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Research Article

THE BENEFITS OF SOY TEMPEH AGAINST IN WOMEN WITH ACNE VULGARIS

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ABSTRACT

Background: Acne vulgaris (AV) is a skin disorder that most often encountered, nearly 80% of teenagers and young adults had suffered from AV, its pathogenesis is not clear, but some studies have shown that dihydrotestosterone (DHT) is the androgen that is most responsible, especially in women, there is a correlation between DHT by the number of lesions.

Soy tempeh contains soy isoflavones with the active component genistein, daidzein and glycitein, consumption in Asian countries four times more than in western countries, with the average of 24-45 mg per day. Soy isoflavones play a role in the metabolism of androgens, which inhibit the enzyme 3SS-hydroxysteroid dehydrogenase (3SS-HSD), 17 β -hydroxysteroid dehydrogenase (17 β -HSD) and 5 α -reductase, whereas as antiinflammatory, which inhibits pro-inflammatory cytokines. The purpose of this study demonstrate the effect of soy tempeh on AV lesions in female patients.

Methods: This study is a clinical study design with randomized pretest-posttest control group design, with 25 samples were randomized into 5 groups: soy tempeh 100 gr, 200 gr, 300 gr, 400 gr, and placebo, for 4 weeks, conducted a double-blind manner.

Results: The study found differences in the mean total AV lesions before treatment among the five groups (p : 0.259) or not significant (p>0.05), whereas after treatment (p : 0.001) or significant (p<0.05). Differences decrease in the mean total AV lesion before and after the inter-group obtained soy tempeh 400 gr group (p < 0.05), while the placebo, 100 gr, 200 gr, 300 gr not significant (p>0.05), and the difference in total lesion AV delta (p:0.001) or significant (p<0.05).

Conclusion: This study of soy tempeh supplementation 400 gr/day can lower total AV lesion.

INTRODUCTION

Acne vulgaris (AV) is a skin disorder that is most often found, nearly 80% of adolescents and young adults have suffered AV (Zanglein *et al.*, 2012; Collier *et al.*, 2008; Azimi *et al.*, 2012). Acne vulgaris pathogenesis is not clear, but several studies have shown that dihydrotestosterone (DHT) is an androgen most responsible and DHT correlation with the number of AV lesions, especially in women (Thiboutot and Chen, 2003; Junkins-Hopkins, 2010). The active component of tempeh soy are isoflavones (Mackinnon and Rao, 2012; Barbara and McCauley, 2011; Basaria, 2009; Dillingham *et al.*, 2010; Legg *et al.*, 2011). Consumption of soy isoflavones in Asian countries four times more than in the western countries, the average daily consumption in Asian countries 24-45 mg (Legg *et al.*, 2011; Pilsakova *et al.*, 2010; Setchell and Clerici, 2010). Role of soy isoflavones on androgen metabolism, by inhibiting the enzyme 3 β -hydroxysteroid dehydrogenase

(3 β -HSD), 17 β -hydroxysteroid dehydrogenase (17 β -HSD) and 5 α -reductase (Steinberg *et al.*, 2011). The relationship between the consumption of soy tempeh with AV is still unknown, so do research on the effect of soy tempeh on the number of AV lesions, and obtained the formulation of the problem whether oral supplementation of soy tempeh affect the number of lesions in women with AV ? The purpose of this study is to prove that oral supplementation of soy tempeh affect the decrease in the number of AV lesions. This research could usefully contribute to science and technology, and improving the quality of health services, as well as contributions of science for the benefit of society. Major hypothesis of research is oral supplementation of soy tempeh affect AV, while the minor hypothesis is soy tempeh varied dosing for 4 weeks will lead to differences in the number of AV lesions.

MATERIALS AND METHODS

The study design is a true experimental research with randomized pretest-posttest control group design. This study used a variation of soy tempeh dose is 100 gr, 200 gr, 300 gr,

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400 gr for 4 weeks, with a sample of 25 people, were randomized into 5 groups and to address the drop out to monitor the schedule of assessment visite guidelines. The sample was female patient who was treated in skin clinic, Ungaran city, Central Java, Indonesia. The selection of subjects of research conducted by consecutive sampling and the double-blind treatment. Standard drug used was 0.025 % tretinoin cream and sunscreen SPF 15, while soy tempeh used in this study is manufactured and standardized by "Rumah Tempe Indonesia", Bogor city, Indonesia. Inclusion criteria were women with mild to severe AV according to Lehmann and not on medication, do not suffer from hyperandrogenism, and willing to sign informed consent.

Exclusion criteria were allergy soy tempeh. The independent variable is the soy tempeh 100 gr/day, 200 gr/day, 300 gr/day, and 400 gr/day. The dependent variable is the total number of AV lesions, examined by two dermatologist, then calculated interclass correlation coefficient and the coefficient alpha. Controlled confounding variables were age, body mass index, the average consumption of isoflavones from soy foods, stress status was measured by a score inventory beck depression (Henkel *et al.*, 2002), hiperandrogenisme clinically assessed that there is amenorrhea, sound like men and hirsutism were assessed by Ferriman and Gallwey scale (Ehrmann *et al.*, 2006). Uncontrolled confounding variables is genetic, racial, environmental pollutants and chemicals. Analysis of the data displayed minor hypothesis test to prove the difference in the mean total lesion AV before and after the study, confounding factors controlled the randomization process. Limit the degree of significance will be determined is $p < 0.05$ with 95 % confidence intervals. This study was approved by the Ethics Committee of the Faculty of Medicine/Hospital Kariadi Semarang city, Indoneisa.

RESULTS

Table 1. Characteristic data age, education, and employment variable

Variable	group					P
	Placebo n= 5	Soy tempeh 100 gr n=5	Soy tempeh 200 gr n=5	Soy tempeh 300 gr n=5	Soy tempeh 400 gr n=5	
age (rmean±SD, year)	20,2 ± 2,28	22,2 ± 6,73	25,6 ± 6,73	26,0 ± 5,96	27,4 ± 6,66	0,307 ^a
graduated (n,%)						
junior school	0 (0)	1(20)	0(0)	0(0)	0(0)	0,408 ^b
high school	5(100)	4(80)	4(80)	5(100)	5(100)	
university	0(0)	0(0)	1(20)	0(0)	0(0)	
employment (n,%)						
did not work	0(0)	0(0)	1(20)	0(0)	0(0)	0,559 ^b
student	2(40)	2(40)	0(0)	1(20)	1(20)	
labour	3(60)	3(60)	3(60)	2(40)	4(80)	
self-employed	0(0)	0(0)	0(0)	1(20)	0(0)	
civil servants	0(0)	0(0)	1(20)	1(20)	0(0)	
body mass index	32,1±0,43	20,68±0,79	21,1±2,08	20,59±2,24	25,9±4,33	0,911 ^b

Description: ^a Kruskal-Wallis ^b Chi square, ^c One way ANOVA

During the period of study found 55 women with AV, after the selection obtained in 25 patients met the inclusion criteria and 30 patients were excluded from the study, due to the 20 patients refused to have blood drawn and 10 people undergoing acne treatment on the other beauty clinics. 25 samples of the study were randomized into 5 groups, namely the group of soy tempeh 100 gr, 200 gr, 300 gr, 400 gr, and placebo groups, the treatment is not obtained until the end of the sample who dropped out in all groups.

Characteristic average age of the entire sample in this study was 24.3 ± 5.71 years with a range youngest is 17 years old and the oldest was 34 years old. The level of education in junior school graduates by 1 (4.0%) samples, high school graduates were 23 (92.0%) samples, and university graduates by 1 (4.0%) samples, and found no primary school graduates. This type of work earned as many as 15 (60.0%) laborers samples, civil servants in 2 (8.0%) samples, and students 6 (24.0%) samples, self-employed and do not work as much as 1 (4.0%) samples. The entire sample in this study, the mean body mass index (BMI) was 20.8 ± 1.39 with a range of 17.3 and the lowest score is the highest score was 23.6. The mean BMI in the placebo group was 21.2 ± 0.43 , soy tenpeh 100 gr was 20.7 ± 0.79 , soy tempeh 200 gr was 21.1 ± 2.08 , soy tempeh 300 gr was 20.6 ± 2.24 , soy tempeh 400 gr was 20.5 ± 1.39 . (Table 1) Overall marital status obtained 19 (74.0 %) samples were not married and 6 (24.0 %) samples were already married, not obtained a sample that is experiencing pregnancy and not being a participant family planning last 1 month.

Age of menarche in this study all samples were from age 11 to 14 years, with details of the experience of menarche from the age of 11 years obtained 3 (12.0 %) samples, obtained 17 to 12 years of age (68.0 %) samples, aged 13 years obtained 4 (16.0 %) samples, and obtained the age of 14 years 1 (4.0%) samples. All samples among 5 groups have regular menstrual cycle period for 28 days, while having a long menstrual 4 days obtained 4 (16.0 %) samples, whereas the 5-day long menstrual obtained 17 (68.0 %) samples, and 6 days obtained 4 (16.0 %) samples. (Table 2). There were no samples with clinical symptoms of hyperandrogenism such as hirsutism signs and sounds like a man, and the entire sample was not obtained extensive skin infections, lumps in the breast, obstetric diseases among 5 groups.

AV sufferers do not experience stress that 21 (84%) and patient samples that mild stress that is 4 (16%) samples. The whole group is not diapatkan AV mild severity, but moderate degrees obtained in the placebo group 3 samples, soy tempeh 100 gr group and 200 gr group each sample obtained 4, 5 samples, 300 gr and 400 gr group each 1 sample. Severity of acne vulgaris in the placebo group obtained 2 samples, 100 gr group and 200 gr group respectively obtained 1 sample, and 400 gr group are as much as 4 samples, whereas 300 gr group found no severe degree.

Table 2 . Marital status, pregnancy, family planning, menarche and long menstruation variable

Variable	group					p
	Placebo n= 5	Soy tempeh 100 gr n=5	Soy tempeh 200 gr n=5	Soy tempeh 300 gr n=5	Soy tempeh 400 gr n=5	
Married						
Yes	0(0)	0(10)	2(40)	2(40)	2(40)	0.261*
No	5(100)	5(100)	3(60)	3(60)	3(60)	
Pregnancy						
Yes	0(0)	0(0)	0(0)	0(0)	0(0)	
No	5(100)	5(100)	5(100)	5(100)	5(100)	
Family planning						
Yes	0(0)	0(0)	0(0)	0(0)	0(0)	
No	5(100)	5(100)	5(100)	5(100)	5(100)	
Menarche						
<12 year	1(20)	1(20)	1(20)	0(0)	0(0)	0.790*
>= 12 year	4(80)	4(80)	4(80)	5(100)	5(100)	
Long menstrual						0.439*
4 days	2(40)	0(0)	1(20)	0(0)	1(20)	
5 days	3(60)	3(60)	3(60)	5(100)	3(60)	
6 days	0(0)	2(40)	1(20)	0(0)	1(20)	

Description: * Chi square

Table 3. The mean difference of total AV lesions before and after treatment

Total AV Lesions	Placebo	Soy tempeh 100 gr	Soy tempeh 200 gr	Soy tempeh 300 gr	Soy tempeh 400 gr	p
Before treatment	112.4 ± 64.47	65.4 ± 58,70	94.6 ± 24.07	88.0 ± 19,65	140.0 ± 70,2	0.259 ^a
After treatment	109.8 ± 59.92	64.4 ± 60,24	93.2 ± 26.08	82.4 ± 22,20	44.8 ± 32.24	0.001 ^b

Description: ^aOne way anova, ^bKruskal Wallis, p<0.05 = significant

Table 4. The mean difference of total AV lesions in all groups

Group	Mean±SD total lesions before treatment	Mean±SD total lesions after treatment	P
Placebo	112.4 ± 64,47	109.8 ± 59,92	0.480 ¹
Soy tempeh 100 gr	65.4 ± 58,70	64.4 ± 60,24	0.715 ²
Soy tempeh 200 gr	94.6 ± 24,07	93.2 ± 26,08	0.624 ¹
Soy tempeh 300 gr	88.0 ± 19,65	82.4 ± 22,20	0.098 ¹
Soy tempeh 400 gr	140.0 ± 70,92	44.8 ± 32,24	0.007 ^{1*}

Description : ¹ Paired t Test, ² Wilcoxon Signed Ranks Test * p<0.05

Table 5 . Kruskal-Wallis test of differences in delta AV lesions delta between the placebo, soy tempeh 100 gr, 200 gr, 300 gr, and 400 gr group

Groups	Mean±SD delta AV lesions	P
Placebo	-2.6 ± 7.470	0.013*
Soy tempeh 100 gr	-1.0 ± 6.325	
Soy tempeh 200 gr	-1.4 ± 5.899	
Soy tempeh 300 gr	-5.6 ± 5.814	
Soy tempeh 400 gr	-95.2 ± 42.287	

Description: *Kruskal Wallis, p<0,05 or significantly different

Table 6. Mann Whitney test of difference between the delta lesions AV placebo, soy tempeh 100 gr, 200 gr, 300 gr, and 400 gr group

Variable	Soy tempeh 100 gr	Soy tempeh 200 gr	Soy tempeh 300 gr	Soy tempeh 400 gr
Placebo	0.753	0.917	0.402	0.009*
Soy tempeh 100 gr	-	0.465	0.295	0.009*
Soy tempeh 200 gr		-	0.251	0.009*
Soy tempeh 300 gr			-	0.009*

Description: * Value of different test unpaired Mann Whitney to delta AV lesion soy tempeh 400 gr group (p : 0.009) or significant (p< 0.05)

The mean total AV lesions before treatment showed different test unpaired One way ANOVA was not significant (p>0.05), whereas the mean total lesion after treatment results of different test unpaired Kruskal-Wallis found significant differences

(p< 0.05). (Table 3) Acne vulgaris mean difference in total lesion before and after treatment in the group with 400 gr soy tempeh with Paired t-test found a significant difference (p <0.05), whereas the placebo group, soy tempeh 200 gr, and soy tempeh 300 gr results Paired t-test did not differ significantly

($p > 0.05$) and soy tempeh 100 gr with Wilcoxon Signed Ranks test, did not differ significantly ($p > 0.05$). (Table 4) Results of Kruskal-Wallis test of difference between the delta lesions AV values obtained 5 groups ($p: 0.013$) or a significant difference ($p < 0.05$) (Table 5) and differences between groups Mann Whitney test result mean delta value soy tempeh 400 gr group ($p: 0.009$) or significantly different ($p < 0.05$) to placebo, soy tempeh 100 gr group, 200 gr group, and 300 gr group, whereas among other groups was not significant ($p > 0.05$). (Table 6)

DISCUSSION

This study using varying doses of soy tempeh, with the aim to see a dose response and determine the most effective dose of soy tempeh that affect the amount of total AV lesions, the dose used in the study were placebo (0 gr/day), 100 gr/day, 200 gr/day, 300 gr/day and 400 gr/day for 4 weeks, it is adapted to regenerate skin will range from 28 days early clinically visible changes of the lesion AV (Gopal and Farahan, 2001). The mean difference in total AV lesions before the second treatment groups was not significant ($p > 0.05$), whereas after treatment was significantly different ($p < 0.05$). Differences decrease in the mean total lesion before and after treatment in the placebo group, soy tempeh 100 gr, 200 gr, 300 gr did not differ significantly ($p > 0.05$), while the soy tempeh 400 gr group found significant differences ($p < 0.05$). Differences delta AV lesions after 4 weeks of the study was significantly different between groups ($p < 0.05$), and soy tempeh 400 gr effect of reducing the total AV lesions were significantly ($p < 0.05$), compared to placebo, 100 gr, 200 gr, 300 gr, so the hypothesis is proved to be minor.

Study the effect of soy tempeh on AV lesions has not previously been done, but some studies have shown that soy isoflavones affect androgen (Dillingham *et al.*, 2010), and the role of androgen hormones the AV especially in women, there is a correlation between the number of lesions AV DHT in women^{4,6}, whereas studies as anti-inflammatory effects of isoflavones can be found in several studies that prove that isoflavones may reduce cytokine pro-inflammatory (Thorpe *et al.*, 2003)¹⁹ Effect of soy tempeh on AV lesions, due to decreased levels of DHT which will improve the condition of the duct pilosebaceous, decrease the secretion of sebaceous glands, fixing duct keratinization infundulum pilosebaceous, cohesion and prevent the formation of corneocytes mikrokomedo, resulting in a drop closed comedones or blackheads open, and will lead to a decrease in AV lesion counts (Thiboutot and Chen, 2003; Cappel *et al.*, 2005). Effect of soy tempeh in inhibiting inflammation in AV, causing a reduction in papules, pustules, and nodules, it will also reduce the total number of lesions.

Role of soy tempeh in the androgen metabolism is inhibit 3β -hydroxysteroid dehydrogenase enzyme (3β -HSD), 17β -hydroxysteroid dehydrogenase (17β -HSD) and 5α -reductase¹⁴. Several studies have shown that soy isoflavones affect androgen¹⁰ The role of androgens against AV, especially in women, compared to men (Thiboutot and Chen, 2003). Levels of DHT There is a correlation with the number of lesions in women with AV (Cappel *et al.*, 2005). Isoflavones also have anti-inflammatory, several studies in postmenopausal women demonstrate the effect of isoflavones on the decline in pro-inflammatory cytokines. Soy tempeh 400 mg contains to 160

mg of isoflavones, other studies using soy isoflavones to lower the AV lesion has never been done, however, some studies have shown the benefits of isoflavones dose of 160 mg for 12 weeks in postmenopausal women, a decrease in the expression of inflammatory mediators (Thorpe *et al.*, 2003). The hormone DHT is the result of metabolism of testosterone through the activity of the enzyme 5α -reductase type 1. Dihydrotestosterone affects sebosit cells and keratinocytes in the infundulum pilosebaceous duct, causing a cellular differentiation, proliferation, lipogenesis, and komedogenesis (Basaria, 2009). Effect of isoflavones on androgen hormones by inhibiting enzymes involved in androgen metabolism. Many diagnostic studies in experimental animals and in humans showed an effect of isoflavones on hormone androgen⁷.

Conclusion

Soy tempeh supplementation 400 gr/day for 4 weeks in women with AV would lead to a significant reduction in the number of lesions AV.

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