

Evaluation of the Efficacy of *Sapta Winsati Guggulu* in the Management of *Shushkarsha*: A Comparative Clinical Study

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ABSTRACT

Introduction: Hemorrhoids, also called piles, co-related with *Arsha* in Ayurveda, are swollen veins in the anus and the lower rectum, similar to varicose veins. Hemorrhoids can develop inside the rectum known as internal hemorrhoids or under the skin around the anus known as external hemorrhoids. Worldwide, the prevalence of symptomatic hemorrhoids is estimated at 4.4% in the general population.

Objectives: This is a clinical study was conducted to evaluate the efficacy of the *Sapta Winshati Guggulu* in the management of *Shushkarsha*.

Methodology: 40 patients diagnosed with *Shushkarsha* were randomly selected to this study and they were randomly divided into two groups and was named as the Group-A (Tested group) and the Group-B (Control group). All the patients (both A and B groups) were treated by *Abhayarishta*, *Chirabilwa Kwatha* and *Sukumara Churna*. Only Group-A (testing group) was additionally treated with *Sapta Winshati Guggulu*. Data collection: Subjective parameters such as pain and Objective parameters such as circumference of the pile and distance of the prolapse were collected.

Data analysis: All the subjective and objective parameters were entered by using reputed methods and were analyzed by using graphs and figures and SPSS Statistical Software.

Results: p-value and t-value of Group-A and Group-B were statistically significant. But, Significant level of Group-A was higher than Group-B.

Conclusion: According to the findings, finally it can be concluded that the *Sapta Winshati Guggulu* has remarkable effect in the management of the *Shushkarsha*.

Key Words: Hemorrhoids, Piles, *Shushkarsha*, *Chirabilwa Kwatha*, *Sapta Winshati Guggulu*

INTRODUCTION

Scope of the Work: Hemorrhoids are classified into two types, depending on their level in relation to anus. Those are internal hemorrhoids and external hemorrhoids. Internal hemorrhoids are further divided into four degrees depending on their symptoms produced. **Grade I:** The hemorrhoids do not prolapse, only bleeding from the rectum can be seen. **Grade II:** The

hemorrhoids prolapse upon defecation, but spontaneously reduce and bleeding may be occur. **Grade III:** The hemorrhoids prolapse upon defecation, but reduce after manipulation. **Grade IV:** The hemorrhoids are prolapsed and remain prolapsed. ^{(1) (2) (3) (4)}

Ayurvedic scholars co-relate *Arsha* with Hemorrhoids and *Raktarsha* and *Shushkarsha* are the main

two types of them. (5) (6) (7) (8) Arsha are considered to be stubborn, whereas Ayurveda provides the best alternative management as it acts on the root cause of the disease. (9) (10) (11) Since there is no surgical intervention, hence there are no chances of complications such as infections and bleedings. Also these treatment modalities are cost-effective and affordable treatment for people of developing countries.

Worldwide, the prevalence of symptomatic hemorrhoids is estimated at 4.4% in the general population. Among people older than 45 years, 25% of people who develop hemorrhoids are female and 15% are men. Research has also shown there is a greater likelihood of men seeking treatment for their hemorrhoids than there is for women. (12)

Hence, in the present study, the efficacy of the Sapta Winshati Guggulu on Shushkarsha was studied clinically and results were presented statistically.

Aim and Objective: The aim of this study was to evaluate the efficacy of the Sapta Winshati Guggulu in the management of Shushkarsha.

Significance of the Study: In spite of many medicinal formulae in Ayurveda, there is no proper study has been done to prove their efficacy of most of Ayurvedic drugs. Therefore, some most effective formulae are slowly slipping away from the system. Sapta Winshati Guggulu is a herbo-mineral drug (Pill) which is mentioned in Ayurveda Pharmacopoeia and one of the above mentioned formulae. Hence, this study is highly valuable for Sri Lankan Ayurvedic Medical System.

MATERIAL AND METHODS

Preparation of the Drug: (13) (14) (15)

Table 1: List of ingredients of Sapta Winshati Guggulu

Sanskrit Name	Common Name	Latin Name	Part used
Shunti	Ginger (dry)	<i>Zingiber officinale</i>	Rhizomes
Maricha	Black Pepper	<i>Piper nigrum</i>	Seeds (Fruits)
Pippali	Long Pepper	<i>Piper longum</i>	Seeds (Fruits)
Haritaki	Myrobalan	<i>Terminalia chebula</i>	Fruits
Vibhitaki	Bastard Myrobalan	<i>Terminalia bellirica</i>	Fruits
Amalaki	Indian Gooseberry	<i>Phyllanthus emblica</i>	Fruits
Musta	Nut Grass	<i>Cyperus rotundus</i>	Rhizomes
Vidanga	False Black pepper	<i>Embelia ribes</i>	Seeds
Guduchi	Heart Leaved Moonseed	<i>Tinospora cordifolia</i>	Stems
Chitraka	Ceylon Leadwort	<i>Plumbago zeylanica</i>	Roots
Shati	Java Galangal	<i>Kaempferia galanga</i>	Rhizomes
Ela	True Cardamom	<i>Elettaria cardamomum</i>	Seeds (Fruits)
Pippali	Long Pepper	<i>Piper longum</i>	Roots
Hapusha	Common Juniper	<i>Juniperus communis</i>	Seeds
Devadaru	Deodar cedar	<i>Cedrus deodara</i>	Stems (Heartwood)
Dhanyaka	Coriander	<i>Coriandrum sativum</i>	Seeds (Fruits)
Kushta	Costus root	<i>Saussurea lappa</i>	Roots
Chavika	Large Betel Pepper	<i>Piper chuyva</i>	Roots
Indravaruni	Bitter Apple	<i>Citrullus colocynthis</i>	Fruits
Nisha	Turmeric	<i>Curcuma longa</i>	Rhizomes
Darvi	Yellow vine	<i>Coscinium fenestratum</i>	Stems
Gajapippali	Gajapippaly	<i>Scindapsus officinalis</i>	Seeds (Fruits)
Ajamoda	Wild Celery / Ajowan	<i>Trachyspermum involucreatum</i>	Seeds
Vid Lavana	-	<i>Ammonium chloride</i>	-
Sauwarchala	Black Salt	Combination of Sodium*	-
Yawkshara	-	<i>Potassium carbonate</i>	-
Swarajakshara	Washing Soda	<i>Sodium bicarbonate</i>	-
Sahindawa	Rock Salt	<i>Sodium chloride</i>	-
Gugul	Indian bdellium-tree	<i>Commiphora wightii</i>	Gum resin

* Black salts are made synthetically from a combination of sodium chloride, sodium sulfate, sodium bisulfate, and ferric sulfate. The salt is then mixed with charcoal and heated before the final product is ready.

** Triphala contains equal amounts of Haritaki, Vibhitaki and Amalaki. Triphala kwatha made from one part of herbs in sixteen parts of water, which is reduced to 1/4th part of liquid after cooking on a low flame.

All the ingredients and accessory ingredients were collected, cleaned and purified and then measured by using a measuring scale (equal amount of all the ingredients). Gugul was purified by using Triphala Kwatha**. Other ingredients were powdered, mixed with purified Gugul and were grinded by using a grinding stone. Finally, it was prepared 2g pills, dried well and stored in a well cleaned-dried glass bottle.

Sample Selection: Forty (40) patients aged between 20 to 60 years, diagnosed as suffering from Shushkarsha were recruited for this study. All the Raktarsha patients were excluded from the study. The patients who are on any other internal or external medications for the last 7 days were also excluded from the study. After collecting details of the patients' history, the selected patients were thoroughly examined. The patients who gave written consent were included in the study. Severity of signs and symptoms were recorded before, during and after completion of treatment and also at the end of follow up period. Then after, patients were randomly divided into two groups such as Group-A (Tested group) and the Group-B (Control group).

Method and Duration of Drug Administration: All the patients (both A and B) were treated from 30ml of Chirabilwa Kwatha and 15ml of Abhayarishta after meals and twice a day. Only Group-A (testing group) was additionally treated with Sapta Winshati Guggulu (02 pills) after meals and twice a day. This treatment schedule was continued for the period of 28 days.

RESULTS

Table 2: Stages of improvement (Grading system)

Stage	Circumference of pile (%)	Distance of prolapse (%)	Score of pain
Excellent (E)	80-100	80-100	0
Good (G)	60-79	60-79	0
Fair (F)	40-59	40-59	1
Poor (P)	Below than 39	Below than 39	2 & 3

This table denotes that the Grading System for the stages of improvement of the signs and symptoms of Arsha for both A and B groups.

Dietary Regimen: The patients were advised to follow dietary restrictions according to the etiology of Shushkarsha.^{(16) (17) (18) (19)} Apart from this, all the patients were restrained from taking other medications (internal and external), strong and spicy foods, coffee, tea, increased quantity of milk and milk products, condiments and other food items supposed to be possessing medicinal value during the study period and directed to take a regular and proper fibrous diet with adequate quantity of drinking water.

Follow-up: Patients were asked to come for clinical assessment once in seven (07) days for a period of one month after treatment procedure.

Data Collection: As a subjective parameter, the pain of the Shushkarsha was measured by using a specially prepared five point grading scale. The Grading scale was as follows:

- 0 = absent = no pain in Arsha
- 1 = minimal = occasionally feels pain in Arsha
- 2 = moderate = intermittently feels pain in Arsha
- 3 = intense = often feels pain in Arsha
- 4 = severe = always feels pain in Arsha

As an objectives parameters, the circumference of the Arsha and Distance of the prolapse were measured by using a thread (converted to millimeters).

Statistical Analysis: Statistical analysis was carried out using the paired samples t-test of IBM SPSS Statistical Software Version 22. Results were tested at 0.05 confidence level.

Table 3: Stages of improvement

Tested Group (Group-A)				Control Group (Group-B)			
Patient Number	Circumference of Pile (%)	Distance of Prolapse (%)	Score of Pain	Patient Number	Circumference of Pile (%)	Distance of Prolapse (%)	Score of Pain
T01	70.0	66.7	0	C01	9.4	12.5	2
T02	43.8	63.6	0	C02	-45.5	64.3	2
T03	75.0	6.7	0	C03	66.7	40	3
T04	62.5	78.6	0	C04	33.3	40	3
T05	92.6	88.9	0	C05	8.3	40	3
T06	52.2	73.3	0	C06	18.03	40	3
T07	44.2	68.8	1	C07	15	14.3	3
T08	100	100	0	C08	16.7	14.3	3
T09	-61.6	28.6	0	C09	-15	0	3
T10	100	100	0	C10	13.3	23.1	2
T11	61.3	60.0	0	C11	2.8	13.3	3
T12	11.1	0	1	C12	7.41	31.3	3
T13	2.8	-42.9	0	C13	25	-63.6	3
T14	43.8	33.3	0	C14	4.8	0	2
T15	35.5	-100	0	C15	41.2	52.4	3
T16	66.7	-140	0	C16	20	50	3
T17	61.5	66.7	0	C17	6.3	20	3
T18	16.7	54.6	0	C18	2.13	70	3
T19	100	100	0	C19	20	55.6	3
T20	100	100	0	C20	20	44.4	3

This table denotes that the overall improvement of both Tested Group (Group-A) and Control Group (Group-B). Further, improvement of the circumference of pile and the distance of prolapse were recorded as percentages and improvement of the pain was recorded as a score mentioned in above table 2.

Table 4: Analysis of p-values

Tested Group (Group-A)				Control Group (Group-B)			
Week	Circumference of Pile	Distance of Prolapse	Pain	Week	Circumference of Pile	Distance of Prolapse	Pain
01	0.202	0.390	0.000	01	0.095	0.040	0.019
02	0.015	0.307	0.000	02	0.067	0.006	0.018
03	0.005	0.009	0.000	03	0.042	0.005	0.005
04	0.000	0.001	0.000	04	0.007	0.041	0.004

This table indicates that the calculated p-values of the symptoms of Arsha of both Group-A and B by week. According to that all the calculated p-values of both A and B groups are below than significant level (p-value < 0.05) after 28 days of treatment.

DISCUSSION

The Sapta Winsati Guggulu has 29 herbo-mineral ingredients. Among these most of ingredients have Shodhana, Lekhana, Arshoghna, Shothahara, Deepana, Shoolaprashamana and Virechana properties.^{(20) (21) (22)} All these properties are beneficial for the management of Arsha. Further, purified Gugul is the main ingredient of the drug and is half of the total weight. Although main action of the Gugul is pacifying the Vata dosha, prepared Guggulu gas Tridosha prashamana action.

In addition to, this drug has Vedanasthapaka (analgesic), Balya (tonic) and etc. qualities.

There was not any previous research for Sapta Winshati Guggulu, but there are so many researches for individual ingredients of this drug. Those researches were proven that these all ingredients are highly significant in the management of Arsha.^{(23) (24) (25)}

CONCLUSION

Statistical data shows that both treatment regimens are clinically significant as a treatment for Shushkarsha. But, after analyzing all the findings in scientifically, it can be concluded that the Sapta Winshati Guggulu has remarkable effect in the management of the Shushkarsha.

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