

A CONTROLLED CLINICAL STUDY EVALUATING THE EFFECT OF SHIVAGUTIKA ON SHONITA ABHISHYANDA (HYPERLIPIDAEMIA)

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ABSTRACT

Objectives: To evaluate the effect of *Shivagutika* in reducing the levels of Serum Lipid Profile, on the symptoms of *Sthoulya* & to assess the change in the Quality of life in patients suffering from *Shonita Abhishyanda*/Hyperlipidemia. **Design:** A single blind placebo controlled clinical study with pre and post test design wherein 30 patients diagnosed with *Shonitabhishyanda* (Hyperlipidemia) fulfilling the Diagnostic and Inclusion criteria were selected from OPD/IPD of SDM Ayurveda Hospital, Udupi, Karnataka. **Intervention:** Oral administration of Tab. *Shivagutika* in a dosage of 2 tablet of 2g each thrice a day for a period of 28 days with Lukewarm water along with standard diet course of Hyperlipidemia in one group and another group was administered with placebo drug. Lipid profile, Body weight, Measurements taken at various levels, Anthropometric features were the Primary outcome measures. Clinical presentations of overweight and obesity, SF-36 Health Survey Score were the Secondary outcome measures. **Results:** *Shivagutika* is proved to be effective in reducing the *Shonitabhishyanda* as indicated by reduced levels of lipid profiles that included Total cholesterol, Triglycerides, LDL cholesterol, VLDL cholesterol & HDL cholesterol. All these changes are statistically significant and beyond the effect of Placebo drug in the study. **Conclusions:** Comparison between the groups shows that *Shivagutika* group had significant improvement compared to Placebo. Therefore, we can conclude that *Shivagutika* is proven to have lipid-lowering effect in the management of *Shonita Abhishyanda*, also its further complications.

Keywords: *Shonita Abhishyanda*, Hyperlipidaemia, *Shivagutika*, Placebo

INTRODUCTION

The concept of *Santarpana Achara* & its consequences very well matches with the sedentary life style & its pathological sequels of Biomedicine. *Shonita Abhishyanda* is a common health problem, which leads to a multitude of chronic and life threatening illnesses.^{1,2} It is the need of hour to find out an economic, safe and effective treatment without hospitalization. There is no gold standard method to counteract this disorder. Research is still in infancy but the problem is looming large. *Shonitabhishyanda* is paralleled to Hyperlipidemia in the modern parlance. Ayurveda too identifies this situation and has grouped certain conditions under the broad heading of *Santarpana vyadhi* and *Shonita Abhishyanda* is one among it.^{3,4,5} It can be managed by using the Theory of Opposites (*Vi esa siddhanta*). Since it's a *Santarpana vyadhi*, management includes protocols that cause *Atarpana* and *Apatarpana*. The literature emphasized the treatment plan to accomplish *apatarpana*, *rukshana* & *chedana* with regards to *shodana* & *shamana* measures.⁶ Oral administration with *shilajithu*, *guggulu*, *haritaki* is a matter of appreciation in this regard.⁷ One such formulation having *Shilajitu* as a main ingredient is *Shivagutika*. It is a *shamana aushadhi*, administered orally for a long duration is said to be very effective in combating the multiple system involvement of this disease and thus effective in bringing down the state of *Shonita Abhishyanda*.⁸ The purpose of this review is to discuss current lifestyle and pharmacological approaches in the management of Hyperlipidemia. Hence, in this study, it is planned to evaluate the efficacy of *Shivagutika* on *Shonita Abhishyanda*/Hyperlipidemia. The present study entitled –“A controlled clinical study evaluating the

effect of *Shivagutika* on *Shonita Abhishyanda* with special reference to Hyperlipidemia” was conducted stressing upon literary, diagnostic as well as therapeutic perspective of Hyperlipidemia under the light of both Ayurveda and modern science.

OBJECTIVES

1. To evaluate the effect of *Shivagutika* in reducing the levels of serum lipid profile in patients suffering from *Shonita Abhishyanda*/Hyperlipidemia.
2. To evaluate the effect of *Shivagutika* on symptoms of *shoulya* in patients suffering from *Shonita Abhishyanda* / Hyperlipidemia.
3. To assess the change in the Quality of life following medications with *shivagutika*.

MATERIALS AND METHODS

STUDY DESIGN

It is a Randomized controlled clinical trial with pre and post-test design.

SOURCE OF DATA

In this study, 30 patients diagnosed as *shonitabhishyanda* / hyperlipidemia irrespective of gender and caste fulfilling the diagnostic/inclusion and exclusion criteria were selected from OPD and IPD of SDM Ayurveda hospital, Udupi. The drugs *shivagutika* and placebo was manufactured at SDM Ayurveda pharmacy, Udupi.

METHOD OF COLLECTION OF DATA

A special Proforma was prepared incorporating all points of history, symptoms, physical signs and laboratory investigations related to *Sthoulya*/ *Shonitabhishyanda* and Hyperlipidemia. 30 patients with *Shonitabhishyanda* / Hyperlipidemia were recruited as per the di-

agnostic, inclusion and exclusion criteria as mentioned in Ayurveda classics.

Selected patients were randomly placed under 2 groups of 15 each using permuted block randomization method. Results obtained were statistically analyzed by Paired t test, Unpaired t test and MannWhitney Rank Sum Test.

DIAGNOSTIC CRITERIA

- The patients having BMI > 25
- Any 2 of the following 4 criteria will be considered:
 - Total cholesterol > 200mg/dl,
 - Triglycerides > 150mg/dl,
 - LDL cholesterol > 100mg/dl,
 - HDL cholesterol < 40mg/dl.

INCLUSION CRITERIA:

- Patient diagnosed to have *Shonitabhislyanda*/Hyperlipidemia belonging to either sex irrespective of socio economic status and caste.
- Age group: 16 – 70years.

EXCLUSION CRITERIA:

- Hyperlipidemia due to endocrine pathologies, renal pathologies
- Patients having other systemic illnesses including IHD, DM, CVA, ILD
- Patient having cardiac problem, malignancy
- Hyperlipidemia due to drugs e.g. Glucocorticoids etc.
- Alcoholics and Drug abusers
- BMI < 25

ASSESSMENT CRITERIA:

a) Primary outcome measures:

- Lipid profile

- Body weight

- Anthropometric features

1) Girth circumference measurements in the areas of

a. Chest - In normal condition at the nipple region

b. Abdomen - At the level of umbilicus.

c. Hip - At the level of highest point of distention of buttock.

d. Mid arm - Mid of arm between shoulder and elbow joint.

e. Mid thigh - Mid of thigh between Hip and knee joint

f. Mid calf - Mid of the calf between knee and ankle joint.

2) Measuring skin fold thickness by using slide calipers

a) Skin fold of the middle portion of the Biceps muscle.

b) Skin fold of the middle portion of the Triceps muscle.

c) Skin fold of the middle portion of the Subscapular region.

d) Skin fold of the middle portion of the Abdomen

e) Skin fold of the middle portion of the thigh region.

b) Secondary outcome measures:

- SF-36 Health Survey Score

- *Lakshanas* of *Sthoulya* will be assessed after scoring.

INTERVENTION:

Group A (*Shivagutika*)

Patients of this group will be given *Shivagutika* as under:

Dose: 12gm/day (2tablet of 2gm each thrice a day)

Dosage form: Tablet of 2gm

Route of administration: Oral

Time of administration: Thrice a day before food

Anupana: Luke warm water

Duration: 28 days

Standard diet course of Hyperlipidemia will be followed

Group B (Placebo)

Patients of this group will be given Placebo as under:

Dose: 12gm/day (2tablet of 2gm each thrice a day)

Dosage form: Tablet of 2gm

Route of administration: Oral

Time of administration: Thrice a day before food

Anupana: Luke warm water

Duration: 28 days

Standard diet course of Hyperlipidemia will be followed.

Duration of the study:

28 days of intervention and 28 days of follow up period

Assessment - once in 14 days i.e. on 14th, 28th day.

Follow up:

28 days after treatment with weekly interval.

INVESTIGATIONS:

Haematological investigations:

- Haemoglobin %, TC, DC, Erythrocyte Sedimentation Rate, Random blood sugar.

Serum Lipid Profile:

- Total Cholesterol
- Serum Triglycerides
- Low Density Lipoprotein(LDL)
- High Density Lipoprotein(HDL)
- Very Low Density Lipoprotein(VLDL)
- Total Cholesterol/ HDL ratio

OBSERVATION & RESULTS:

In group-A maximum number of patients (93.3 %) were consuming mixed diet and in group B maximum numbers of patients (80 %) were also consuming a mixed diet. Majority of patients (50 %) were between the weight group of 71 – 80kgs and BMI was between 25.0 -29.9. Analysis of *Prakriti* showed that most of the patients were belonging to *Kaphavata* (56.7%). Analysis of *Satmya* revealed that 83.3% of patients had *Madhyama satmya*. It was seen that 83.3% of the cases had *Madhyama vyayama shakti*, 56.7% of the cases had *Pravara abhyavarana shakti* as well as *Pravara jarana shakti*.

EFFECT OF TREATMENT:

Effect on Lipid profile –

Group A (SG): In the *Shivagutika* Group, a reduction of 62mg/dl in total cholesterol level was recorded from the initial level of 250.933. The mean value of triglyceride before the treatment was 209mg/dl. The same after the treatment reduced to149 mg/dl. Thus, recording a reduction of 59.4 mg/dl. A reduction of 10.2mg/dl in HDL cholesterol level was recorded from the initial level of 46.067. The mean value of LDL cholesterol before the treatment was 177.46 mg/dl. The same after the treatment reduced to104.4 mg/dl. Thus, recording a reduction of 73.067 mg/dl. The mean value of VLDL cholesterol before the treatment was 40.8 mg/dl. The same after the treatment reduced to 33.8 mg/dl. Thus, recording a reduction of 7mg/dl.

Group B (PLB): Contrary to this, in the Placebo group- a marginal increase in all the levels of lipid profile was observed, which was statistically insignificant.

Effect on Weight -

Group A: The mean value of body weight before the treatment was 73 kg. The same after the treatment reduced to 70.83 kg. Thus, recording a reduction of 2.167 kg. This improvement also proved to be statistically highly significant as proved by the paired t test.

Group B: Contrary to this, in the Placebo group- a marginal increase in the body weight was observed which is statistically insignificant.

Effect on Anthropometric measures-

Group A: The mean value of chest circumference before the treatment was 99.5cm which was reduced to 97.7 cm after the treatment. Thus, recording a reduction of 1.8 cm. The mean value of abdomen circumference before the treatment was 99.87 cm which was reduced to 98.1 cm after the treatment. Thus, recording a reduction of 1.77 cm. The mean value of hip circumference before the treatment was 106.8cm which was reduced to 105.06 cm after the treatment. Thus, recording a reduction of 1.8 cm. The mean value of mid-arm circumference before the treatment was 29.13 cm which was reduced to 27.93 cm after the treatment. Thus, recording a reduction of 1.2 cm. The mean value of mid-thigh circumference before the treatment was 52 cm which was reduced to 50.43cm after the treatment. Thus, recording a reduction of 1.56cm. The mean value of mid-calf circumference before the treatment was 35.13 cm which was reduced to 34.1 cm after the treatment. Thus, recording a reduction of 1.03 cm. The mean value of biceps thickness before the treatment was 39.3 cm which was reduced to 37.8 cm after the treatment. Thus, recording a reduction of 1.45 cm. The mean value of triceps thickness before the treatment was 30.133 cm

which was reduced to 28.7 cm after the treatment. Thus, recording a reduction of 1.42 cm. The mean value of abdomen thickness before the treatment was 40.267 cm which was reduced to 38.73 cm after the treatment. Thus, recording a reduction of 1.534 cm. The mean value of sub-scapular thickness before the treatment was 32.2 cm which was reduced to 30.987 cm after the treatment. Thus, recording a reduction of 1.213 cm. The mean value of thigh thickness before the treatment was 33.800 cm which was reduced to 32.67 cm after the treatment. Thus, recording a reduction of 1.12 cm. This improvement also proved to be statistically highly significant as proved by the paired t test.

Group B: Contrary to this, in the Placebo group- the value remained the same before and after the treatment, though it is statistically insignificant.

Effect on Lakshana -

Group A: Mean score observed for the *Udaraa spik stana vridddhi* before the treatment was 1.467. After the treatment, value reduced to 0.667, the effect of treatment showed mild improvement, with statistical significance (P=0.103). Mean score observed for the *Javoparodha* before the treatment was 2.267. After the treatment, value reduced to 1.000, the effect of treatment showed marked improvement, with statistical significance (P<0.001). Mean score observed for the *Atikshudha* before the treatment was 1.200. After the treatment, value reported was 0.667, the effect of treatment showed significant improvement, with statistical significance (P=0.428). Mean score observed for the *Atipipasa* before the treatment was 1.200. After the treatment, value reported was 0.667, the effect of treatment showed marked improvement, with statistical

significance (P=0.428). Mean score observed for the *Kshudraswasa* before the treatment was 1.600. After the treatment, value reported was 0.667, the effect of treatment showed marked improvement, with statistical significance (P=0.018). Mean score observed for the *Nidradhikya* before the treatment was 2.333. After the treatment, value reported was 1.133, the effect of treatment showed significant improvement, with statistical significance (P<0.001). Mean score observed for the *Swedadhikya* before the treatment was 1.533. After the treatment, value reported was 0.667, the effect of treatment showed marked improvement, with statistical significance (P=0.088). Mean score observed for the *Snigdhangata* before the treatment was 1.600. After the treatment, value reported was 0.733, the effect of treatment showed marked improvement, with statistical significance (P=0.012).

Group B: The values remained the same before and after the treatment, with no any statistical significance.

Effect on Quality of Life–

Group A: Mean score observed before the treatment was 40.000. After the treatment, value reported was 75.000, the effect of treatment showed significant improvement, with statistical significance (P<0.001).

Group B: Mean score observed before the treatment was 38.333 and after the treatment it was 40.000, with marginal improvement, d (-1.667) with p=0.735. The comparison of reduction in the mean symptom score clearly indicates that the effect is better in the patients of group A rather than the group B. Further the changes when subjected to statistical tests of significance, it revealed better response in Group A, which rules out the factor of chance.

DISCUSSION

Excessive consumption of sweet and fatty foods above the ability of one's digestion precipitates excessive greasiness of initial *Rasa dhatu* which is termed as *Ama-rasa*. On the other hand, same is referred as *Shonitabhishyanda* with the understanding of collective secretion of fluid *dhatu* in the body that includes *Rasa-raktha dhatu*. Excessive nutrition in combination with minimal activity referred as *Santarpana nidana*, also results in *Shonitabhishyanda*. The pathological meaning of *Shonitabhishyanda* as accumulation of *kapha* and *medas* in the *sira*, translates Hyperlipidemia. Further, *Shonitabhishyanda* is regarded as initial pathology, capable of progressing with plethora of diseases. Excessive accumulation of *kapha* and *medas* tend to infiltrate the blood vessel causing its abnormal thickening, tortuosity, reduced distensibility and finally generation of mass. This sequential event finally terminates in the unique pathology of *Margavarana*, which itself is the cause of several diseases like *Shiro-marmabhighata*, *Unmada*, *Hritshoola*, *Gulma*, *Atisara*, *Mutraukasada*, and *Vatarakta*. More to add, these events of *Margavarana* at different locations causing plural illness is characterized by the spontaneous occurrence and most of them are fatal. Needless to say, correction of *Shonitabhishyanda* can prevent all the events of *Dhamani pratichaya* as well as *Margavarana*. Hence, rectification of excessive *kapha* and *medas* in the blood is emphasized in the literature. Antagonising the properties of pathological body elements is the basic principle of *Dosha-dhatu virudha chikitsa*. Centered on the same principle, the regimens that are effective as *Chedana*, *Lekhana*, *Rukshana* are prescribed as effective treatment of *Shonitabhi-*

shyanda. *Sroto- Shodana*, is the basic therapeutic effect that is demanded in patients with *Shonitabhishyanda*. Considering all these requirements of therapeutic effects, formulation of *Shilajithu* was planned in the study accounting for the action of *deepana*, *pachana*, *vatanulomana* and *lekhana* effects adding to the *medohara* properties. *Shivagutika* is a unique and popular formulation selected for the present study wherein *Shilajatu* is the major ingredient along with 52 other herbs. The analysis of *Dravya guna* of these drugs indicates that, it is effective in diseases caused due to *Santarpana nidana* in general and *Shonitabhishyanda* in particular. *Agni* plays a pivotal role either in the proper digestion or generation of *Ama*. *Agnivaishamya* is best treated by *Deepana*, *Pachana* drugs of *Shivagutika* and the formulation contains *pippali*, *marchia*, *nagara*, *gajapippali* etc. which helps in the proper digestion, assimilation of the ingested food thereby exhibits the progressive biotransformation of body aliments from *Rasa to Sukra dhatu*. Symptoms related to *Pranavaha srotas* are common in *Shonitabhishyandha* co-existing with *Sthoulya*, which includes *Kshudra swasa*, *krathana* and so on. *Shivagutika* is a unique combination having drugs like *talisapatra*, *pushkaramoola*, *pippali*, *kantakari*, *bruhathi* etc which counteract the symptoms. Also, the reduction of *Kshudra swasa* from 1.600 to 0.533 by the drug *Shivagutika* further confirms this effect. *Shivagutika* is efficacious as *Lekhana*, *Chedana*, *Rukshana* effects, more than anything it is claimed as *Medohara*. In the present study, the marked reduction in the lipid profiles that include Total cholesterol, LDL cholesterol, VLDL cholesterol and Triglyceride prove the efficacy of *Shivagutika* in reducing the *Shonitabhishyanda*. This effect is

beyond doubt as the efficacy is significantly different from the placebo effect. The paired t test that analysed the results proved the change observed by the effect of medicine and not by chance. Extending the same principle for the therapeutic benefit, this particular reduction in *Shonitabhishyanda* can be effectively planned in all these sequels of the *Shonitabhishyanda*. The study included the effect of *Shivagutika* in *Sthoulya*, this portrays the effect of *Shivagutika* in diseases stemming out from the basic pathology of *Amarasa*. Statistically significant reduction much beyond the effect of placebo in relation to symptoms of *Sthoulya* like *Javoparodha*, *Dourbalya*, *Snigdhagata*, & other features prove the same. Also, the reduction in the anthropometric measures corroborates the definite therapeutic benefit of *Shivagutika* in *Sthoulya*. Put together, *Shivagutika* is effective in correcting the basic pathology of *Shonitabhishyanda* as well as its sequel *Sthoulya*. The rectification of *Shonitabhishyanda* is near normal in 28 days in all the patients, also the dosage is well-tolerated with no any adverse effects. The test also admits continuous usage of *Shilajithu* for longer duration. From this, it can be said that *Shivagutika* is safe & effective medication for the effective control of *Shonitabhishyanda* and related disorders for a prolonged period until the desirable effect is obtained.

CONCLUSION

Shivagutika is proved to be effective in reducing the *Shonitabhishyanda* as indicated by reduced levels of lipid profiles that included Total cholesterol, Triglycerides, LDL cholesterol, VLDL cholesterol & HDL cholesterol. All these changes are statistically significant and beyond the effect of Placebo drug in the study.

Shivagutika is also effective in reducing the symptoms of *Sthoulya/Overweight & Obesity*. The reduction in the anthropometric values like skin fold thickness & circumference of various parts of the body, that are also statistically significant prove the same. The subjective symptoms of *Overweight & Obesity*, also exhibited remissions following oral medication with *Shivagutika*. Also, significant improvement was recorded in the Quality of Life.

Justifying the role of Placebo & Duration of the study:

Shonitabhishyanda is a phenomenon that can show marked variations in regards to change in the food habits & activity including seasonal influence. Since the lipid profile can show a variation in this regard without any intervention. A placebo control is ideal for comparison so as to assess the actual efficacy of medication on the levels of different forms of Serum Lipids.

To assess the change in the Lipid profile, there should be a minimum duration of about a month. Further, to see the efficacy of the Test drug on the lipid profile & other parameters, this can be achieved by a minimum duration of 28 days. Also, our Classics like *Bhavaprakasha* suggest that a Treatment principle can be applied for a minimum duration of 7 days, then to assess the effect of the Treatment, further to change or continue the treatment. Holding on to these two principles, a minimum duration of 28 days has been kept.

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Tables and illustrations-

Table A: DEMOGRAPHIC PROFILE

Data	Group	Total Patients	% of Patients
Age	16-20	0	0
	21-30	7	23.3
	31-40	3	10
	41-50	5	16.7
	51-60	6	20
	61-70 yrs	09	30.0
Sex	Male	13	43.3
	Female	17	56.7
Religion	Hindu	21	70.0
	Christian	06	20
	Muslim	03	10
Marital status	Married	23	76.7
	Unmarried	07	23.3
Profession	Employee	03	10
	House wife	09	30
	Business	13	43.3
	Student	05	16.7
Socio-economic status	Lower-mid class	02	6.7
	Middle-Class	16	53.3
	Upper-class	12	40
Domicile	Urban	21	70.0
	Rural	09	30
Diet	Mixed	26	86.7
	Veg	04	13.3
Day sleep	Present	26	86.7
	Absent	04	13.3
Family History	Present	20	66.7
	Absent	10	33.3
Initial Body Wt	51-60kg	0	0
	61-70kg	12	40
	71-80kg	15	50
	81-90kg	01	3.3
	91kg+	02	6.7
BMI	25-29.9	26	86.7
	30.0-34.9	03	10
	35.0-39.9	01	3.3

Table B: EFFECT OF TREATMENT

Effect of treatment on lipid profile										
Cholesterol	Group	Data	Values				Within group*		Comparison**	
			Mean	± SD	± SE	Difference	T	P	T	P value
	SG	BT	250.933	50.777	13.111	62.000	6.847	<0.001	-4.497	<0.001
		AT	188.933	21.059	5.437					
	PLB	BT	240.467	41.295	10.662	-2.467	-2.828	0.013		
		AT	242.933	41.462	10.705					
Triglyceride	SG	BT	209.000	61.070	15.768	59.4	5.197	<0.001	-2.348	0.026
		AT	149.600	37.572	9.701					
	PLB	BT	185.467	48.320	12.476	-1.067	-2.359	0.033		
		AT	186.533	47.942	12.379					
HDL Cholesterol	SG	BT	46.067	9.460	2.443	10.200	5.484	<0.001	-5.161	<0.001
		AT	35.867	3.739	0.965					
	PLB	BT	47.133	7.708	1.990	-0.133	-0.0474	0.963		
		AT	47.267	7.695	1.987					
LDL Cholesterol	SG	BT	177.467	49.474	12.774	73.067	7.239	<0.001	-4.247	<0.001
		AT	104.400	17.912	4.625					
	PLB	BT	159.000	46.591	12.030	-0.333	-0.403	0.693		
		AT	159.333	46.780	12.079					
VLDL Cholesterol	SG	BT	40.800	10.571	2.729	7	3.949	=0.001	-3.586	= 0.003
		AT	33.800	6.327	1.634					
	PLB	BT	39.600	8.870	2.290	-1.400	-2.168	= 0.048		
		AT	41.000	8.856	2.287					
Effect of treatment on symptoms of Sthoulya										
Udara sphikstana vridhhi	SG	BT	1.467	1.302	0.336	0.8	270.500	0.103	242.000	0.681
		AT	0.667	0.617	0.159					
	PLB	BT	0.733	1.100	0.284	-	232.500	0.980		
		AT	0.733	1.100	0.284					
Javoparodha	SG	BT	2.267	1.033	0.267	1.267	312.000	<0.001	194.000	0.101
		AT	1.000	0.535	0.138					
	PLB	BT	1.733	1.335	0.345	-	232.500	0.982		
		AT	1.733	1.335	0.345					
Atikshudha	SG	BT	1.200	1.424	0.368	0.533	250.500	0.428	189.000	0.057
		AT	0.667	0.816	0.211					
	PLB	BT	1.667	1.447	0.374	-	232.500	0.982		
		AT	1.667	1.447	0.374					
Atipipasa	SG	BT	1.200	1.424	0.368	0.533	250.500	0.428	189.000	0.057
		AT	0.667	0.816	0.211					
	PLB	BT	1.667	1.447	0.374	-	232.500	0.982		
		AT	1.667	1.447	0.374					
Kshudraswasa	SG	BT	1.600	1.242	0.321	1.067	287.000	0.018	229.000	0.889
		AT	0.533	0.640	0.165					
	PLB	BT	0.667	0.900	0.232	-	232.500	0.981		

		AT	0.667	0.900	0.232					
Nidradhikyata	SG	BT	2.333	0.816	0.211	1.2	317.000	<0.001	154.000	<0.001
		AT	1.133	0.640	0.165					
	PLB	BT	2.400	1.056	0.273	-	232.500	0.980		
		AT	2.400	1.056	0.273					
Swedadhikyata	SG	BT	1.533	1.356	0.350	0.866	272.000	0.088	193.000	0.088
		AT	0.667	0.724	0.187					
	PLB	BT	1.533	1.356	0.350	-	232.500	0.982		
		AT	1.533	1.356	0.350					
Snigdhangha	SG	BT	1.600	1.056	0.273	0.867	290.500	0.012	270.500	0.080
		AT	0.733	0.594	0.153					
	PLB	BT	0.533	1.125	0.291	-	232.500	0.976		
		AT	0.533	1.125	0.291					
Effect of treatment on Quality of life										
QOL	SG	BT	40.000	12.677	3.273	-35	129.000	<0.001	336.000	<0.001
		AT	75.000	13.363	3.450					
	PLB	BT	38.333	12.910	3.333	-1.667	225.000	0.735		
		AT	40.000	12.677	3.273					

Source of Support: Nil

Conflict Of Interest: None Declared

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