study was conducted to investigate the effect of wet cupping therapy on serum lipid profiles.

MATERIALS AND METHODS

Study design

This single-center, open-label, parallel-group, randomized controlled trial was conducted in Clinical Lab of Community Medicine, School of Medical Sciences, Universiti Sains Malaysia Kubang Kerian, Kelantan, Malaysia from January 2012 until June 2012. The sample size was calculated using STATA software (sample size calculation for test of means with repeated measures), with 5% type I errors and 20% type II errors. After accounting for a 20% drop-out rate, the total number of participants required was 31 participants per group. Sixty-two (62) participants, aged between 30 and 60 years old, without chronic disease, a blood disorder or history of dyslipidaemia were randomized into two equal-sized groups; a control group (n=31) and an intervention group (n=31) using block randomization. The randomization sequence was concealed using sealed envelopes, and was executed without any adaptation.

Wet cupping procedure

Subjects in the intervention group were assigned to two sessions of wet cupping at the beginning of the study and at the third month; individuals in the control group did not undergo any cupping procedure. Wet cupping was performed using a manual hand suction pump with disposable plastic vacuum cups at five points: both scapula, both lumbar region and vertex. The participants were instructed to lie down on a couch during the procedure. Each procedure took approximately 20 minutes and was conducted aseptically. The steps for wet cupping therapy were as follows [12]. The cups were placed on the selected sites and suction was created. Then, the cups were depressurized after five minutes. Later on, the skin was pricked using a lancet pen, and the cups were re-applied until they were filled with blood. Once the blood flow stopped, the cups were removed and the blood was safely discarded.

Measurement of serum lipid profile

Five millimeters of venous blood was taken from each of the study subjects at the beginning of the study first month, third month (before the second session of cupping) and fourth month for all participants; which was intended for serum lipid profile (total cholesterol, high density lipoprotein, low density lipoprotein and triglycerides. Lipid profile was measured using enzymatic method with Architect c8000 Analyser.

Statistical analysis

Data was entered and analysed using SPSS Statistics version 19.0. Data was checked for normality by comparing the mean and median, evaluating the skewness and kurtosis values with their standard error, test of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests), and histogram with the overlaid normal curve as well as Box and Whisker plot.

Data was presented as mean and standard deviation (SD) for numerical variables and frequency with their percentage (%) for categorical variables. Baseline characteristics were compared using an independent *t*-test for variable age and c^2 tests for variable gender. Repeated Measure analysis of variance (ANOVA) were used to evaluate the within and between group comparison of means at baseline, first, third months and fourth months.

Ethical consideration

This research was approved by the Human Research Ethics Committee, Universiti Sains Malaysia (Ref:USMKK/PPP/JEPeM[243.3(13)]). This study complies with the Declaration of Helsinki in all aspects. The study procedures were explained to all participants before they volunteered to participate as study participants. Verbal and written informed consents were taken from all participants before starting the study as well as before each procedure.

RESULTS

A total of 90 healthy adults were screened for eligibility. Sixteen adults did not fulfill the study criteria, and 12 adults refused to participate (response rate: 83.8%). Sixty-two participants were enrolled in this study, and they were all randomized into either the cupping (n=31) or the control (n=31) group. As illustrated in figure 1, all 62 participants completed the study. Table 1 shows a comparison of socio-demographic characteristic between cupping and control group. Age and gender were equally distributed between both groups.

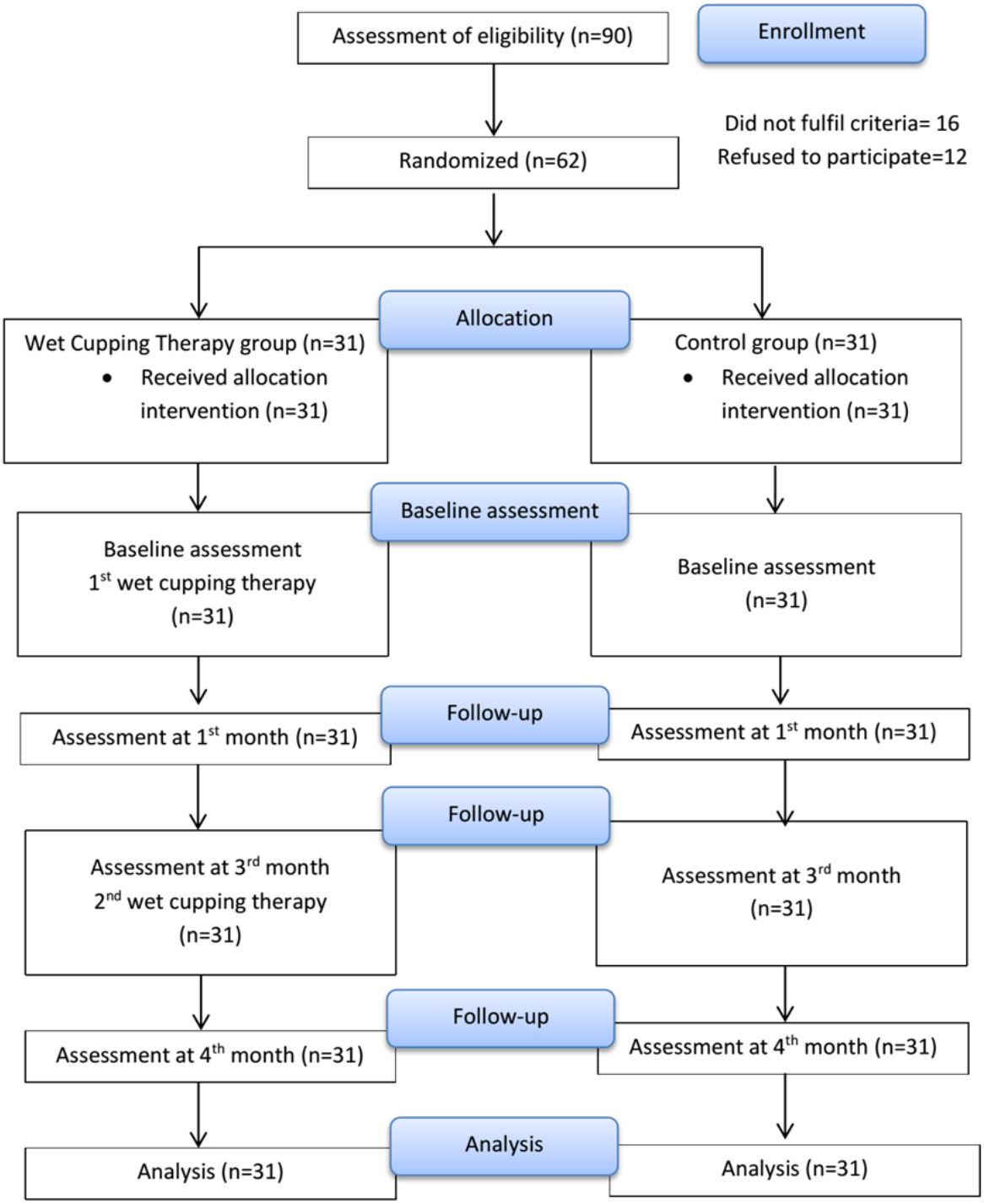

Figure 1: CONSORT flowchart of the study

Table 1: Comparison of sociodemographic characteristics between the cupping and control groups

Variables	Cupping group (n=31)	Control group (n=31)	Test-statistics (df)	*P*-value
Age	44.97 (6.44)	43.23 (7.39)	0.67 (60)	0.326[a]
Gender Female Male	14 (45.2) 17 (54.8)	21 (60.0) 10 (67.7)	3.22 (1)[b]	0.073[b]

Mean (SD) for age
Frequency (%) for gender
[a]Independent t-test
[b]Chi-squared test

The comparisons of serum TC, HDL-C, LDL-C and triglycerides for within and between groups are presented in table 2 and 3, and figure 2. Subjects in the cupping group had significant improvements from baseline to third and fourth month for TC, HDL -C and LDL-C. There was also a significant reduction from baseline to first and fourth month for triglycerides.

For between group comparisons, subjects in the cupping group had significantly better values in serum TC, HDL-C and LDL-C as compared with the control group at the third and fourth month. There were also significantly lower levels of triglyceride in the cupping group at fourth month. In the control group, there was no significant improvement in any serum lipid profiles.

Table 2: Comparison of serum lipid profiles within cupping and control group based on time

5454	Comparison	Cupping group (n=31)		Control group (n=31)	
		MD (95% CI)	*P*-value	MD (95% CI)	*P*-value
TC	Baseline-1st month	0.16 (-0.19, 0.50)	>0.95	-0.06 (-0.31, 0.19)	>0.95
	Baseline-3rd month	0.38 (0.06, 0.71)	0.014	-0.03 (-0.34, 0.28)	>0.95
	Baseline-4th month	0.46 (0.12, 0.79)	0.004	-0.03 (-0.48, 0.42)	>0.95
HDL-C	Baseline-1st month	-0.09 (-0.23, 0.06)	0.594	-0.04 (-0.11, 0.04)	>0.95
	Baseline-3rd month	-0.14 (-0.27, -0.10)	0.048	-0.02 (-0.10, 0.07)	>0.95
	Baseline-4th month	-0.22 (-0.33, -0.11)	<0.001	-0.09 (-0.19, 0.01)	0.078
LDL-C	Baseline-1st month	0.19 (-0.20, 0.58)	>0.95	-0.03 (-0.31, 0.26)	>0.95
	Baseline-3rd month	0.48 (0.12, 0.83)	0.004	0.07 (-0.26, 0.39)	>0.95
	Baseline-4th month	0.58 (0.19, 0.97)	0.001	0.13 (-0.35, 0.60)	>0.95
Triglycerides	Baseline-1st month	0.17 (0.02, 0.31)	0.017	0.04 (-0.16, 0.24)	>0.95
	Baseline-3rd month	0.15 (-0.04, 0.34)	0.193	-0.16 (-0.35, 0.04)	0.215
	Baseline-4th month	0.38 (0.15, 0.62)	<0.001	-0.15 (-0.38, 0.08)	0.480

MD=Mean difference, TC=Total cholesterol, HDL-C=High density lipoprotein cholesterol, LDL-C=Low density lipoprotein cholesterol

Table 3: Comparison of serum lipid profiles among cupping and control group based on time

Variables	Time	Mean (SD)		Mean diff (95% CI)	p-value
		Cupping (n=31)	Control (n=31)		
TC	Baseline	5.73 (0.92)	5.80 (1.20)	-0.07 (-0.61 ,0.46)	0.804
	1st month	5.58 (0.96)	5.86 (1.02)	0.25 (-0.79, 0.22)	0.270
	3rd month	5.35 (0.83)	5.52 (0.96)	-0.48 (-0.93, -0.02)	0.040
	4th month	5.27 (0.76)	5.83 (1.11)	-0.56 (-1.04, -0.07)	0.025
HDL-C	Baseline	1.38 (0.17)	1.39 (0.25)	-0.12 (-0.13, 0.10)	0.775
	1st month	1.48 (0.24)	1.43 (0.22)	0.05 (-0.07, 0.16)	0.404
	3rd month	1.53 (0.21)	1.41 (0.21)	0.12 (0.01, 0.22)	0.035
	4th month	1.61 (0.15)	1.48 (0.19)	0.13 (0.11, 0.28)	<0.001
LDL-C	Baseline	3.53 (0.86)	3.68 (1.1)	-0.15 (-0.66, 0.37)	0.567
	1st month	3.34 (0.89)	3.71 (0.97)	-0.37 (-0.84, 0.11)	0.127
	3rd month	3.06 (0.80)	3.62 (0.85)	-0.56 (-0.98, -0.14)	0.010
	4th month	2.95 (0.77)	3.56 (1.10)	-0.60 (--1.09, -0.12)	0.015
Triglycerides	Baseline	1.82 (0.72)	1.60 (0.66)	0.23 (-0.13, 0.58)	0.203
	1st month	1.66 (0.65)	1.56 (0.72)	0.10 (-0.25, 0.45)	0.557
	3rd month	1.67 (0.68)	1.75 (0.75)	-0.08 (-0.44, 0.29)	0.673
	4th month	1.44 (0.47)	1.75 (0.66)	-0.31 (-0.60, -0.01)	0.040

MD=Mean difference, TC=Total cholesterol, HDL-C=High density lipoprotein cholesterol, LDL-C=Low density lipoprotein cholesterol

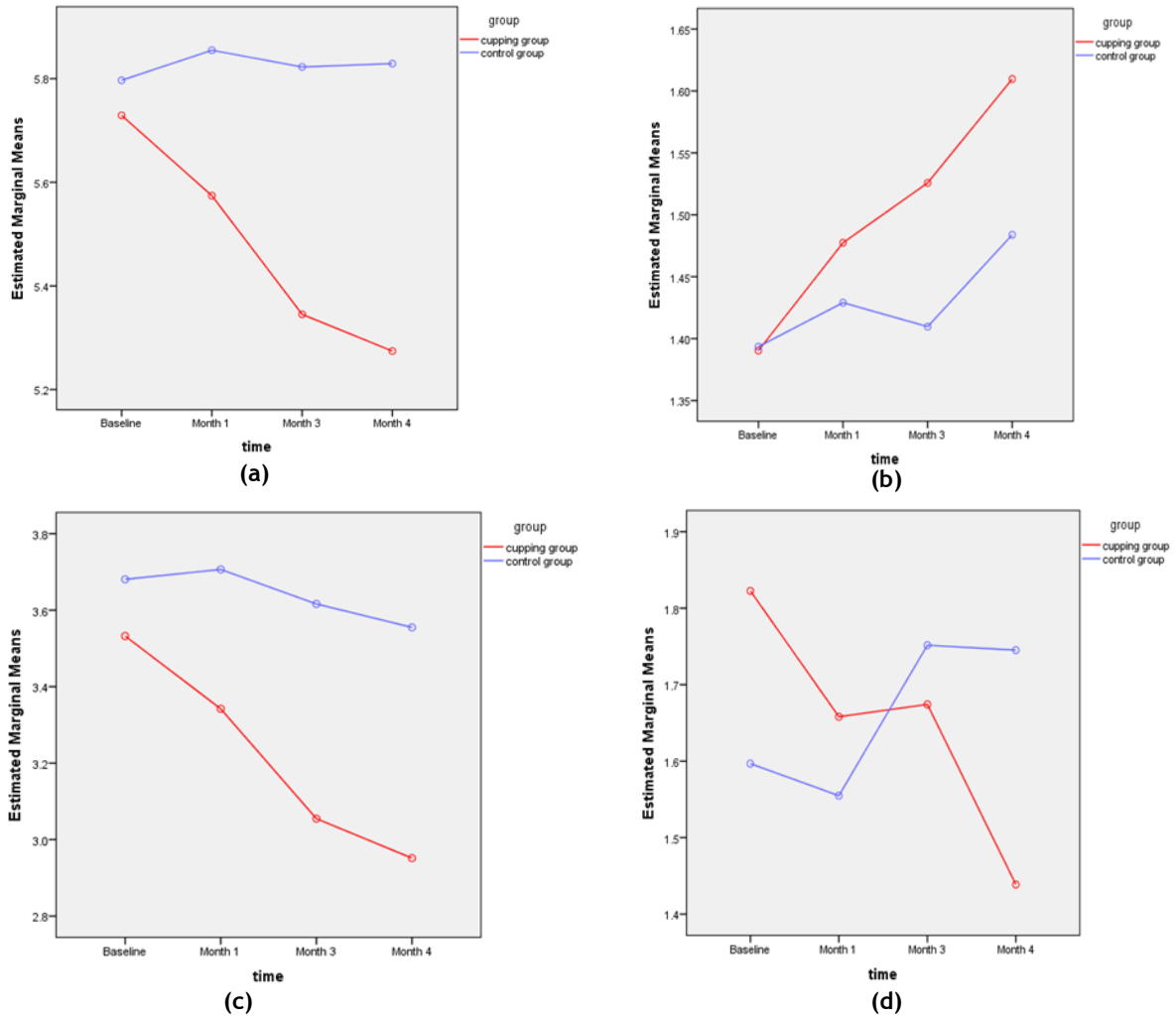

Fig 2: Profile plot of estimated marginal mean for serum cholesterol (a), HDL-C (b), LDL-C (c) and triglycerides (d)

DISCUSSION

Many studies have shown that dyslipidaemia has been identified as one of the main risk factors for cardiovascular disease [13, 14]. In the United States of America, it is estimated that 15% of the population aged 20 years and older have serum total cholesterol ≥ 6.2 mmol/L/. It is a primary and major risk factors, even among a prerequisite for coronary heart disease, which occur before other major risk factors come into play[15].

In a randomized controlled trial study conducted in Iran involving 47 healthy individuals, it was found that the effect of wet cupping on serum lipid profiles was seen mostly within the first week after cupping was conducted[4]. The findings were different with our study since the significant improvements in TC, HDL-C and LDL-C were present after three months of wet cupping and further improved at fourth month, which was after the second session of wet cupping. In this study, the first assessment was conducted one month after the first session of wet cupping therapy, which could reflect the effect of wet cupping on serum lipid profiles. The subsequent assessment was conducted after three months, in order to determine how long the effect of wet cupping on lipid profiles could be seen and maintained. It was assessed after three months as the functional lifetime of an erythrocyte is about 90 to 120 days. The second session of wet cupping was performed and the assessment was conducted after one month. Any further improvements in the serum lipid profiles could truly reflect the effect of wet cupping.

Our findings have been supported by several other studies. Layla A. Mustafa et al. reported that there were significant reductions in TC and LDL-C as early as after the first and second week of cupping[16]. There was another study conducted in Indonesia involving 18 hypercholesterolemia subjects, which showed a significant reduction in TC by 12 % in the cupping group as compared to control group.[17]

The serum TC in this present study was significantly reduced by 0.47 mmol/L with a 8.2% reduction at fourth month, after two sessions of wet cupping therapy. Meta-analysis of individual data from 61 prospective studies showed that 1 mmol/L lower in the serum TC was associated with about a half and a third lower in ischemic heart disease mortality in

both sexes aged between 40-49 years and 50-69 years respectively[13]. Another study showed that 10% decreased in serum TC was found to be associated with a decreased in incidence of ischemic heart disease by 54% at the age 40 years and 39% at the age of 50 [8].

In our study, serum triglyceride was reduced by 20.8% to 1.44 mmol/L at fourth month. In a meta-analysis study in Asia Pacific region, it was found that after adjustment for major CVDs risk factors, people with serum triglycerides level more than 1.9 mmol/L had 70% higher risk of coronary heart disease death, 80% greater risk of fatal or nonfatal coronary heart disease and a 50% increased risk of fatal or nonfatal stroke. The association between triglycerides and coronary heart disease death was found similar across subgroups defined by ethnicity, age and sex[18]. According to Clinical Practice Guidelines on the Management of Dyslipidaemia, the target value for serum triglycerides is less than 1.7 mmol/L, usually can be achieved by lifestyle changes such as low carbohydrate diets, exercise and cessation of smoking. Drug therapy is rarely required [7, 14].

In our present study, the mean of serum LDL-C at month, four was 2.95 mmol/L, and it was significantly reduced by 0.58 mmol/L, with 16.4% improvement, which made the classification changed to near optimal. Studies have shown that atherogenesis occur at significant rates, especially in the presence of other major risk factors with the level of serum LDL-C above 3.4 mmol/L. Thus, LDL-C should be the primary target in the cholesterol therapy. Meta-analysis have found that the reduction of serum LDL-C by 1% will reduce the coronary heart disease risk by 1%[19]. Therefore the changes of serum LDL-C in the present study were equivalent to 16% reduction in coronary risk. Another meta-analysis study have shown that, for a 0.26 mmol/L reduction in LDL-C, the reduction in relative risk for coronary heart disease death and events were 7.2% and 7.1% respectively, when adjusted for change in HDL-C and drug class [20].

There were several limitations in this present study. In this study, we did not blind, both the investigators and participants. The effect of wet cupping was therefore measured quantitatively using biomarkers that eliminated the bias of using self-reported outcomes. Biological markers are known to reduce the risk of bias in clinical research. We controlled for confounding effects of age and gender during our study by randomizing participants into two equal-sized groups. Minimizing the age span of the group also helped to reduce the confounding effects of age since we only included participants with ages between 30 and 60 years. As a result, the confounders such as age and sex were equally distributed between cupping group and control group.

CONCLUSION

In this present study, at fourth month, after two sessions of wet cupping, TC, HDL-C, LDL-C and triglycerides were significantly improved by 8.2%, 13.7%, 16.4% and 20.8% respectively. Two sessions of wet cupping therapy also had significantly improved the classification of serum LDL-C and triglycerides from borderline high to near optimal and normal, respectively, according to the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III[21]. Thus, wet cupping therapy was beneficial to be performed in every three months or more. Repeated wet cupping therapy was also useful in further improving the CVDs risk factors. Therefore the potential effects of wet cupping in improving the serum lipid profiles could give new perspectives in reducing and preventing the risk of CVDs at low cost, being easy to perform and minimally invasive technique.

CONFLICT OF INTREST

The authors had no conflict of interest to declare.

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