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A pharmaceutical study of *Bharangiguda Avaleha* prepared by two different processes and its efficacy on *Tamaka Shwasa*

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Abstract
Today man has achieved high peaks in the field of medicine with the development of various techniques. However, *"Ayurveda"* the ancient Indian system of medicine, which has its roots in *Vedas* is still enjoying high profile in serving man-kind.
All the time less theories of *Ayurveda* is availed to the patient only by means of *Bhaishajya Kalpana. Avaleha Kalpana* is the formulation, which is efficacious as well as preferred by the patients and thence, in the present study, two different samples of *Bharangiguda Avaleha* was prepared following two different processes as mentioned in *Chakradatta 12/25-30* and Iatro Chemistry of *Ayurveda* by *Bhagvandas* based on *Ayurveda Saukhya of Todarananda* citing *Acharya Gopura Rakshita* at 1/301, Pg. No. 70

- एक द्वित्रि श्रृतं कृत्वा दापयेद् गुणवृध्धये ।।

In this present clinical study, total numbers of 106 patients of *Tamaka Shwasa Roga* from OPD & IPD of I.P.G.T. & R.A., Jamnagar were registered and divided in three groups randomly. In Group A patients were treated with *Bharangiguda Avaleha-I*, in Group B patients were treated with *Bharangiguda Avaleha-II* and in Group C *Bharangi Churna* was given as control drug. *Bharangiguda Avaleha-I & II*, each were advised 12 g b.i.d with lukewarm water for 30 days & *Bharangi* Churna, given 3 g b.i.d for 30 days. Follow up for all the entire test drugs was 30 days. The effect on the signs and symptoms were assessed before and after treatment noted and also assessed by a specially prepared proforma. It was found that Bharangiguda Avaleha-I treated patients show better result in the disease Tamaka Shwasa.

Keywords: Bharangiguda Avaleha-I & II, Tamaka Shwasa

Introduction
Everything in the nature can be beneficial but everything raw cannot be ingested as it is. This insidiously led to the development of art of modifying the raw materials rendering it fit and many a times improving its beneficial effects besides eliminating the unwanted aspects. Here in the concept of *Bhaishajya Kalpana* was embarked on viz. the concept of modification of natural substances to promote and preserve the health besides alleviating the disease.
Ayurveda can be concised and understood in *"Trisutra"* i.e. *Hetu, Linga* and *Aushadha* from which *Aushadha* means *Bhaishaja* -

भैषजं नाम तद्यदुपकरणायोपकल्पते भिषजो... ।[1]

Among, *"Anekavidha Kalpana"* of *Bhaishaja* (drug) the five basic *Kalpanas* has their own importance. This five basic *Kalpanas* are -

पञ्चविधं कषाय कल्पनमिति तद्यथा स्वरसः कल्कः, श्रृतः, शीतः, फाण्टः कषाय इति ।।[2]

Since these basic *Kalpanas* had several drawbacks such as short shelf life, taste, palatability etc., several *Upakalpanas* came into existence on the basis of "*Panchavidha Kalpana"* for e.g. *Avaleha Kalpana, Sandhana Kalpana, Sneha Kalpana* etc.

Among the above *Kalpanas* study of *"Avaleha Kalpana"* has been selected to evaluate the efficacy of these of *"Bahukalpam"* and to explore the hidden pharmaceutical properties.

Several formulations can be prepared out of a single drug or a physician can alter the formulation to get better results according to his requirements. This is clearly mentioned by Acharya Charaka.

स्वबुध्धयैवं सहस्त्राणी कोटीर्वाडपि प्रकल्पयेत् ।
बहुद्रव्य विकल्पत्वाद्योगसंख्या न वियते ।। [3]

Hence, in the present study, two different samples of *Bharangiguda Avaleha* was prepared following two different processes as mentioned in *Chakradatta 12/25-30* and Iatro Chemistry of *Ayurveda* by Bhagvandas based on *Ayurveda Saukhya of Todarananda* citing *Acharya Gopura Rakshita*

– एक द्वित्रि श्रृतं कृत्वा दापयेद् गुणवृध्धये ।। [4]

Here these two processes are different in sense of preparation of *Kwatha.* In method of *Chakradatta,* Kwatha has been prepared only once and whereas in method of *Todarananda,* Kwatha has been prepared twice with objectives to increase therapeutic efficacy.

Most of drugs of *Bharangiguda Avaleha* compound are also mentioned as *having Shwasaghna properties and are indicated in treating Tamaka Shwasa*.

Tamaka Shwasa Roga of the *Pranavaha Srotas* is very commonest disease, occurring in worldwide population.

Aims and objects

The present study is planned with following aims and objects.

- To compile the relevant literature about *Avaleha Kalpana* (*Bharangiguda Avaleha*) & *Tamaka Shwasa* as per details available in Ayurvedic & contemporary pharmaceutical and medical science respectively.
- To prepare two samples of *Bharangiguda Avaleha* prepared by two different processes as per pharmaceutical principle of Avaleha Kalpana -
- First sample as per the process indicated in Chakradatta[5]
- Second sample as per the process indicated in *Iatro Chemistry of Ayurveda by Bhagvandas* based on *Ayurveda Saukhya of Todaranand* citing *Acharya Gopura Rakshita*[6]
- Interpretation & co-relation of *Avaleha Siddhi Lakshnas* on parameters of Ayurvedic [7] and modern pharmaceutical.
- To compare the efficacy of both differently processed samples of *Bharangiguda Avaleha* in related to their therapeutic use and clinically with special reference to Tamaka Shwasa Roga.

Materials and methods

For the present study, three type of material have been utilized viz. the literary material, clinical material and the laboratory materials.

Conceptual study

Conceptual section is divided into 4 chapters viz. *Avaleha Kalpana,* Drug review and Disease review.

Avaleha Kalpana

This section deals with conceptualize 4 topics – paradigms of *Avaleha Kalpana,* constituent material, pharmaceutical procedure and related modern review.

Paradigm of *Avaleha Kalpana*

This chapter covers up the etymology, derivation, definition and synonyms of the *Avaleha Kalpana. Rasakriya, Phanita, Avaleha, Ghana,* which comes under the category of *Avaleha Kalpana* were considered with similarities and their specification.

Constituent material

Drava Dravya, Madhura Dravya and *Prakshepa Dravya,* the main component drugs of *Avaleha Kalpana* were elaborated under the perspective of proportion and their role to form *Avaleha Kalpana*. Concepts of regarding the time of addition of *Prakshepa* are also discussed.

Pharmaceutical procedure

This subsection is divided into *Purva Karma, Pradhana Karma* and *Paschata Karma* along with *Avaleha Siddhi Lakshanas.* Preparation of aqueous solution (*Kwatha, Swarasa* etc.) and preparation of *Prakshepa Dravya* are to be contemplated in the *Purva Karma* before executing the pharmaceutical operation. The *Pradhana Karma* as a pharmaceutical operation includes method of preparation of *Avaleha Kalpana.* The *Paschata Karma* is contemplated in terms of time for addition of *Sneha Dravya* (if mentioned) and *Prakshepa Dravya.*

It also throws some light on parameters framed under the name of *Avaleha Siddhi Lakshana* by ancient scholars. *Assanapakvavastha Lakshanas* denotes the sugar concentration while final form was assessed through *Pakvavastha Lakshanas*.

The other factors like storage, shelf life, dose, vehicle (*Anupana*) and Time of administration *(Sevana Kala)* are also mentioned.

Modern review

Here definition of confections, conserve or electuary and role of carbohydrate, effect of water and temperature on carbohydrates, role of fatty material and their impact on the qualities of formulation is also dealt with.

Drug Review

Drug review with highlight on Compound and Individual drugs has been described.

Compound Drug Study

The compound drug – *Bharangiguda Avaleha* selected for the present study is sorted out from the classics, checked for any aberration between different readings and is expounded with all possible details here.

Bharangiguda Avaleha

A scan through the *Ayurvedic* classics reveals that seven citations are available for *Bharangiguda Avaleha* viz. *Vrinda Madhava, Chakradatta* [8], *Vangasen* [9] *(Swarabheda Chikitsa), Gadanigraha* [10], *Bhava Prakash* [11], *Yogachintamani* [12] *and Bhaishajya Ratnavali.*[13] There is no difference between the seven versions. The elaboration of the compound drug *Bharangiguda Avaleha* and the exact verse with the faithful meaning is as follows:

शतं संगृह्य भार्ग्यास्तु दशमूल्यास्तथा शतम्।
शतं हरीतकीनाश्च पचेत्तोये चतुर्गुणे ।।
पादावशेषे तस्मिस्तु रसे वस्त्रपरिस्रु ते ।
आलोऽय च तुलां पूतां गुडस्य त्वभया ततः ।।
पुनः पचेन्मृदावग्नौ यावल्लेहत्वमागतम् ।
शीते च मधुनश्चात्र षट्पलानि पृथक पृथक ।।
त्रिकटु त्रिसुगंध च पलिकानि पृथक पृथक ।
कर्षद्वयं यवक्षार सञ्चूर्ण्य प्रक्षिपत्ततः ।
भक्षयेदभयामेकां लेहस्यार्द्धपलं लिहेत् ।
श्वासं सुदारूणं हन्ति कासं पञ्चविधं तथा ।।
स्वरवर्णप्रदो ह्येषं जठराग्नेश्च दीपनः ।
पल्लोल्लेखागते माने न द्वेगुण्यामिहेष्यते ।
हरीतकी शतस्यात्र प्रस्थत्वादाढकं जलम् ।। (Chakra. 12/25-30)

Table 1: Ingredients

Sr. No.	Ingredients	Quantity		
		Acco. to ref.	In %)	In part
1.	*Bharangi*	100 *Pala*	100	1.0
2.	*Dashamula*	100 *Pala*	100	1.0
3.	*Haritaki* (Big size)	100 Nos.	20	0.2
4.	Water	4 times	4 times	4 times
	Reduced to (Vol. of Water)	1/4th	1/4th	1/4th
5.	*Guda* (Jaggery)	1 Tula	100	1.0
***Prakshepa Drayas* -**				
6.	*Madhu*	6 *Pala*	6.0	0.06
7.	*Trikata*	3 *Pala*	3.0	0.03
8.	*Trijata*	3 *Pala*	3.0	0.03
9.	*Yavakshara*	2 Karsha	0.5	0.005

Note: The ingredients of *Bharangiguda Avaleha-II* are same as *Bharangiguda Avaleha-I.*

Individual Drug Study

The ingredient drugs of the chosen formulation is expanded in this section with respect to the botanical source, vernacular names, *Rasa Panchaka*, officinal part, chemical constituents and related established pharmacological actions.

Disease review

The disease *Tamaka Shwasa* is reviewed emphasizing the etymology, derivation, definition, classification of *Shwasa*, types of *Tamaka Shwasa*, etiological factors, etiopathogenesis, signs and symptoms *(Nidana Pachaka)*, prognosis and line of treatment. The following chapter elucidates the modern review of the disease bronchial asthma with respect to its definition, classification, pathogenesis, prognosis and management.

Pharmaceutical study

The details of the practical are recorded and documented in the form of tables. Each practical is elucidated in the form of name of the practical, reference, ingredients and their proportion, unit operation, equipment used, date of starting and completion. The observation found and errors are also recorded.

Bharangiguda Avaleha-I was prepared into 7 batches and *Bharangiguda Avaleha-II* was documented into 8 batches. Duration & temperature are recorded into preparation of *Bharangi + Dashamula Kwatha* and observations are recorded into preparation of *Bharangiguda Avaleha-I & II*. Temperature at the time of addition of *Prakshepa Dravya* and *Madhu* (honey), total duration and total yield obtained from *Bharangiguda Avaleha-I & II* were noted. In *Bharangiguda Avaleha-I & II, Paka* was done were brownish black in colour and *Madhura, Kashaya* in taste.

Preparation of *Bharangiguda Avaleha-I*

Name of Practical : *Bharangiguda Avaleha-I Nirmana*
Reference : *Chakradatt*[14]
Apparatus **:** Steel vessels, ladle, sieve, clean cloth, gas stove, etc.

Table 2: Ingredients

Sr. No.	Ingredients	Quantity	
		Batch- I to IV	Batch- V to VII
1.	*Bharangi Yavakuta*	1 Kg. (1.9 Litre)	4 Kg. (7.6 Litre)
2.	*Dashamula Yavakuta*	1 Kg. (3.6 Litre)	4 Kg. (14.4 Litre)
3.	*Haritaki* (Big size)	200 g. (300 ml)	800 g. (1.2 Litre)
4.	Water	23.2 Litre	92.8 Litre
	Reduced to (Vol. of Water)	5.8 Litre	23.2 Litre
5.	*Guda* (Jaggery)	1 Kg.	4 Kg.
Prakshepa Dravyas -			
6.	*Madhu* (Honey)	60 g.	240 g.
7.	*Trikatu*	30 g.	120 g.
8.	*Trijata*	30 g.	120 g.
9.	*Yavakshara*	05 g.	20 g.

Method of Preparation

The procedure of *Avaleha Kalpana* is followed in the following steps -

1. The fixed quantity of *Kwatha Dravyas - Bharangi Yavakuta* and *Dashamula Yavakuta* are taken in a suitable vessel, specified quantity of water is added and placed for heating and it is reduced to 1/4th.
2. The *Haritaki Phala* is washed thoroughly and dried in shade.

3. *Haritaki Phala* is bundled in a piece of clean cloth, which is immersed in the *Kwatha Drava*.
4. The whole apparatus is subjected for *Mandagni* (mild fire) as per classical directive.
5. When *Kwatha* reaches the stage of completion, it is brought down from fire and filtered through clean cloth.
6. The *Pottali* containing *Haritaki* is taken out, remove the seeds and pulp is made by Mixer.
7. The *Haritaki* pulp and *Guda* (Jaggery) are added to the filtered *Kwatha* in the said quantity and heated in mild fire (*Mandagni*).
8. When the *Paka* reaches the stage of *Siddhi Lakshanas* - the tests for completion are done to confirm the actual *Paka Lakshanas.*
9. The vessel is now removed from fire and allowed to cool and *Prakshepa Dravya* is added with vigorous stirring.
10. When cooled, *Madhu* (Honey) is added with vigorous stirring.
11. Then the *Avaleha* is packed in a container, which is air tight, labeled and packed.

Observations

1. After mixing of Jaggery in *Kwatha*, colour of mixture becomes darker.
2. As the *Paka* was continued slowly the colour become darker and thicker in consistency.
3. Typical odour of Jaggery was being emitted during procedure.
4. When the *Paka* of *Avaleha* reaches its completion, it has got all the *Siddhi Lakshanas* of *Avaleha*.
5. When got cooled semi solid consistency was attained.

Paka Siddhi Lakshanas

- The drop sinks to bottom but does not spread and easily picked with finger i.e. *Apsumajjanatvam* with *Sthiratvam*.

Table 3: Practical Details of *Bharangiguda Avaleha – I*

BATCH	Date of starting	Date of completion	*Kwatha* preparation		*Avaleha* preparation		Temp. (·C) when *Prakshepa Dravya* is added	Temp. (·C) when Honey is added
			Duration (In hrs.)	Temp. (·C)	Duration (In hrs.)	Temp. (·C)		
I	30/07/04	31/07/04	7.00	85-95	7.35	85-95	55	35
II	30/07/04	31/07/04	7.00	75-85	7.30	75-90	55	35
III	10/09/04	11/09/04	7.40	80-95	8.00	75-85	65	34
IV	10/09/04	11/09/04	7.30	80-95	8.00	75-85	63	37
V	12/10/04	13/10/04	8.25	85-98	9.00	85-90	58	33
VI	17/12/04	18/12/04	8.30	85-98	9.15	80-95	50	30
VII	18/03/05	19/03/05	8.40	80-96	9.05	80-90	60	36

Table 4: Final Yield of *Bharangiguda Avaleha-I*

Batch	*Kwatha* (In litre)	Mixture after addition of jaggery (In litre)	Yield (In Kgs.)	Average Yield (In Kgs.)
I	05.80	06.50	1.480	1.510
II	05.85	06.65	1.500	
III	05.85	06.65	1.500	
IV	05.80	06.60	1.560	
V	23.20	26.60	6.585	6.570
VI	23.20	26.60	6.575	
VII	23.30	26.60	6.550	

Preparation of *Bharangiguda Avaleha-II:*

Name of Practical: *Bharangiguda Avaleha - II Nirmana*

Reference: Modification on the basis of Iatro-chemistry [15]

Apparatus : Steel vessels, ladle, sieve, clean cloth, gas stove, etc.

Ingredients :

Table 5

Sr. No.	Ingredients	Quantity
		Batch- I to VIII
1.	*Bharangi Yavakuta*	2 Kg. (3.8 Litre)
2.	*Dashamula Yavakuta*	2 Kg. (7.26 Litre)
3.	*Haritaki* (Big size)	400 g. (600 ml)
4.	Water	46.4 Litre
	Reduced to (Vol. of Water)	11.6 Litre
5.	*Guda* (Jaggery)	2 Kg.
	Prakshepa Dravyas -	
6.	*Madhu* (Honey)	120 g.
7.	*Trikatu*	60 g.
8.	*Trijata*	60 g.
9.	*Yavakshara*	10 g.

Method of Preparation

The procedure of *Avaleha Kalpana* is followed in the following steps -

1. The *Haritaki Phala* is washed thoroughly and dried in shade.

2. *Haritaki Phala* is bundled in a piece of clean cloth, which is immersed in the *Kwatha Drava*.
3. *Bharangi Yavakuta* and *Dashamula Yava*kuta are added with 4 parts of water and boiled to prepare *Chaturthavashesha* (1/4th reduced) *Kwatha*, filter and separate the herbal marc.
4. The herbal marc obtained as above is again added with 4 parts of water, boiled to prepare 1/4th reduced *Kwatha*, filtered and the herbal marc is discarded.
5. The filtrate collected after straining the herbal marc twice as above is subjected to heating on a low flame *(Mandagni)* and reduced to 1/2nd to get the original proportion of the *Kwatha* to continue the *Avaleha* preparation.
6. The *Pottali* containing *Haritaki* is taken out, remove the seeds and pulp is made by Mixer.
7. The *Haritaki* pulp and *Guda* (Jaggery) are added to the filtered *Kwatha* in the said quantity and heated in mild fire (Mandagni).
8. When the *Paka* reaches the stage of *Siddhi Lakshanas* - the tests for completion are done to confirm the actual *Paka Lakshanas*.
9. The vessel is now removed from fire and allowed to cool and *Prakshepa Dravya* is added with vigorous stirring.
10. When cooled, *Madhu* (Honey) is added with vigorous stirring.
11. Then the *Avaleha* is packed in a container, which is air tight, labeled and packed.

Observations

1. After mixing of Jaggery in *Kwatha*, colour of mixture becomes darker.
2. As the *Paka* was continued slowly the colour become darker and thicker in consistency.
3. Typical odour of Jaggery was being emitted during procedure (*Paka*).
4. When the *Paka* of *Avaleha* reaches its completion, it has got all the *Siddhi Lakshanas* of *Avaleha*.
5. When got cooled semi solid consistency was attained.

Table 6: Practical Details of *Bharangi + Dashamula Kwatha*

Batch	Date of starting	Date of completion	*Kwatha*$_1$ preparation		*Kwatha*$_2$ preparation		*Kwatha*$_1$ + *Kwatha*$_2$ preparation	
			Duration (In hrs.)	Temp. (·C)	Duration (In hrs.)	Temp. (·C)	Duration (In hrs.)	Temp. (·C)
I	25/05/05	26/05/05	8.00	90-95	8.00	85-96	3.30	85-90
II	31/05/05	01/05/05	8.00	90-95	8.00	90-95	3.20	93-95
III	04/06/05	05/06/05	8.10	86-95	8.20	90-96	2.50	94-96
IV	08/06/05	09/06/05	7.50	93-97	7.55	92-96	2.55	96-97
V	04/08/05	05/08/05	7.55	96-97	7.50	95-98	3.10	90-95
VI	04/08/05	05/08/05	8.05	90-96	8.00	92-96	3.30	85-92
VII	11/08/05	12/08/05	8.00	90-95	8.00	85-95	3.30	85-90
VIII	20/10/05	21/10/05	8.15	85-90	8.20	93-98	3.40	90-95

K1 = As per ref. Prepared of Kwatha; K2 = repeatedly prepared of Kwatha

Table 7: Practical Details of *Bharangiguda Avaleha – II*

Batch	Date of starting	Date of completion	*Avaleha* preparation		Temp. (·C) when *Prakshepa Dravya* is added	Temp. (·C) when Honey is added
			Duration (In hrs.)	Temp. (·C)		
I	25/05/05	27/05/05	7.50	88-96	60	36
II	31/05/05	02/05/05	7.50	85-96	63	34
III	04/06/05	06/06/05	8.00	94-96	64	30
IV	08/06/05	10/06/05	8.10	80-95	55	35
V	04/08/05	06/08/05	8.20	85-90	65	33
VI	04/08/05	06/08/05	8.00	80-90	58	36
VII	11/08/05	13/08/05	8.15	86-95	60	32
VIII	20/10/05	22/10/05	7.55	85-92	66	35

Table 8: Final Yield of Bharangiguda Avaleha-Ii

Batch	*Kwatha* (In litre)			Mixture after addition of jaggery (In litre)	Yield (In Kg.)	Average Yield (In Kg.)
	Kwatha$_1$	*Kwatha*$_2$	*Kwatha*$_1$+ *Kwatha*$_2$= Reduced to 1/2nd			
I	11.6	11.6	23.2=11.6	12.400	3.223	3.2225
II	11.6	11.6	23.2=11.6	12.400	3.225	
III	11.6	11.6	23.2=11.6	12.400	3.215	
IV	11.6	11.6	23.2=11.6	12.400	3.210	
V	11.6	11.6	23.2=11.6	12.400	3.230	
VI	11.6	11.6	23.2=11.6	12.400	3.220	
VII	11.6	11.6	23.2=11.6	12.400	3.230	
VIII	11.6	11.6	23.2=11.6	12.400	3.220	

Precautions

1. All the apparatus/ equipments must be clean.
2. Kwatha has to be prepared in mild fire according to classical procedure.
3. The 1/4th of the total quantity of *Kwatha Drava* are marked beforehand for practical convenience.
4. Mild fire must be maintained throughout the procedure.
5. Continuous stirring is essential during procedure.
6. The *Pottali* of *Haritaki* should neither settle at bottom of the vessel nor to the sidewall of the vessel (outside the liquid - *Kwatha*)
7. *Prakshepa* must be added little by little at the end with continuous stirring while *Paka* is attaining its completion.
8. Honey should be added after complete cooling.

Clinical study

Comparative efficacy of the test formulations *Bharangiguda Avaleha-I, Bharangiguda Avaleha-II* and *Bharangi Churna* was evaluated against the disease *Tamaka Shwasa*. All the drugs were tested for their effect in the patients pertaining to signs and symptoms described in the classics for the disease *Tamaka Shwasa*.

Table 9: Status of 106 patients of *Tamaka Shwasa*

Groups	Number of Patients		
	Total Registered	LAMA	Completed
Bharangiguda Avaleha-I	35	02	33
Bharangiguda Avaleha-II	34	01	33
Bharangi Churna	37	03	34

106 patients of *Tamaka Shwasa* were registered, out of which 100 patients completed the course of the treatment with follow up, whereas 06 patients left the treatment against medical advice (Table-9).

An effect was assessed by the occurrence of the signs and symptoms were before treatment and relief obtained after completion of treatment. For this assessment, scoring pattern was prepared according to severity of the symptoms.

Selection of Patients

Criteria for Diagnosis

1. The patients having classical sign and symptoms of *Tamaka Shwasa* were selected.
2. Patients were selected randomly irrespective of their age, sex, religion, etc. from O.P.D. and I.P.D. of Rasashastra and Bhaishajya Kalpana Dept. Including Drug Research, I.P.G.T. & R.A., G.A.U., Jamnagar.
3. A detailed history was taken on the basis of a special proforma incorporating all signs and symptoms of the disease and filled for record of B.T. & A.T. data.

Criteria for Exclusion

1. *Tamaka Shwasa* with cardiac complication was excluded.
2. *Tamaka Shwasa* as a sequel to other disease such as Koch's etc. was excluded.
3. *Tamaka Shwasa* with diabetes mellitus was excluded.

Investigations

- Haematological Investigation specially Hb, TC, DC, ESR, AEC and Blood sugar (if required).
- Routine & Microscopic examination of Urine and Stool

Management of the patients

Groups

Selected patients were randomly divided into three groups viz.

Group-A: Treated with *Bharangiguda Avaleha - I*.
Group-B: Treated with *Bharangiguda Avaleha - II.*
Group-C: Control group treated with *Bharangi Churna*.

Dose, *Anupana* and Duration

- *Bharangiguda Avaleha – I* : 12 g. b.i.d. with Luke warm water.
- *Bharangiguda Avaleha – II* : 12 g. b.i.d. with Luke warm water.
- *Bharangi Churna* : 3 g. b.i.d. with Luke warm water.

Duration was kept 30 days for all three trial drugs.

Follow up

Patient was observed for one month after completion of treatment.

Criteria for the Assessment

1. Efficacy of the treatment was assessed on the relief produced by drugs on the cardinal sign and symptoms before and after treatment.
2. Laboratory investigations conducted before and after treatment were also considered as criteria for assessment.

Discussion

Drug review

- *Acharya* indicates *Avaleha Kalpana* in *Shamana* therapy. Also disease *Tamaka Shwasa* results due to vitiation of *Pranavayu* hence *Avaleha Kalpana* is useful to act on *Pranavayu*. Contents of *Bharangiguda Avaleha-I & II* were *Bharangi, Dashamula & Guda* (jiggery) - in equal proportion, *Haritaki -20%*, *Trikatu & Trijata-3%* each, *Madhu -6%* and *Yavakshara -0.5%*.
- Review of literature (pharmacological activity) pertaining to *Clerodendron serratum* (*Bharangi*), the main plant around which the formulations used in the present study have been built, indicate the presence among other effects anti-allergic, anti-histaminic, bronchoconstrictor activity. But the concentrated extract possesses anti-histaminic and anti-asthmatic action probably due to oxidation during the boiling procedure.
- Various research works showed that Piperine enhances the bioavailability of the drugs by increasing absorption of drug and preventing the enzymatic metabolism of drug in liver. It acts as an anti-allergic, analgesic and relieves depressant activity on CNS.

- *Haritaki* does not show any Bronchodilator action but it is mentioned as Srotovibandhanashini. Major surgeon Dr. Thomson from Chennai suggests the *Dhumrapana* of powder of *Haritaki* fruits while treating Shwasa effectively.[16]
- Besides Bharangi, *Dashamula* and *Haritaki*, *Guda* (Jaggery) is also one of the major ingredients of *Bharangiguda Avaleha-I & II.*

Pharmaceutical study

- The accomplishment of pharmaceutical operation of *Bharangiguda Avaleha-I & II* is detailed in this section. *Bharangiguda Avaleha-I* was prepared according to the reference *Chakradatta* [17] with ingredients as *Bharangi*, *Dashamula* and *Guda* (Jaggery) in equal proportion, *Haritaki* 20%, *Madhu* (honey) 6%, *Trikatu* and *Trijata* 3% each and *Yavakshara* 0.5%.
- It was hypothesized that the extraction of the therapeutically active principles from the drug was rather incomplete during the regular *Kwatha Nirmana* process. Citation of *Acharya Gopura Rakshita* quoted in Iatro-chemistry based *on Ayurveda Soukhya of Todarananda* [18].
- This was found as a solution for this problem and was adopted for the pharmaceutical preparation of *Bharangiguda Avaleha-II* sample. The *Bharangi* and *Dashamula were* exhausted with 4 parts of fresh water twice, the filtrate were concentrated by reducing to1/2nd, rest of the Avaleha procedure being similar to *Bharangiguda Avaleha-I* sample.

Clinical study

- All the 3 test samples had shown statistically highly significant results on the cardinal symptoms such as *Shwasakashtata, Kasa, Pinasa, Ghurghurkam, Urahshula*, etc. On analyzing the data pertaining to the effect on the three test samples on the cardinal symptoms it can be seen that *Bharangiguda Avaleha-I* is consistent in all of the parameters in providing statistically highly significant relief to the patient.
- Also, statistically highly significant results on associated symptoms such as *Krichchhrabhashitam, Kanthodhwamsa, Lalate Sweda* etc. of *Tamaka Shwasa Roga,* were seen in groups treated with *Bharangiguda Avaleha-I & II,* and statistically highly significant result on associated symptoms like *Lalate Sweda, Asino Labhate Saukhyam & Shleshma Vimokshante Muhurtam Sukham* were observed whereas significant result was found on *Krichchhrabhashitam, Kanthodhwamsha, Vishushkasyata & Ushnabhinandati* in *Bharangi Churna* administered group but comparatively *Bharangiguda Avaleha-I* displayed better results.
- Statistically highly significant results were observed in frequency, intensity and duration of Shwasa in the entire three test formulations, but comparatively *Bharangiguda Avaleha-I* more effective than other two formulations.
- Adventitious sound like wheezing and rhonchi were reduced markedly which was statistically highly significant in all the three test samples. Also statistically significant decrease in crepitus was observed in *Bharangiguda Avaleha-II* administered group and insignificant decrease was found in the treated groups with *Bharangiguda Avaleha-I* & *Bharangi Churna* respectively.
- Absolute Eosinophils Count index was found reduced by statistically significant level in *Bharangiguda Avaleha-I* treated group and statistically significant reduction in Erythrocyte Sedimentation Rate was recorded in *Bharangi Churna* administered group. Other investigative parameters like Total Leukocyte Count, DC, and Fasting blood sugar were found statistically insignificant in all the three test formulations.
- Overall effect of therapy in *Bharangiguda Avaleha-I*, complete remission was observed in 05 patients i.e. 15.15%. Markedly improvement was found in 25 patients i.e. 75.76% and moderately improvement was obtained in 03 (8.82%). Mildly and no improvement was not found in any patient.
- Overall effect of therapy in *Bharangiguda Avaleha-II*, complete remission was observed in 02 patients i.e. 06.06%. Markedly improvement was found in 20 patients i.e. 60.61%. Moderately improvement was obtained in 11 patients i.e. 33.33%. Mildly and no improvement was not found in any patient.
- Overall effect of therapy in *Bharangi Churna*, complete remission was not observed in any patients. Markedly improvement was found in 03 patients i.e. 08.82%. Moderately improvement was obtained in 11 patients i.e. 32.35%, mildly improvement was found in 10 patients i.e. 29.41% and 10 patients i.e. 29.41% in Bharangi Churna remain no improved.

Prpbable Mode of Action

Ayurvedic Review

- Action of a compound is decided either by the action of a major ingredient or by the synergetic action of all the ingredients.
- In the present test formulations – *Bharangiguda Avaleha-I & II*, although the *Prakshepa* drugs might have their synergetic effect in the formulation.
- The disease *Tamaka Shwasa* characterized by the involvement of *Vata* and *Kapha Dosha, Rasadhatu Dushya* and *Pranavaha, Annavaha* and *Udakavaha Srotas.*
- The pathology is marked by narrowing, leading to spasm caused by *Vata* by all probabilities and secretions obstructing the channel caused by deranged *Kapha*. Of course, the vitiation of the *Pitta Sthana* has been described to be the root cause.
- This indicates towards the derangement of certain enzymatic or hormonal activities which result into further changes, leading to inflamed bronchial mucosa in turn leading to spasm by *Vata* or obstructing secretions by *Kapha*. Hence, logically, the drug administered for the treatment of *Tamaka Shwasa*, should be able to overcome *Vata* and *Kapha* for immediate and symptomatic relief but should also pacify the *Pitta* for a permanent or quasi-permanent relief.
- *Acharya*s agreed on the use of *Vata-Kaphaghna, Ushna, Vatanulomana* drugs as a first line of treatment of *Tamaka Shwasa* [19].
- Chief therapeutic indication of *Bharangi* is *Shwasa* and *Kasa, Acharya Vagbhatta* proclaiming it to be *Agraya Aushadhi* for the disease *Shwasa.*

- Almost all the classics have used *Dashamula* in treating the disease *Tamaka Shwasa (Shwasa).*
- *Dashamula* attributed with *Tridosha Hara* especially *Vata Hara* and *Shwasa Hara* action [20] may be inferred to discharge its *Shwasa Hara* action by pacifying *Vata.* Its site of action may be the level of higher centre regulating respiration.
- *Bharangi* having *Katu Tikta Rasa, Ushna Virya, Katu Vipaka* and *Kapha-Vataghna* property and *Dashamula* with *Ushna Virya, Katu Vipaka* and *Tridoshaghna* seems to quite naturally antagonize the *Tamaka Shwasa Roga*, which is *Kapha-Vata Pradhana* disease.
- ……तमके तु विरेचनम् [21] *Virechana* causes *Vatanulomona* leads to pacify the *Tamaka Shwasa, Haritaki* having the *Vatanulomana* property thus restrains the *Pratiloma Vayu*.
- Jaggery (*Guda*) having *Ushna Virya, Anulomana Guna* and *Tridoshaghna* property pacifying *Vata-Kapha* [22].
- *Trikatu* as *Prakshepa Dravya* possess *Kapha-Vatanashaka* as well as *Shwasa Hara* property. By its *Tikshna* and *Ushna* property cleansifies and clarifies the *Srotases* thus relieving the *Tamaka Shwasa.*
- *Trijata* as *Prakshepa Dravya* also possesses *Kapha-Vatanashaka* property. Also, due to its volatile principles, it imparts good aroma increasing the acceptability by the patient besides enhancing the drug action in mitigating *Tamaka Shwasa*.
- Pungent taste, *Ushna Virya, Sara Guna, Kapha-Vatanashaka* and quick acting property of *Yavakshara* contribute to the Shwasa Hara action of the drug.
- *Madhura, Kashaya Rasa, Katu Vipaka* and *Tridosha Hara* property of *Madhu* (Honey), enhancing the drug action as well as the drug acceptance.
- The compound preparation attributed with *Agnideepaka* property rectifies the *Udbhavasthana* of the disease *Shwasa* i.e. *Pittasthana – Amashaya*.
- The *Ushna Virya, Katu Vipaka* and *Vata-Kapha Shamak*, property along with *Deepana, Pachana* property of *Bharangiguda Avaleha*, in total, effectively breaking the *Samprapti* of *Tamaka Shwasa*.

Modern Review

- *Bharangi* the drug of choice by *Vagbhatta* in treating *Shwasa* is known to possess Phytosterols, Phenolic glycosides, Saponins such as histamine stimulants and anti-cholinesterase. But the concentrated extract possesses anti-histaminic and anti-asthmatic action probably due to oxidation during the boiling procedure.
- Effect of *Dashamula* in management of sensory and motor disorders pertaining to sympathetic and parasympathetic out flow amongst the patients presenting with primary neurological disorders have been investigated in Database on Medicinal Plants Used in Ayurveda [23]. Significant improvement in nerve conduction velocity was observed. The pattern of "H" reflex also improved in all these patients along with clinical response. Out of 50 patients of nutritional neuropathy 40 patients showed improvement in nerve conduction velocity.
- Antihistamine, antibiotic action of the *Bharangi* might be responsible for reducing the local congestion and checking the infectious microorganisms. This action of *Bharangi* might be complemented and synergised by the compound *Dashamula* whose action extends upto the higher centers pacifying in nature apart from the local action - antibiotic and reducing the swelling / congestion due to diuretic activity.
- Thus both the drugs, like this might act synergistically in the compound form to clear off the local congestion, infectious organism if any, which may contribute to the therapeutic efficacy of the test drug in asthma and pacify the higher centers of respiration, thus effectively controlling the breathlessness.

Conclusion

- *Acharya Vrinda Madhava* was the first *Aapta* to contribute *Bharangiguda Avaleha* to the Ayurvedic pharmaceutics, and various *Acharyas* repeated this in six different classics.
- All the three formulations i.e. *Bharangiguda Avaleha-I*, *Bharangiguda Avaleha-II* and *Bharangi Churna* had shown statistically highly significant result on *Tamaka Shwasa*, but in comparison to control group *(Bharangi Churna)*, the *Bharangiguda Avaleha-I* is more effective than *Bharangiguda Avaleha-II.*

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