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A CRITICAL STUDY OF *SOMANATHI TAMRA BHASMA*- A MERCURO-ARSENICAL FORMULATION

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ABSTRACT:

Background: *Tamra Bhasma* has been mentioned in classics for its wider therapeutic utility, at the same time it is reported as poison as or more than that if not processed properly as per classical guidelines. To emphasize its toxic potential, *Ashtamahadoshas* (eight major ill effects) have been quoted in classics. Numerous methods of preparation of *Tamra Bhasma* were available in the classics of Rasashastra among them *Somanathi Tamra Bhasma* (STB) is a specialized method. Hence present study is planned to compile available research works and published research articles and provide brief information on pharmaceutical, analytical, pharmacological, and clinical studies. **Material and methods:** Research works carried out at different institutes and using search engines like PubMed, Google Scholar, and Scopus, a thorough search of the scientific literature was conducted. Somanathi Tamra Bhasma, Safety, and Ayurveda were the keywords that were employed. Only articles that have been published in the previous ten years were examined. **Results:** Total four dissertation works and seven published research articles were found. After screening of dissertation works, four were related to pharmaceutical, three were related to pharmacological study and two were related to clinical study. Among published research articles one is related to literary review, two are related to pharmaceutical, four were related to pharmacological study. **Conclusion:** *Somanathi Tamra Bhasma* requires 3-36 hours of duration with intermittent heating pattern (highest temperature 615°C) by both traditional heating method and *Kupipakwa* method. Pharmaceutical study has determined that *Somanathi Tamra Bhasma* can be prepared using both the traditional and modified (Kupipaka technique) methods. In the analytical study, it is found to be a mixture of copper sulfide (CuS) and copper oxide (CuO). Pharmacologically it is found safer after *Amritikarana* upto repeated dose 90-days oral toxicity study at therapeutic dose with appropriate adjuvant. Clinically it is found more effective than *Tamra Bhasma* in *Shwasa, Grahani,* and *Medoroga.*

Keywords: Arsenic, Ayurved, Copper, Mercury, Safety, Somanathi Tamra Bhasma.

INTRODUCTION:

Somanathi Tamra Bhasma (STB) is one such unique method for preparation of *Tamra Bhasma,* which is mentioned first in Rasendra chudamani (12th century). *Shuddha Parada* (processed mercury), *Shuddha Gandhaka* (processed sulphur), *Shuddha Haratala* (arsenic trisulphides), *Shuddha Manahshila* (arsenic disulphide) are integral ingredients of STB and indicated in the management of *Udara* (ascites), *Pandu* (anemia), *Grahani* and *Yakritavikara*(liver diseases) etc.[1] Comparatively, this method involves minimum pharmaceutical procedures and less duration than preparation of *Tamra Bhasma* by other methods. Total ten references of STB were available in different classics of Rasashastra with slight modifications in ingredients, duration of heating and instruments. Considering this multiple research works were carried out in different institutes to evaluate pharmaceutical, pharmacological and clinical effects of STB.

Hence present study is planned to compile available research works and published research article and provide brief information of pharmaceutical, analytical, pharmacological studies.

MATERIAL AND METHODS:

Research works carried out at different institutes and using search engines like PubMed, Google Scholar, and Scopus, a thorough search of the scientific literature was conducted. Somanathi Tamra Bhasma, Safety, pharmaceutical study and Ayurveda were the keywords that were employed. Only articles that have been published in the previous ten years were examined. Following a categorization of the papers based on the study design used, a detailed evaluation was conducted. Total seven research articles were found related to pharmaceutical, pharmacological, and therapeutic effects. Present study includes review of all available research articles because there is a very limited number of published data available across all search engines.

Observation and results:

All *Rasa* classics mentioned the ingredient of STB as *Tamra* (copper), *Parada* (mercury), *Gandhaka* (sulfur), *Haratala* (Arsenic trioxide) and *Manahshila* (Arsenic dioxide) and ratio of ingredients in all Rasa classics is as *Tamra, Parada, Gandhaka* in equal quantity, *Haratala* is half to that of *Gandhaka* and *Manahshila* is half to that of *Haratala*. Exception to this, Rasa Tarangini has mentioned the different ratio as *Tamra, Parada, Gandhaka* in equal quantity and *Manahshila* is 1/4th to that of *Gandhaka* and *Haratala* is 1/8th to that of *Manahshila*.[2] All *Rasa* classics have advocated *Garbha Yantra* for its pharmaceutical preparation except, Rasa Paddhati (*Bhanda Puta*)[3], Yogratnakara (*Valuka Yantra*)[4], Rasayogsagara (*Sikata Yantra*)[5] and Rasa Tarangini (*Puta*)[2] method. Most of the *Rasa* classics have mentioned the 1 *Yama* duration for its preparation except Yogratnakar (2 *Yama*) and 1 *Yama* in commentary (Table 1)[4] Rasayogsagar has mentioned (12 hr) duration.[5]

Research works of *Somanathi Tamra Bhasma*

Trivedi SC *et al*. carried out a comparative study between *Tamra Bhasma* and *Somanathi Tamra Bhasma* in 1965. In this study total three batches of

STB were prepared by preparing *Pishti* of processesd *Parada* and processed *Tamra* and later subjected to the preparation of *Kajjali* of STB. This prepared *Kajjali* is subjected to the heating process in *Valuka Yantra* (traditional heating instrument) for 36 hours. Total 56% yield was obtained in final product. This prepared drug is administered in the dosage of 125 mg along with *Pippali Churna* as *Anupana* to six diagnosed patients *Shwasa* (bronchial asthama), *Kaphaja Kasa* and *Yakrita-pliha Vruddhi*. It was significant in relieving the signs and symptoms of *Shwasa, Kaphaja Kasa* and *Yakrit-Pliha Vriddhi* with promising results. On comparison of the clinical efficacy, *Somanathi Tamra Bhasma* was reported to have better results over *Tamra Bhasma*.[6]

In 2004 Solanki *et al*. carried out study on pharmaceutical standardization of *Somanathi Tamra Bhasma* and its effect on *Grahani Roga*. In this study also for preparation of STB, *Kajjali* was prepared by same method as of Trivedi *et al*. Prepared *Kajjali* was filled in mud smeared glass bottle (*Kachkupi*) and 2 different samples of STB were prepared subjecting it to the heating in Vertical electric muffle furnace (STB-1) and *Valuka Yantra* (STB-2). Heating was given for average duration of 14 hours with highest temperature of 615°. Total 51.14 and 48.58% yield was obtained in the final product STB-1 and STB-2 respectively. For pharmacological study total 21 animals were divided into 3 groups. Group-I (5×TED) is administered with STB-1 in dosage of 120 mg/kg, Group-II (5×TED) is administered with STB-2 in dosage of 120 mg/kg and Group-III was control group and administered with normal feed for 43 days and animals were sacrificed on 44th day. Results of histopathological paramateres of Group-I showed mild to moderate degenerative changes in liver, kidney and heart whereas Group-II showed moderate degenerative changes in kidney only. For clinical study, total 14 patients were enrolled and divided into 2 groups and administered in the dosage of 125 mg/kg with honey for 21 days. Both the drugs showed highly significant results in both the groups.[7]

In 2005 Nayak *et al*. carried out study on comparative pharmaceutico-pharmaco-toxicity study of *Tamra Bhasma* (TB) and *Somanathi Tamra Bhasma* (STB). In this study pharmaceutical procedure of STB was same as of Solanki *et al*. average duration of 14 hours with highest temperature of 600°. Total 45.05% average yield was obtained in the three batches. For acute toxicity study, total 24 animals were divided into 8 groups each containing 3 animals. Group-I (5×TED) was administered with TB in dosage of 27 mg/kg, Group-II (10×TED) was administered with TB in dosage of 54 mg/kg and Group-III (20×TED) was administered with TB in dosage of 108 mg/kg and Group-IV (30×TED) was administered with TB in dosage of 162 mg/kg. Group-V (5×TED) was administered with STB in dosage of 67.5 mg/kg, Group-VI (10×TED) was administered with STB in dosage of 135 mg/kg and Group-VII (20×TED) was administered with STB in dosage of 270 mg/kg and Group-VIII (30×TED) was administered with STB in dosage of 305 mg/kg. For chronic toxicity study, total 21 animals were divided into 3 groups. Group-I

(5×TED) is administered with TB in dosage of 27 mg/kg, Group-II (5×TED) is administered with STB in dosage of 67.5 mg/kg and Group-III was control group and administered with normal feed for 30 days and animals were sacrificed on 31st day. Results of hematological, biochemical and histopathological parameter showed that comparatively TB is more prone to produce mild to moderate untoward effects than STB when administered in the higher dosage. Both the drugs found safe at therapeutic dose and STB was found safe even at 30×TED. For clinical study, total 14 patients were enrolled and divided into 2 groups. Group-I was administered with TB in the dosage of 30 mg/kg and Group-II was administered with STB in the dosage of 75 mg/kg with water for 21 days. Both the drugs showed highly significant results in both the groups. Results showed that STB is better than TB in lipid lowering capacity in hypercholastremia.[8]

In 2019 Dalvi A *et al.* carried out study on evaluation of safety (acute & repeated dose 90-days oral toxicity study) profile of *Somanathi Tamra Bhasma* with *Amritikarana*. This study was planned to develop the SMP of *Somanathi Tamra Bhasma* with *Amritikarana* (STBA). For this total three batches of *Somanathi Tamra Bhasma* with *Amritikarana* were prepared by following the reference of Rasendra Chudamani. Intermittent heating pattern with duration of 12 hrs i.e *Mridu Agni* (3 hrs), *Madhyamagni* (6 hrs), *Tikshnagni* (3 hrs) given by traditional method. Average 45.86 % yield was observed in 3 batches of STB and 9.68 g (12.85 %) weight loss was observed after *Amritkarana* of *Somanathi Tamra Bhasma*. In acute toxicity, STBA was administered at a maximal dose of 2000 mg/kg to overnight fasted rats and observed closely for 14 days. In the chronic toxicity evaluation, the test drug was administered daily at the doses of 67.5, 337.5 and 675 mg/kg along with *Pippali Churna* and honey as an adjuvant to rats for 90 days in divided dose followed by a 30-day recovery period. Animals were sacrificed on the 91st day and hematological, serum biochemical parameters and histopathology of organs were studied. In acute toxicity results showed that, STBA at the dose of 2000 mg/kg did not produce any observable toxic effects or mortality. In repeated dose 90-days toxicity study results showed that, STBA did not produce any significant changes in hematological, biochemical and histopathological parameters at TED & TEDx5 dose levels but mild fatty and inflammatory changes were observed in liver at TEDx10 dose level. These changes were returned to normal at recovery groups. STBA was found safe at therapeutic dose levels when used judiciously along with specified adjuvants.[9-10]

Table 1: Review on pharmaceutical study of *Somanathi Tamra Bhasma*;

Scholar Name	Ingredients ratio	Batch size (gm)	Duration of heat (hrs)	Highest temperature (°C)	Mode of Heating	Yield (%)
Trivedi S *et al.*	*Parada*- 1 p *Tamra*- 1 p	225	36	*Tivragni*	*Valuka Yantra*	56

	Gandhaka-1 p *Haratala*-1/4th p *Manahshila*- 1/8th p					
Nayak S *et al*.	Same	283.66	14	600	EMF	45.01
Solanki T *et al*.	Same	285.33	13.66	615.33	EMF	48.69
Dalvi A *et al*.	Same	150	12	500	*Garbha Yantra*	45.86
Chandran H *et al*.	Same	-	First batch-10:45	600	EMF	45.55
	Same		Second batch-23:40			41.55
Honwad S *et al*.	Same		3	605	Dry husk	63.61

Research articles published on *Somanathi Tamra Bhasma*.

Honwad S *et al*. published article on litrary review of *Somanathi Tamra Bhasma*. In this article total 10 references of STB were mentioned along ingredients, instrument, and duration of heating, dose and indications of STB.[11]

Chandran H *et al*. published article on pharmaceutical study of *Somanathi Tamra Bhasma*. In this article pharmaceutical preparation of STB was prepared by following reference of Rasaratnasamucchaya. Initially *Tamra+Parada Pishti* were prepared and then STB was prepared by *Kupipakwa* method. Total two batches of STB were prepared with different batch size and different duration of heating. For first batch total duration of heating was 10 hours 45 minutes hours and highest temperature noted was 600°C. 45.55% yield was obtained in first batch. For second batch total duration of heating was 23 hours 40 minutes and highest temperature noted was 600°C. 41.55% yield was obtained in second batch. This prepared *Bhasma* passed all *Bhasma Siddhi Lakshana*.[12]

Honwad S *et al*. published article on pharmaceutical study of *Somanathi Tamra Bhasma*. For the preparation of *Somanathi Tamra Bhasma* reference of Rasendra Chudamani was adopted. Heat treatment was given for 3 hours of duration by using dry husk and 605°C highest temperature was noted during the study. Average 63.61 % yield was observed 778 g (12.85 %) weight loss was observed in final product. In analytical study, XRD showed that final product is mixture of copper sulfide and copper oxide. Particle size STB was found between 4 µm to 5.6 µm.[13]

Honwad S *et al*. published article on chronic toxicity study of *Somanathi Tamra Bhasma* wistar strain albino rats. In this study *Somanathi Tamra Bhasma* was administered orally to different groups of albino rats in TED (Therapeutically effective dose), TED×5 (5 times the therapeutically effective dose) and TED×10 (10 times the therapeutically effective dose) doses for 3 months by following Ayush

guidelines for evaluation of ASU drugs. Behavioural, ponderal, hematological, biochemical and histopathological parameters were considered for the assessment of data. STB was found to be relatively safe at TED and TED×5 dose levels and moderate toxic at TED×10 treated groups. The overall chronic toxicity study data indicates that the test substance STB at TED and TED×5 dose levels is very well tolerated since no toxicity symptoms were observed in these groups in any of the parameters analyzed.[14]

Joseph et al. published article on evaluation of immunomodulation activity of *Somanathi Tamra Bhasma*. Effect of STB on cell mediated Immunity were evaluated by using Immunological paw edema method in albino rats and effect of STB on humoral antibody formation were evaluated by noting Antibody titer and Biochemical, Haematological, and Histopathological findings. Analysis of the results obtained from the Immunomodulation study, clearly shown that, the test drug STB has CMI suppression effect. This effect is produced without affecting anti-body formation indicating specific nature of the observed effect. It is suggested that this effect may be due to modulation of the Th-1 pathway of adaptive immune reaction. Haematological parameter assessment did not reveal any remarkable change. Among the biochemical parameters elevation of SGOT was observed after SRBC injection and was moderately reversed by the test formulation. Thus it can be suggested that this formulation can be employed in clinical conditions involving inappropriate increase in CMI.[15]

Hepatoprotective activity of *Somanathi Tamra Bhasma* was evaluated in paracetamol induced liver toxicity in albino- rats. The degree of protection was determined by measuring levels of serum marker enzymes like serum glutamate oxaloacetate transminase (SGOT), Serum glutamate pyruvate transminase (SGPT), alkaline phosphate (ALP) etc., and histopasthological studies. Silymarin was used as standard drug for comparison. Administration of STB (67.5 mg/1kg. Bd. Wt.) markedly prevented paracetamol induced elevation of levels of SGOT, SGPT and alkaline phosphate etc,. The results are comparable to that of silymarin. A comparative histopathological study of liver exhibited almost normal architecture as compared to control group. Treatment with STB significantly reduced the paracetamol induced hepatotoxicity. A comparative histological study of liver from different groups further confirmed the hepatoprotective activity of STB.[16]

DISCUSSION:

In recent era safety issues of medicines prepared from metals and minerals is matter of concern. In Ayurved though those medicines are in practice since ancient period but there is lack of evidences of safety. *Somanathi Tamra Bhasma* is also one such formulation containing heavy metals and scheduled E (I) drugs. Hence it is necessary to evaluate safety of this formulation and to generate safety data. For the same many scholars studied this formulation on pharmaceutical, analytical, pharmacological and clinical grounds. Total four dissertation works and seven published research articles were found. Among four dissertation works

four were related to pharmaceutical, three were related to pharmacological study and three were related to clinical study. Among published research articles one is related to literary review, two are related to pharmaceutical, four were related to pharmacological study.

In studies related to literary review among All *Rasa* classics mentioned the ingredient as *Tamra, Parada, Gandhaka, Haratala* and *Manahshila* and ratio of ingredients in all Rasa classics is as *Tamra, Parada, Gandhaka* in equal quantity, *Haratala* is half to that of *Gandhaka* and *Manahshila* is half to that of *Haratala*. Exception to this, Rasa Tarangini has mentioned the different ratio as *Tamra, Parada, Gandhaka* in equal quantity and *Manahshila* is 1/4th to that of *Gandhaka* and *Haratala* is 1/8th to that of *Manahshila*.[2] All *Rasa* classics have advocated *Garbha Yantra* for its pharmaceutical preparation except, Rasa Paddhati (*Bhanda Puta*),[3] Yogratnakara (*Valuka Yantra*),[4] Rasayogsagara (*Sikata Yantra*)[5] and Rasa Tarangini (*Puta*)[3] method. Most of the *Rasa* classics have mentioned the 1 *Yama* duration for its preparation except Yogratnakar (2 *Yama*) and 1 *Yama* in commentary,[4] Rasayogsagar has mentioned (12 hr) duration.[5]

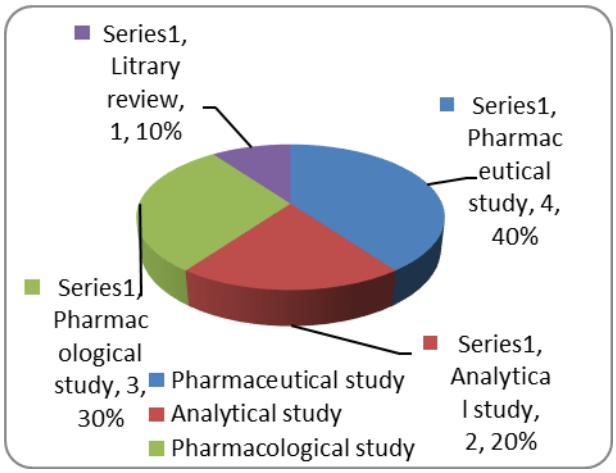

Figure 1: Showing distribution of types of study (dissertation work)

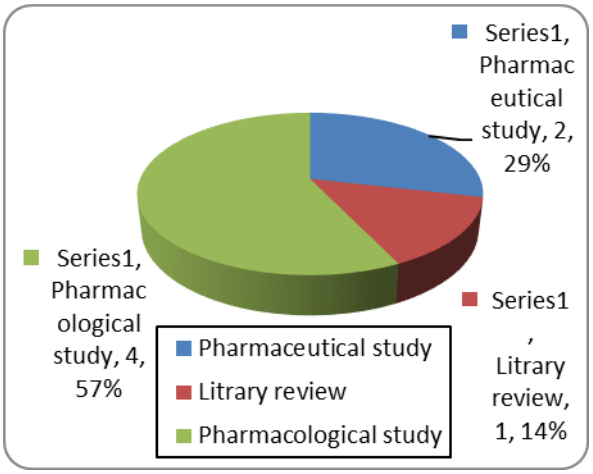

Figure 2: Showing distribution of types of study (research article)

Pharmaceutical findings

Screening of previous researches on *Somanathi Tamra Bhasma* and its ingredients have been done and found that Trivedi S *et al*. has taken all the ingredients as per mentioned quantity in classics but he had made slight change in pharmaceutical process. In classics, it is advised that *Tamra Patra* and *Kajjali* is to be added in *Garbha Yantra* by alternative layers but Trivedi S *et al*. had prepared *Pishti* of *Shuddha Tamra* and *Parada* first and then remaining ingredients were added to this amalgam and *Kajjali* was prepared. Later this *Kajjali* was filled in *Kupi* and subjected to heat by *Valuka Yantra* for 36 hrs.[6] Similarly, Nayak S *et al*. and Solanki T *et al*. had also made slight difference in proportion of ingredients. Both of them had taken *Parada*, *Tamra* and *Haratala* in equal quantity, *Gandhaka* was double to that of *Shuddha Tamra* and *Manahshila* was half of *Haratala*. They had also made slight changes in pharmaceutical process and prepared

Pishti of *Shuddha Tamra* and *Parada* first and then remaining ingredients were added to this amalgam and *Kajjali* was prepared. Later this *Kajjali* was filled in *Kupi* and subjected to heat by EMF for 14 hrs (average).[7-8] among all studies only two scholars were prepared STB by following classical guidelines otherwise other scholars prepared STB by modification i.e by preparing the *Pishti* of *Parada*+*Tamra* and later subjecting it to the heating process by *Kupipakwa* method.

Analytical findings

In most of the studies *Somanathi Tamra Bhasma* is found to be mixture of copper sulphide (CuS) and copper oxide (CuO).

Pharmacological findings

Comparatively *Somanathi Tamra Bhasma* is found safe than *Tamra Bhasma* when assessed in wistar albino rats. STB was found safe at 30×TED dosage in acute toxicity study. STB was prone to produce mild to moderate untowards effects at 5×TED and 10×TED dose levels but found safe at TED dose level. STB with *Amritikarana* was found safe at 2000 mg /kg dosage when assessed through the OECD 425 guidelines and when assessed for repeated dose 90-days oral toxicity study by following OECD 408 guidelines found safe at therapeutic dosage and produced mild inflammatory changes at 10×TED dose levels but those changes were not found in recovery group (10×RTED). STB is found effective hepatoprotective in paracetamol induced liver toxicity in albino- rats. STB found effective in Immunomodulation activity on cell mediated Immunity by using Immunological paw edema method in albino rats and on humoral antibody formation.

Clinical findings

Effect of *Somanathi Tamra Bhasma* is found better than *Tamra Bhasma* when evaluated clinically in *Shwasa and Udara*. STB is possesses significant effect in reducing sign and symptoms of *Grahani* and also it is found clinically effective in reduction of hyperchloestramia.

CONCLUSION:

It can be concluded that *Somanathi Tamra Bhasma* is specialized method of preparation of *Tamra Bhasma* requires duration of range between 3-36 hours with intermittent heating pattern (highest temperature 615°C) by both traditional heating method and *Kupipakwa* method. For pharmaceutical preparation both traditional and modified (Kupipaka method) method was found suitable. It is found to be mixture of copper sulphide (CuS) and copper oxide (CuO). Pharmacologically it is found safe at therapeutic dose with appropriate adjuvant. Clinically it is found more effective in *Shwasa, Grahani* and *Medoroga* than *Tamra Bhasma*. Hence if this formulation is used by following classical guidelines will be safe and effective without any untoward effects.

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