CLINICAL TRIAL

A randomized, double-blind, comparative study on the safety and efficacy of virgin coconut (*Cocos nucifera l.*) oil against 1% hydrocortisone lotion as an anti-inflammatory and anti-pruritic preparation for mosquito reactions

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Background: Virgin coconut oil (VCO) has been reported to have anti-inflammatory and anti-pruritic properties and can be used as an alternative to corticosteroids for mosquito bites. No studies on VCO for mosquito bites have been published.

Objective: To compare the safety and efficacy of VCO against 1% Hydrocortisone as an anti-inflammatory and anti-pruritic preparation for mosquito bites.

Method: This is a randomized, double-blind study comparing the anti-inflammatory and anti-pruritic effect of VCO versus 1% Hydrocortisone on *Aedes aegypti* bites, by measuring the mean lesion size, subjective assessment of the effects on bites, pruritus intensity through the visual analog, and verbal rating scale in 91 subjects at baseline, 1 hour, days 1, 3, and 7.

Results: During the first hour and throughout the seven-day period, there was a decrease in the mean lesion size, visual, and verbal scale score for both VCO and Hydrocortisone groups. The mean lesion size for both groups were not statistically significant on the 1st and 24th hour. On day 3, the mean lesion size for the VCO group was 0.02 and 0.71 for the Hydrocortisone group which was statistically significant in favor of VCO. The mean visual and verbal scale scores for pruritus for both treatment groups were not statistically significant. As early as the 1st hour, the proportion of patients who reported total clearance of lesions in the VCO group was 34.09% compared to 6.38% in the Hydrocortisone group. On day 7, both treatment groups had resolution of lesions. No adverse reactions were noted.

Conclusion: Virgin coconut oil is safe, cost-effective, and comparable to 1% Hydrocortisone as an anti-inflammatory and anti-pruritic agent.

Keywords: virgin coconut oil, mosquito bite reactions, hydrocortisone lotion

INTRODUCTION

Nearly everyone is sensitive to insect bites. The reactions are mostly due to the presence of allergens found in the saliva, which contains pharmacologically active compounds causing anticoagulation, impaired platelet formation, and vasodilatation. Studies shown that the reaction from bites of different species of mosquitoes differed among individuals. [1-3]

Histopathologic studies indicate that the intensity of the tissue response depends upon the sensitivity of the individual and the duration of feeding. Initially, edema may be the only feature followed by a perivascular polymorphonuclear and lymphocytic response, then finally, recruitment of eosinophils. The persistence of the insect bite reaction

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depends to some extent on the degree of inflammatory response and is prolonged by scratching and rubbing which aggravate the insect bite reaction by increasing tissue damage.[2]

Topical corticosteroids (TCS) are the mainstay of treatment in skin inflammation and control the recruitment of inflammatory cells, prevent the release of chemical mediators, and downregulate tissue responses. TCS induce lipocortins to inhibit phospholipase A2 and prevent the subsequent cell surface liberation of platelet-activating factor, arachidonic acid, and other potent inflammatory mediators. TCS also affect the vascular component of inflammation by augmenting the vasoconstrictive response to epinephrine and norepinephrine and reducing the responses to antihistamine and bradykinin.[4]

TCS molecules can be absorbed percutaneously in significant quantities to cause systemic adverse effects identical to systemically administered corticosteroids-suppression of hypothalamic-pituitary-adrenal axis, iatrogenic Cushing's syndrome, and growth retardation in infants and children.[4]

Virgin coconut oil is obtained from the separation of the oil from the fermented milk, obtained through cold-pressed method.[7] A study by Evangelista and colleagues showed that VCO is superior to mineral oil in retarding transepidermal water loss, improving the SCOring Atopic dermatitis (SCORAD) clinical assessment index in pediatric atopic dermatitis (AD) patients, and resolving pruritus by improving barrier function. In addition to improving the skin barrier, VCO may also address the chronic inflammation characteristic of AD with medium chain fatty acids (MCFA) as the active component responsible.[7]

Medium chain fatty acids (MCFAs) are acted upon by lipases produced by the resident flora of the skin and are broken down into free fatty acids which penetrate the dermis and reduce inflammation.[7] VCO has also been shown to destroy free radicals which in turn may promote inflammation. The antioxidant property may be due to phenolic compounds, ferrulic acid, and p-coumaric acid found in VCO.[7] VCO was also found to have anti-nociceptive activity, blocking peripheral and centrally mediated nociception induced by chemical and thermal stimuli.[8] Fatty acids such as oleic and stearic acids have been shown to attenuate the activity of polymorphonuclear leukocytes leading to the suppression of the inflammatory process.[8] Moreover, VCO has been shown to have antihistamine properties due to the presence of active phenolic compounds called flavonoids which not only inhibit histamine release but also inhibit the synthesis of IL-4, IL-13, and CD40 ligand expression by basophils.[9]

The processes used to obtain VCO which involve the use of controlled temperature are believed to result in a preparation that has more beneficial effects than the traditional copra oil due to the greater retention of its active components such as squalene, tocopherols, and sterols. The antioxidant property and free fatty acids in coconut are adversely affected by refining, heat and solvent extraction which is not the case with VCO.[7] Topical application of coconut oil has a very low risk of allergic reaction or adverse effects.[9]

Since VCO has been reported to have anti-inflammatory[6-8,10] and antipruritic[7] properties with a very low risk of allergic reaction or adverse effect[11], studies involving human subjects with mosquito bites was pursued in this study to prove its efficacy and safety.

OBJECTIVES

The general objective of this study was to compare the safety and efficacy of VCO versus 1% Hydrocortisone lotion as an anti-inflammatory and anti-pruritic preparation on mosquito bite reactions.

The specific objectives were to compare the anti-inflammatory effect of VCO and 1% hydrocortisone lotion on mosquito bites by measuring changes in lesion size and subjective assessment of improvement of lesions, and to compare the anti-pruritic effect of virgin coconut oil and 1% hydrocortisone lotion using the visual analog scale for pruritus and verbal rating scale for pruritus at baseline or 15 minutes after mosquito bite, 1 hour after application, and at days 1, 3, and 7. Another objective was to monitor, compare, and record adverse cutaneous reactions of VCO and 1% hydrocortisone lotion using a four-point scale at 1 hour after application and at days 1, 3, and 7.

MATERIALS AND METHODS

Patients and study design

The study was a randomized double-blind clinical trial which compared the anti-inflammatory and anti-pruritic effects of VCO versus 1% Hydrocortisone by measuring the mean lesion size, subjective assessment of the effect on lesions, pruritus intensity through the visual analog and verbal rating scale among subjects at baseline, 1 hour, days 1, 3, and 7. Adverse reactions were monitored up to 2 weeks.

The study consisted of two phases: Phase I is the 96-hour IQ chamber Irritancy patch testing, while Phase II of the clinical trial is a randomized, double

blind study comparing the efficacy of Virgin coconut oil against 1% Hydrocortisone lotion as an anti-inflammatory and anti-pruritic preparation for mosquito bites.

Subjects included in the study were 18-60-year-old male and female healthy subjects who are able to read and write and who are willing to comply with the study protocol requirements, sign an informed consent after having clearly understood its contents, and have photos taken for documentation purposes during the experiment. Pregnant and lactating women, those with history of severe reactions to mosquito bites, who have active skin lesions or other dermatologic disorders, and those with a history of co-morbid conditions such diabetes and hypertension were excluded from this study.

This study was approved by the institutional review board of the Research Institute for Tropical Medicine and was conducted at the Department of Dermatology of the same institution. Informed consent from the subjects included in the study was secured after being briefed on the study procedure.

Materials

VCO, manufactured locally in accordance with the GMP (Good Manufacturing Practice) and HACCP (Hazard Analysis and Critical Control Point) systems with approval from the Food and Drug Administration of the Philippines, was used in this study.

1% Hydrocortisone lotion was prepared by a licensed pharmacist. Both test products were funneled into identical 120 ml white bottles free from any identification marks.

Randomization, treatment allocation and blinding

Randomization of participants, identified with numbers, into two test groups, designated as letters (Group A and B) was done using a computerized randomization program. The participants and their corresponding identifying numbers were known only by an encoder who was blinded to the treatment groups. A pharmacist, blinded to the participant identity codes and test groups was assigned to dispense the products to the participants based on the assignment generated by the computerized randomization program. The codes were only revealed to the primary investigator at the end of the study.

Study Intervention

PHASE I: IQ Chamber Patch Testing

Subjects who were eligible for the study were enrolled in the 96-hour I.Q Chamber Irritancy Patch testing. The I.Q. chamber with VCO, 0.5% sodium laurel sulfate as positive control and water as negative control were applied to the back of the subjects. Assessment of the patch test site was noted after 48, 72, and 96 hours. Subjects who did not develop positive reactions were included in the Phase II clinical trial. No topical preparations were applied throughout the whole duration of the study. Patients were instructed to report immediately any delayed reactions (reactions noted up to 2 weeks after onset of patch test procedure) on the patch test site.

PHASE II: Clinical Trial

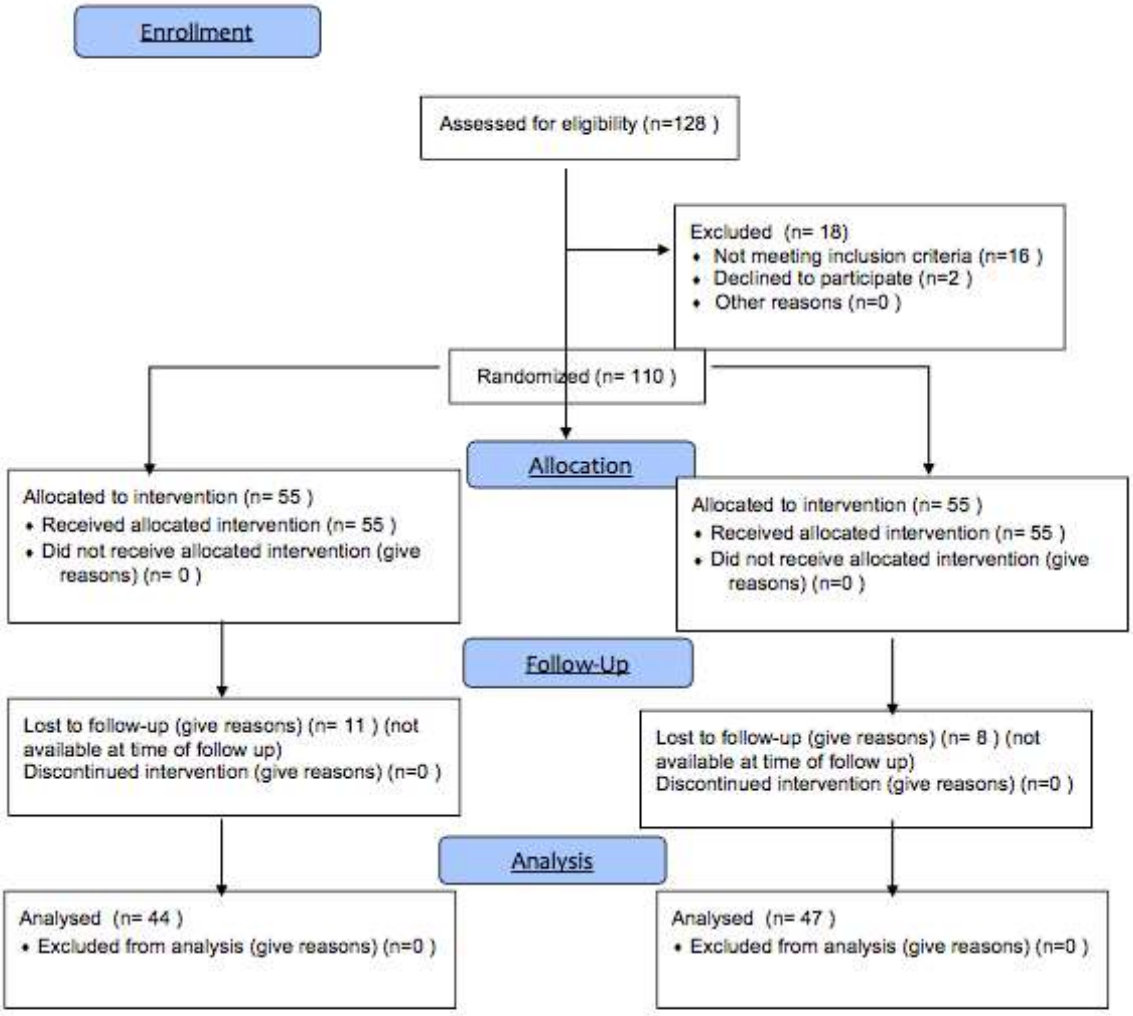
Subjects who did not develop positive reactions on the Phase I of the trial were included in the study. Subjects were assigned equally into two treatment groups by computer-generated randomization.

A screened aluminum cage measuring 60 x 60 x 60 cm with a 15 x 15 cm square opening fitted with cloth sleeves was used in the study. All the mosquitoes used were sterile sucrose-starved for 48 hours prior to the test, ensuring biting. A batch of 50 female laboratory-reared *Aedes aegypti* mosquitoes were introduced in the cage every exposure period.

Subjects were instructed to wash their forearms with plain water and a mild soap provided by the investigator and to dry with a clean towel prior to exposure to mosquitoes. The subjects were asked to wear rubber gloves with an 8 x 3.5 cm opening on the volar aspect. This was done to limit the area where the bites were not wanted. Bite exposure with *Aedes aegypti* mosquitoes were performed between noon and 3 pm. Only 1 arm was exposed for each participant for 5 to 10 minutes. The mosquitoes that had landed or fed were removed using a micropipette tip apparatus and were placed in a holding chamber and subsequently disposed. A fresh batch of mosquitoes was placed in the cage to maintain 50 mosquitoes every exposure period after a minimum of 5 mosquito bites within the 5 to 10 minutes exposure time. After such period, the participants were asked to remove their forearm from the chamber.

During the whole test period, the subjects were instructed not to rub or scratch the mosquito bites, not to take or apply any other medication, and to use only the mild soap provided by the primary investigator.

Patients were then instructed to apply the assigned solutions to the lesions twice a day for 7 days with assessment of the lesions done at baseline or 15



Adapted from Schultz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials. PLoS Med 2010;7(3):e1000251. doi:10.1371/journal.pmed.1000251

Figure 1. Flowchart of Study Procedure

minutes after the mosquito bite, 1 hour after application of solutions, and at days 1, 3, and 7.

Clinical Assessment

Demographic data which include patient's code, age, and sex were gathered from a self-administered questionnaire. Outcome measures were assessed by the principal investigator at baseline or 15 minutes after mosquito bite, 1 hour after application of solutions, day 1, day 3, and day 7.

The variable assessed during Phase I (IQ Chamber Patch Testing) of the study was lesion appearance interpreted based on the recommendation by the International Contact Dermatitis Research Group at 48, 72, and 96 hours for VCO, water, and sodium laurel sulfate. A weak/ non-vesicular positive reaction (+) is characterized by the presence of erythema, infiltration, and papules. Presence of the above characteristics and lesions at patch testing sites together with the appearance of vesicles constitute a strong vesicular positive reaction (++), while presence of bullae indicates extremely positive reaction. Patients who demonstrated positive reactions to patch testing were not included in the study. Subjects were instructed to come back after 1 week and 2 weeks after the last application of the test products to monitor any delayed type of reactions to the treatment products.

Variables assessed during Phase II (Clinical Trial) are 1.) objective changes in lesion size measured in millimeters; 2.) subjective perception of improvement of lesions measured as "no change", "improvement", and "total clearing"; 3.) Pruritus intensity quantified using the 100 mm Itch Visual analog scale; and 4.) Pruritus intensity described using the Verbal rating scale (no itch, low, moderate, severe itch) at baseline or 15 minutes after mosquito bite, 1 hour after application of solutions, and at days 1, 3, and 7.

A research assistant was present on each day of assessment of lesions to confirm attendance of the participants and to take note of dropouts defined as participants who were unable to return for assessment of lesions and whose outcomes were unknown by the end of the study period.

Sample Size

The sample size for Phase II or the clinical trial phase was calculated using OpenEpi Version 3.03 sample size calculation for the estimation of the difference between the two means. Values were based on a study on the anti-inflammatory effects of capsaicin compared to hydrocortisone cream by Godinez et al. Using a 95% level of significance and a power of 80%, a total of 92 participants (46 participants per group) was needed in the study. However, adjusting for 20% drop out rates and 20% for patch testing failure rates, a total of 128 participants were included in the study.

Data Management/ Data Analysis

Data collected were encoded via double data entry using Microsoft Excel program. Key stroke validation was done. For qualitative variable such as subjective assessment of change of lesions, data were presented as proportions. For quantitative variables such as change in lesion size, visual analog scale, itch verbal rating scale, mean, standard deviation, and range were used.

T-test and Paired t-test for related samples were used to compare the mean lesion size between different time periods for subjects given VCO and Hydrocortisone lotion. Mann Whitney U Test and Wilcoxon signed rank test were used to compare the median scores for Visual analog scale and Verbal rating scale between VCO and Hydrocortisone group. Chi square was done to compare the subjective assessment of change of lesion ("no change", "improved", and "total clearing") between the VCO and Hydrocortisone group.

RESULTS

The demographic characteristics of subjects were similar for the two treatment groups. (Tables 2a & 2b) A total of 110 subjects were included, all of which passed the Phase I or 96-hour IQ chamber irritancy patch testing and all of which were recruited for the Phase II of the study.

Table 2a. Comparison of age of participants by treatment group

Treatment group	mean	standard deviation	t score	p-value
VCO	25.85	3.45	1.80	0.0740
Hydrocortisone	27.22	4.42		

Table 2b. Comparison of sex of participants by treatment group

Treatment group	Male		Female		Chi square	p-value
	Number	%	Number	%		
VCO	32	58.18	23	41.82	0.04	0.8472
Hydro cortisone	31	56.36	24	43.64		

Recording of the patch test results was based on the recommendation by the International Contact dermatitis group (Table 10) and the National Institute for Occupational Safety and Health interpretation of skin ratings (Tables 11 & 12). None of the participants showed any adverse reactions to VCO or to Hydrocortisone. (Tables 16 & 17)

Subjects randomized to the control group had VCO applied to their forearms at the site of mosquito bites twice a day for 7 days. Parameters were assessed at baseline or 15 minutes after biting, 1 hour, and at days 1, 3, and 7.

The change in mean lesion size in all observation periods for both treatment groups was statistically different compared to baseline as shown in Figure 2 and Tables 3a & 3b.

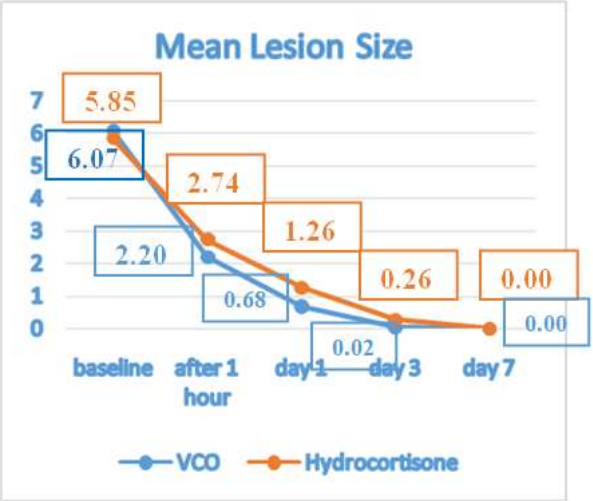


Figure 2. Graph showing the comparison of change in mean lesion size in mosquito bites treated with Virgin coconut oil and 1% Hydrocortisone lotion during the 7-day study period

Table 4 shows that at baseline, the mean lesion size for VCO was 6.07 and for the Hydrocortisone group, it was 5.85. As early as the first hour, there was a decrease in the mean lesion size for both treatment groups, 2.20 for VCO and 2.74 for Hydrocortisone. Comparing both groups, it was not statistically significant. During the 7-day observation period, there was a continuous decrease in the mean lesion size for both treatment groups. Using t test and paired t test, the mean lesion size for both treatment groups was not statistically significant after 1 hour and 1 day. On day 3, the mean lesion size for the VCO group was 0.02 and 0.71 for the Hydrocortisone group, and this was statistically significant in favor of VCO. On day 7, both treatment groups had resolution of lesions.

At baseline, the mean visual scale score for pruritus for the VCO group was 5.68 compared to the Hydrocortisone group which was 3.66, and these were statistically different. As early as the first hour, there was a decrease in the mean visual scale score for pruritus for both treatment groups, 0.95 for VCO and 1.02 for Hydrocortisone. All throughout the 7-day observation period, there was a decrease in the mean visual scale score for pruritus for both treatment groups as seen in Figure 3. Table 6 shows that the mean visual scale score for pruritus for both treatment groups was not statistically significant. On day 7, there was absence of pruritus for both treatment groups.

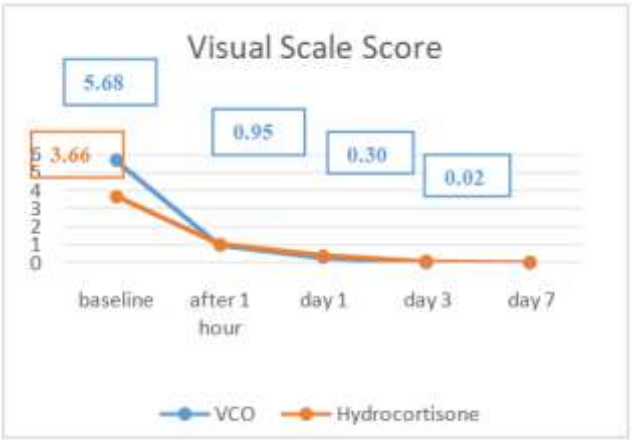


Figure 3. Line graph showing the comparison of Visual Scale Scores in mosquito bites treated with Virgin coconut oil and 1% Hydrocortisone lotion during the 7-day study period

The verbal scale score for pruritus in all observational periods were statistically different compared to baseline for the two treatment groups as shown in Figure 4 and Tables 7a & 7b.

Tables 3a & 3b. Comparison of mean lesion size at baseline and during different observation periods for VCO and hydrocortisone treatment groups.

VCO (n=44)					
Time period	Mean	Standard deviation	Range	t score	p- value
Baseline	6.07	2.64	3-15		
After 1 hr	2.20	2.06	0-8	11.01	<0.001
After 1 day	0.68	1.29	0-6	13.75	<0.001
After 3 days	0.02	0.15	0-1	15.39	<0.001
After 7 days	0.00	0.00	0-0	15.28	<0.001

Hydrocortisone (n=47)					
Time period	Mean	Standard deviation	Range	t score	p- value
Base-line	5.85	2.02	3-10		
After 1 hr	2.74	1.80	0-8	14.56	<0.001
After 1 day	1.26	1.65	0-6	20.63	<0.001
After 3 days	0.26	0.71	0-3	20.49	<0.001
After 7 days	0.00	0.00	0-0	19.84	<0.001

Table 4. Comparison of mean lesion size during different observation periods between VCO and Hydrocortisone treatment groups

Time period	VCO (n=44)		Hydrocortisone (n=47)		t score	p-value
	Mean	Standard devia-tion	Mean	Standa rd devia-tion		
Base-line	6.07	2.64	5.85		-0.44	0.6591
After 1 hr	2.20	2.06	2.74		1.33	0.1859
After 1 day	0.68	1.29	1.26		1.84	0.0691
After 3 days	0.02	0.15	0.26	2.14	2.14	0.0176
After 7 days	0.00	0.00	0.00	0.00	NA	NA

Tables 5a & 5b. Comparison of visual scale scores at baseline and during different observation periods for VCO and hydrocortisone treatment groups

VCO (n=44)					
Time period	Mean	Standard deviation	Range	t score	p- value
Baseline	5.68	3.04	0-10		
After 1 hr	0.95	1.78	0-8	5.71	<0.001
After 1 day	0.30	1.09	0-6	5.72	<0.001
After 3 days	0.02	0.15	0-1	5.72	<0.001
After 7 days	0.00	0.00	0-0	5.72	<0.001

Hydrocortisone (n=47)					
Time period	Mean	Standard deviation	Range	t score	p- value
Baseline	3.66	2.44	0-9		
After 1 hr	1.02	1.71	0-6	5.92	<0.001
After 1 day	0.38	0.95	0-5	5.95	<0.001
After 3 days	0.09	0.46	0-3	5.95	<0.001
After 7 days	0.00	0.00	0-0	5.95	<0.001

Table 6. Comparison of visual scale scores during different observation periods for VCO and hydrocortisone treatment groups

Time period	VCO (n=44)		Hydrocortisone (n=47)		t score	p-value
	Mean	Standard deviation	Mean	Standard deviation		
Baseline	5.68	3.04	3.66	2.44	-3.46	0.0006
After 1 hr	0.95	1.78	1.02	1.71	0.26	0.7973
After 1 day	0.30	1.09	0.38	0.94	1.22	0.2208
After 3 days	0.02	0.15	0.09	0.46	0.54	0.5859
After 7 days	0.00	0.00	0.00	0.00	NA	NA

Tables 7a & 7b. Comparison of verbal scale score for pruritus at baseline and during different observation periods for VCO and hydrocortisone treatment groups

VCO (n=44)					
Time period	Mean	Standard deviation	Range	z score	p- value
Baseline	1.48	0.76	0-3		
After 1 hr	0.23	0.43	0-1	5.67	<0.001
After 1 day	0.02	0.15	0-1	5.81	<0.001
After 3 days	0.00	0.00	0-0	5.81	<0.001
After 7 days	0.00	0.00	0-0	5.81	<0.001

Hydrocortisone (n=47)					
Time period	Mean	Standard deviation	Range	z score	p- value
Baseline	1.28	0.58	0-2		
After 1 hr	0.21	0.41	0-1	6.19	<0.001
After 1 day	0.09	0.28	0-1	6.13	<0.001
After 3 days	0.00	0.00	0-0	6.13	<0.001
After 7 days	0.00	0.00	0-0	6.13	<0.001

Table 8. Comparison of verbal scale score for pruritus during different observation periods between VCO and hydrocortisone treatment groups

Time period	VCO (n=44)		Hydrocortisone (n=47)		t score	p-value
	Mean	Standard deviation	Mean	Standard deviation		
Baseline	5.68	3.04	3.66	2.44	-3.46	0.0006
After 1 hr	0.95	1.78	1.02	1.71	0.26	0.7973
After 1 day	0.30	1.09	0.38	0.94	1.22	0.2208
After 3 days	0.02	0.15	0.09	0.46	0.54	0.5859
After 7 days	0.00	0.00	0.00	0.00	NA	NA

Table 9a. Comparison of subjective assessment of change in lesion scores between VCO and Hydrocortisone group at 1 hour

Subjective rating	VCO (n=44)		Hydrocortisone (n=47)		chi square	p-value
	Number	Percent	Number	Percent		
Total clearing	15	34.09	3	6.38	11.0000	0.0005
With improvement	29	65.91	44	93.62		

Table 9b. Comparison of subjective assessment of change in lesion scores between VCO and Hydrocortisone group at day 1

Subjective rating	VCO (n=44)		Hydrocortisone (n=47)		chi square	p-value
	Number	Percent	Number	Percent		
Total clearing	33	75.00	21	44.68	8.6583	0.0033
With improvement	11	25.00	26	55.32		

Table 9c. Comparison of subjective assessment of change in lesion scores between VCO and Hydrocortisone group at day 3

Subjective rating	VCO (n=44)		Hydrocortisone (n=47)		Fisher exact p value
	Number	Percent	Number	Percent	
Total clearing	43	97.73	45	95.74	0.525
With improvement	1	2.27	2	4.26	

Table 9d. Comparison of subjective assessment of change in lesion scores between VCO and Hydrocortisone group at day 7

Subjective rating	VCO (n=44)		Hydrocortisone (n=47)		chi square	p-value
	Number	Percent	Number	Percent		
Total clearing	44	100.00	47	100.00	NA	NA
With improvement	0	0.00	0	0.00		

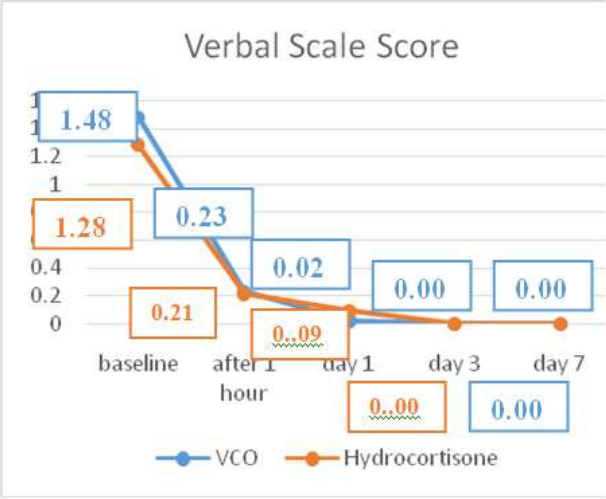


Figure 4

At baseline, the mean verbal scale score for pruritus for the VCO group was 1.48 compared to the Hydrocortisone group which was 1.28, and these were not statistic

ally different. As early as the first hour, there was a decrease in the mean verbal scale score for pruritus for both treatment groups, 0.23 for VCO and 0.21 for Hydrocortisone. All throughout the 7-day observation period, there was a decrease in the mean verbal scale score for pruritus for both treatment groups as seen in Figure 4. Table 8 shows that the mean verbal scale score for pruritus for both treatment groups was not statistically significant. On days 3 and 7, there was absence of pruritus for both treatment groups.

As early as 1 hour, the proportion of patients having total clearance in the VCO group was 34.09% compared to 6.38% in the Hydrocortisone group. Using Chi square with a p value of 0.0005, these were statistically significant as shown in Table 9a in favor of the VCO group.

At day 1, the proportion of patients having total clearance in the VCO group was 75.00% compared to 44.68% in the Hydrocortisone group. Using Chi square with a p value of 0.0033, these were statistically significant as shown in Table 9b.

At day 3, the proportion of patients having total clearance in the VCO group was 97.73% compared to 95.74% in the Hydrocortisone group. Using Chi square with a p value of 0.525, these values were not statistically significant as shown in Table 9c.

At day 7, both treatment groups showed 100% of patients reporting total clearance of lesions as shown in Table 9d.

There were no reported adverse reactions using the four-point scale for the two test products throughout the study. (Tables 15 and 16)

DISCUSSION

Mosquito bite reactions are a common cause of physician consultation among children and adults. These bites appear to be allergic in nature due to both the presence of allergens in the saliva [1] and foreign body deposition during a bite[3]. Ige mediated and T lymphocyte mediated mechanisms are involved in the development of mosquito allergy with Type I hypersensitivity reactions responsible for immediate reactions.[12]

Figure 2 and Table 4 show that the mean lesion size for VCO and Hydrocortisone was statistically not significant on the 1st hour and 1st day. On day 3, the mean lesion size was smaller for the VCO group compared to the Hydrocortisone group, and this was statistically significant in favor of the VCO group. However, both treatment groups had resolution of all lesions on day 7. Subjective assessment by the patient showed that there was a greater proportion of patients who had total clearing with VCO compared to 1% Hydrocortisone after 1

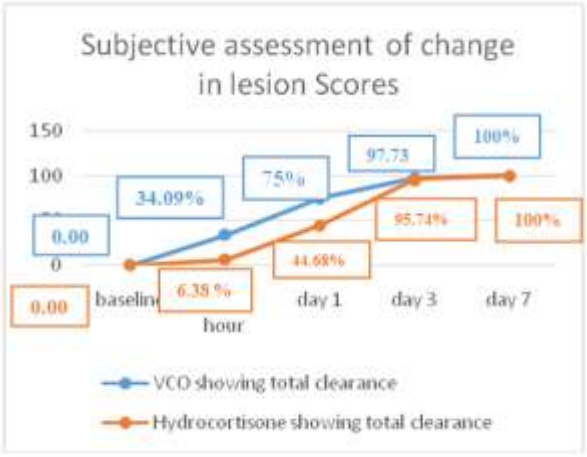


Figure 5. Line graph showing the comparison of the subjective assessment by the patient of change in lesion scores in mosquito bites treated with VCO and 1% Hydrocortisone lotion during the 7-day study period. It compares the percentage of patients having total clearance using VCO and 1% Hydrocortisone.

hour and at day 1, in favor of VCO. However, on day 3, subjective assessment by the patient showed that there was no statistically significant difference between the two groups and on day 7, there was total clearing of lesions for both treatment groups. This shows that VCO has an anti-inflammatory property comparable to 1% Hydrocortisone. (Tables 9a-d).

Figure 3 and Table 6 show that the mean visual scale score for pruritus for the VCO group and the Hydrocortisone group was not statistically significant throughout the 7-day observation period. In Figure 4 and Table 8, the mean verbal scale score for pruritus for both groups was also not statistically significant throughout the 7-day observation period. This shows that VCO has an anti-pruritic property comparable to 1% Hydrocortisone.

The results of this study can be explained by research studies done to assess the anti-inflammatory[6-8, 10] and anti-pruritic effect of VCO[7]. VCO contains many fatty acids which have been shown to inhibit the activity of polymorphonuclear leukocytes leading to suppression of inflammation.[8] Medium chain fatty acids converted to free fatty acids by lipases of resident flora of the skin penetrate the dermis to reduce inflammation.[7] VCO also contains Lauric acid which has been shown to modulate immune cell proliferation and possess antinociceptive properties in studies.[8] In addition, polyphenols found in VCO have anti-inflammatory and antioxidant properties which inhibit ROS activity which contribute to inflammation.[7] This explains the anti-inflammatory effect of VCO on the inflammation caused by mosquito bites. In addition, VCO also contains flavonoids which are active phenolic substances which have been shown to have antiallergic activity by inhibiting the release of histamine and inhibiting the synthesis of IL-4, IL-13, and CD40 ligand expression by basophils.[9] Histamine is a well-known mediator of pruritus and the anti-histamine effect of these flavonoids in VCO can make VCO a potential antipruritic agent in various inflammatory diseases.

Topical application of virgin coconut oil has a very low risk of allergic reaction or adverse effects. The absence of adverse cutaneous reactions in the study shows that VCO is safe with no reported side effects. This is further emphasized in a study done on VCO as a moisturizer for xerosis, which demonstrated negative patch test results and absence of adverse reactions of VCO application during the study.[11]

Commercially available VCO in 50ml bottles is priced at 42 Philippine pesos (Php) compared to 110 Php which is the price of a 50-ml bottle of Hydrocortisone lotion. VCO offers a cheaper alternative to Hydrocortisone for mosquito bite reactions.

CONCLUSION

Virgin coconut oil is safe, cost-effective, and comparable to 1% Hydrocortisone as an anti-inflammatory and anti-pruritic agent.

RECOMMENDATIONS

Researchers should conduct clinical trials on the safety and efficacy of virgin coconut oil on the treatment of other inflammatory dermatoses such as contact dermatitis, seborrheic dermatitis, and other eczemas to further validate claims on its anti-inflammatory properties.

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