

Evaluation of effects of *Spilanthes acmella* extract on muscle mass and sexual potency in males: A population-based study

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ABSTRACT

Introduction: Spilanthal, an active metabolite of the herb *Spilanthes acmella*, has many biological and pharmacological effects with limited studies on humans. **Objectives:** To determine the extent of increase/decrease in muscle mass and sexual frequency over a period of 3 weeks and 2 months in participants consuming SA3X capsules (containing 500 mg of *Spilanthes acmella* extract, standardized to 3.5% spilanthal delivering 17.5 mg spilanthal). **Materials and Methods:** The study is longitudinal in nature and is conducted among 240 male participants consuming SA3X capsules at three points – first at recruitment, second at the end of 3 weeks, and lastly at the end of 2 months in Hyderabad and Secunderabad who were assessed for muscle gain by measuring mid upper-arm circumference (MUAC), chest circumference (CC), thigh circumference (TC), and for sexual activity by a change in frequency of sexual activity and duration of penile erection. The nutrient intake was assessed by 24-h dietary recall method at each visit along with the daily activity. **Results:** A significant increase in the MUAC, ($P = 0.050$), frequency of sexual intercourse ($P = 0.028$), and duration of penile erection ($P = 0.032$) were observed at the end of 3 weeks; however, no changes were observed in CC and TC. At the end of 2 months, a significant increase in the parameters MUAC ($P = 0.031$), frequency of sexual intercourse ($P < 0.001$), duration of penile erection ($P = 0.029$) along with significant increase in CC; ($P = 0.048$) and TC; ($P = 0.036$) was observed. **Conclusion:** The study reflects the herb *Spilanthes acmella* to be a potent muscle gainer and aphrodisiac. However, further studies on humans need to be carried out to establish the temporality of the association of spilanthal with its claimed benefits.

Keywords: Aphrodisiac, muscle, spilanthes acmella, spilanthal, testosterone

Introduction

Spilanthes acmella (Akarkara), an annual herb belonging to the family Compositae, has been used as a folk medicine for

toothache, and is also known to reduce the redness of gums and increase salivation.^[1-3] The major active constituent of the herb is spilanthal (N-isobutyl-2E, 6Z, 8E-decatrienamide),^[4,5] which exerts an array of biological and pharmacological effects including analgesic, neuroprotective, antioxidant, anti-mutagenic, anti-teratogenic, anti-inflammatory, anti-microbial, anti-larvicidal, and insecticidal activities.^[5-11]

Apart from the above mentioned properties, spilanthal has also been shown to have aphrodisiac qualities,^[6] and some

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murine studies have shown that it also improved male sexual performance as indicated by penile erection, mounting frequency, intromission frequency, and ejaculation frequency which had prolonged effects of 2 weeks or more after discontinuing its administration.^[12]

However, studies concerning humans with a representative sample have not yet been carried out. Recent advancements have been made by a few industries exploring the potential of such medicines. Stiriti Ayur Therapies Pvt. Ltd. is known to manufacture SA3X capsules which contains 500 mg of *Spilanthus acmella* extract, standardized to 3.5% spilanthol, thus delivering 17.5 mg spilanthol. A further probe into this matter revealed facts that this product is already being consumed by certain group of people, especially frequent gym-goers for its perceived benefits. Thus, owing to the paucity of the literature and to establish scientific evidence for proving the efficacy of these capsules, the current study was carried out with the objectives to determine the extent of increase/decrease in muscle mass and sexual frequency over a period of 3 weeks and 2 months in participants consuming SA3X capsules.

Materials and Methods

Study population

This longitudinal study was conducted among 240 males consuming SA3X capsules (500 mg of *Spilanthus acmella* extract, standardized to 3.5% spilanthol) in the city of Hyderabad and Secunderabad from October 2020 to February 2021. Inclusion criteria were as follows: apparently healthy and asymptomatic, age 18 years and older. Patients with previous history of HIV/AIDS, immunocompromised conditions, shock, heart failure, ischemic heart disease, hyperthyroidism, chronic renal failure, multiple system atrophy, and an abnormal electrocardiogram were excluded, along with those on medications such as vasodilators, diuretics, antiarrhythmics, beta-blockers, alpha-agonist, or alpha blocker. The study was approved for conduct by the institute research ethics committee, Apollo Hospitals, Jubilee Hills, Hyderabad (AHJ-ACD-045/03-21), and all patients provided a written informed consent.

A line listing of all the stores selling SA3X capsules was made, and the participant information sheet along with consent form was distributed to them. People purchasing the capsules for the first time were asked to participate in the study process. The participants were contacted at three points, first at recruitment, second at the end of 3 weeks, and lastly at the end of 2 months. All the participants were asked to continue intake of SA3X capsules throughout the course of the study along with regular exercise (4–5 days/week) as they have been practicing before the commencement of study.

Assessment of muscle mass

The weight and height were measured to the nearest 0.1 kg and 0.1 cm with light clothing and no shoes using digital

weighing scales and stadiometer, respectively. The BMI was calculated as weight (kg)/height (m)². The mid-upper arm circumference (MUAC) was taken as the marker of muscle growth in the arms. The mid-point was marked in between the olecranon process and the acromion, and the circumference was measured with a tailor's measuring tape at all three visits. The chest circumference (CC) and thigh circumference (TC) were also treated as markers of muscle mass. The CC was measured in normal erect posture at the level of nipples, and the measurement was taken with the chest at rest between maximum inspiration and maximum expiration. In order to measure the TC, the mid-thigh measurement was calculated in both the legs, and the average was taken. The mid-point was first marked in between the inguinal crease and the proximal border of the patella, followed by measuring the circumference.

Assessment of sexual activity

The consumers were asked about the number of times they indulge in sexual activity in a week. They were also asked to report the minutes they are able to retain the penile erection without being flaccid in the first instance of sexual arousal. These were assessed in each of the three visits.

Assessment of daily activity

The participants consuming SAX3 are regular goers (5 days/week) to the gymnasium. The assessment of duration of cardio exercises was done by querying about the time spent on treadmill, jumping rope, burpees, and squat jumps or similar. The duration of strength training/resistance training was calculated by total time spent on exercising specific muscle groups including free-weights, weight machines, or own body weight. Apart from the exercises specific to the gym, their occupation and daily activities were also noted.

Assessment of nutrient intake

A 24-h dietary recall method in each trimester was adopted to obtain information regarding nutrition in all three visits. The Indian Food Composition Tables were used to assess the amount of intake of each food and was analyzed in the Nutrifly India Now application developed by NIN, India.^[13,14]

Statistical analysis

Data were analyzed using SPSS version 21.0 (SPSS, Inc., Chicago, Illinois) and expressed as mean \pm SD after Kolmogorov-Smirnov assessment of normality of distribution. Normally distributed continuous variables were compared using the independent *t*-test. The mean nutritional values were derived by patient-individual averaging. Multiple linear regression analysis was performed to isolate the role of spilanthol intake from anthropometric indicators, exercise duration, and nutrient intake that may also influence muscle gain (factors were retained if *P* value was <0.20). Statistical significance was defined by *P* < 0.05 .

Results

A total of 240 male participants consuming spilanthol were recruited for the study who were of an average age of 34 years. Of them, 22 (9.16%) were lost to follow-up, and the difference in baseline characteristics with those who were followed up has been highlighted in Table 1. However, no significant difference was found between the groups of participants.

Among the participants who were followed up, 15 (6.9%) were underweight with a BMI $<18.5 \text{ kg/m}^2$, 124 (56.8%) had normal BMI ($18.5\text{--}24.9 \text{ kg/m}^2$), 60 (27.52%) were overweight ($25\text{--}29.9 \text{ kg/m}^2$), and the rest (8.71%) were obese (BMI $\geq 30 \text{ kg/m}^2$). All the participants exercised in gymnasiums located in the city 5 days a week with an average of 10.45 min of cardio session followed by 30.65 min of strength exercises. As per the occupation, 66 (30.27%) were involved in occupation demanding strenuous activities like physical education training coaches, athletes, construction workers etc., and about 50 (22.93%) were involved in desk jobs.

Follow-up visits

The first follow-up was done after 3 weeks of consuming SA3X capsules regularly which found a significant increase in the MUAC ($P = 0.050$), the frequency of sexual intercourse ($P = 0.028$), and the duration of penile erection ($P = 0.032$). However, no changes were observed in the CC and TC at the end of 3 weeks course. It was also observed that there was no significant difference in the exercise duration or food intake among the participants as shown in Table 2. Out of the 218 participants, 40 (16.12%) had shown an increase in MUAC $\geq 2.5 \text{ cm}$, 35 (16.05%) and 32 (14.67%) had shown $\geq 2.5 \text{ cm}$ in CC and TC, respectively. Of them, 25 (11.46%) had an increase of 2.5 cm in all the three markers.

The second follow-up was conducted at the end 2 months of consuming SA3X capsules regularly, which found a significant increase in the parameters MUAC ($P = 0.031$), frequency of sexual intercourse ($P < 0.001$), duration of penile erection ($P = 0.029$) along with significant increase in CC ($P = 0.048$) and TC ($P = 0.036$). [Table 2]

Multivariate regression

Association of nutritional intake on MUAC gain, CC gain, and TC gain

As presented in Table 3, it was found that in the participants consuming spilanthol, each gram of protein intake was significantly responsible for about 0.161 mm of MUAC gain ($P < 0.001$), 0.118 mm of CC gain ($P = 0.038$), and 0.126 mm of TC gain ($P = 0.048$), whereas each gram of fat intake was associated with an increase of 0.192 mm in MUAC ($P < 0.001$), 0.134 mm in CC ($P < 0.001$), and 0.168 mm in TC ($P < 0.001$). It was also found that for each kcal intake there was a significant increase of TC by 0.154 mm ($P = 0.024$).

Discussion

In this study, it was found that at the end of 3 weeks of consuming SA3X capsules, there was an increase in muscle mass – MUAC by 0.90 cm. However, the CC and TC remained unchanged statistically. On the contrary, by the end of 2 months, while there was an increase of MUAC by 2.09 cm as compared to the baseline, both CC and TC reverberated the findings showing an increase of 2.28 cm and 1.77 cm, respectively. This increase in muscle mass can be as a result of the effect of spilanthol on participants, as there was neither any significant change in the exercise duration and quality – $10.45 \pm 3.12 \text{ min}$ vs $10.54 \pm 2.98 \text{ min}$; $P = 0.076$ – nor was there any change in total calorie intake – $2387.23 \pm 512.34 \text{ kcal}$ vs $2454.32 \pm 502.13 \text{ kcal}$; $P = 0.423$ – in 2 months. Though protein and fat intake were found to have significant impact on MUAC, CC, and TC as shown in Table 3, however the increase in muscle mass cannot be entirely attributed to these two factors. As mentioned by Sharma V. *et al.*,^[12] spilanthol increases testosterone and also showed effect on luteinizing hormone after 28 days of usage. A transdermal increase in absorption of testosterone was also shown with spilanthol by De Spiegeleer *et al.*^[15] Thus, the observed increase in muscle mass in the participants could be as a consequence of raised testosterone levels due to spilanthol. However, no study on humans exists till date, which has evaluated the direct effects of spilanthol on testosterone.

Table 1: Comparison of baseline characteristics of study participants with respect to those lost to follow-up

Characteristics	Total (n=240)	Participants (n=218)	Lost to follow-up (n=22)	P
Age (years)	34.65 \pm 3.58	35.53 \pm 3.76	33.98 \pm 3.47	0.191
Weight (kg)	60.89 \pm 8.62	60.56 \pm 8.61	61.01 \pm 8.64	0.621
Height (cm)	160.87 \pm 5.75	161.50 \pm 5.95	160.23 \pm 5.56	0.233
BMI (kg/m ²)	23.17 \pm 2.76	23.89 \pm 3.47	22.78 \pm 1.98	0.432
MUAC (cm)	33.08 \pm 3.71	33.65 \pm 3.67	32.87 \pm 3.78	0.761
Chest Circumference (cm)	98.97 \pm 9.16	98.34 \pm 8.67	99.87 \pm 9.21	0.986
Thigh Circumference (cm)	50.95 \pm 4.93	50.34 \pm 5.32	51.32 \pm 4.23	0.677
Frequency of sexual intercourse (times per week)	3.17 \pm 1.58	3.21 \pm 1.76	2.97 \pm 1.23	0.397
Duration of penile erection (minutes)	20.97 \pm 4.76	20.13 \pm 5.19	21.96 \pm 4.32	0.764
Cardio exercise duration/day (minutes)	11.03 \pm 3.01	10.45 \pm 3.12	11.43 \pm 2.97	0.232
Strength training/day (minutes)	29.65 \pm 10.85	30.65 \pm 10.17	28.76 \pm 11.28	0.872

Values are presented as mean \pm standard deviation. *t*-test has been used as the test of significance for the continuous variables to determine significant difference between participants who were followed up and those lost to follow-up. BMI, Body Mass Index; MUAC, Mid-Upper Arm Circumference

Table 2: Distribution of study participants based on follow-up visit after 3 weeks and 2 months of spilanthol intake (n=218)

Characteristics	At recruitment	After 3 weeks	P ^b	After 2 months	P ^c
Weight (kg)	60.56±8.61	61.04±7.86	0.312	61.66±8.03	0.325
MUAC (cm)	33.65±3.67	34.55±3.98	0.050*	35.74±4.01	0.031*
Chest Circumference (cm)	98.34±8.67	99.45±7.98	0.052	100.62±8.02	0.048*
Thigh Circumference (cm)	50.34±5.32	51.21±5.76	0.061	52.11±5.29	0.036*
Frequency of sexual intercourse (times per week)	3.21±1.76	4.97±2.01	0.028*	6.23±1.98	<0.001*
Duration of penile erection (minutes)	20.13±5.19	22.31±4.95	0.032*	25.56±5.01	0.029*
Cardio exercise duration (minutes)	10.45±3.12	10.67±3.41	0.054	10.54±2.98	0.076
Strength training (minutes)	30.65±10.17	31.02±9.98	0.634	30.87±10.21	0.213
Total calorie intake (kcal)	2387.23±512.34	2401.54±494.87	0.239	2454.32±502.13	0.423
Carbohydrate (g)	309.65±75.12	345.63±78.71	0.546	328.59±73.15	0.089
Protein (g)	86.12±15.95	87.92±16.21	0.092	87.43±17.32	0.075
Fat (g)	76.98±25.12	78.21±28.16	0.495	77.53±26.96	0.512

Values are presented as mean±standard deviation. *t*-test has been used as the test of significance for the continuous variables. MUAC, Mid-Upper Arm Circumference. **P*<0.05; ^btest of significance showing difference at recruitment and after 3 weeks of Spilanthal intake; ^ctest of significance showing difference at recruitment and after 2 months of Spilanthal intake

Table 3: Multivariate Regression Analysis between muscle gain parameters and nutritional intake

Outcome variables	Parameters	B	SEM	t [‡]	P*
MUAC gain (mm)	Weight (kg)	-0.312	0.271	-0.182	0.674
	BMI	-0.871	0.113	-2.148	0.391
	Calorie intake (kcal)	0.001	0.013	0.953	0.292
	Protein (g)	0.161	0.027	4.195	<0.001*
	Fat (g)	0.192	0.072	3.371	<0.001*
Chest Circumference gain (mm)	BMI	-0.451	0.377	-1.825	0.267
	Calorie intake (kcal)	0.313	0.264	1.976	0.387
	Protein (g)	0.118	0.063	4.983	0.038*
	Fat (g)	0.134	0.049	5.147	<0.001*
	Calorie intake (kcal)	0.154	0.018	3.218	0.024*
Thigh Circumference gain (mm)	Protein (g)	0.126	0.095	3.871	0.048*
	Fat (g)	0.168	0.052	4.179	<0.001*

All the explanatory variables (age, weight, BMI, and their nutrient intakes) entered the regression model and only those variables with *P*<0.2 were included and the final model was determined. SEM, Standard Error of Mean; BMI, Body Mass Index; **P*<0.05; [‡]Test statistic

In 2011, Sharma V *et al.*^[12] proved the efficacy of spilanthol in improving the male sexual performance in rats. Studies concerning humans are not available in electronic media. The current study, however, reflected on an increase in sexual performance, where the frequency of intercourse increased nearly twice after consuming SAX3 capsules for 2 months. Also, interestingly the participants reported they were having longer duration of penile erection –20.13 min vs 25.56 min; *P* = 0.029. Aphrodisiac properties of spilanthol has also been mentioned by Dubey *et al.*^[6] in their study in 2013. As discussed earlier, the increase sexual potency could also be ascertained to increase in testosterone levels; however, conclusive statements cannot be drawn based on a single study, and further probe is necessary in this regard.

Apart from the effects evaluated in this study, spilanthol also has other therapeutic potentials and health effects. However, most studies have been limited to laboratories and animals with no experimentation on human subjects. Studies evaluating the potency of spilanthol as a muscle gainer and aphrodisiac has also been limited.

A lot of ayurvedic products have been observed to be bought over the counter in primary care settings without any evidence,

which often results in many complications.^[16] The present study throws light upon the validity of consumption of SA3X capsules, though it cannot be accepted as a conclusive study, and further research needs to validate the findings.

Some of the limitations of the study, which needs to be addressed are that the initial recruitment was not done randomly. Secondly, the frequency of sexual activity and duration of penile erection was self-reported which might not be coherent with the actual duration. Also, the nutrient intake was obtained based on 24 h dietary recall method once in each visit which might not have reflected the exact diet followed throughout the study duration. Lastly, the population selected for study are frequent gym-goers and generalizing the findings to whole population needs further evaluation and careful assessment. However, this study is a first-of-its-kind in evaluating the effects of spilanthol on human subjects.

Conclusion

The results deduced in the study reflects *Spilanthes acmella* to be a potent muscle gainer and aphrodisiac. The plant spilanthol also holds a promising position in improving other aspects of

health such as an antioxidant, antimicrobial agent, antinociceptive agent, diuretic, vasorelaxant, anti-human immunodeficiency virus, toothache relief, and anti-inflammatory agent. However, the extent of their impact on human has not been thoroughly tested, even though have been consumed traditionally as folk medicines since years. The current study paves the way for future research to evaluate these aspects by means of randomized clinical trials and cohort studies where the temporality of association of *Spilanthol acmella* with its claimed benefits could be established.

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Conflicts of interest

There are no conflicts of interest.

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