

Clinical and metabolic markers based study of Swas Kasa Chintamani Rasa (An Ayurvedic herbo-metallic preparation) in childhood bronchial asthma (Tamak Swas)

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Background: Asthma is a problem worldwide, with an estimated 300 million affected individuals. It is a disease of the respiratory system, characterised by intermittent inflammation, constriction or obstruction of the airways leading to a temporary reduction in airflow, and associated shortness of breath. **Aims:** In Ayurveda, there are lots of drugs to treat the bronchial asthma (Tamak Swas), among them Swas-Kasa-Chintamani Rasa (SKCR) is considered a good drug to cure. **Materials and Methods:** A total of consented 23 children of both sex under 12 years of age were included in the study and divided into three groups, blood samples were collected before treatment and after the completion of therapy for the metabolic markers like Hb gm%, TLC, AEC, S. Protein, S. Albumin, SGOT, SGPT, alkaline phosphatase and S. Bilirubin. SKCR was given for a total of 45 days in a dose of 4 mg/kg/dose \times 12 hourly with garlic, ginger and honey in ratio of 1:2:4. **Statistical Analysis Used:** In the present study, SPSS software was used to get statistical data such as Mean (\bar{X}), Mean Difference (d), Standard Deviation (SD) and Student's "t" test, etc. **Results and Conclusions:** The findings suggest that the drug is more effective in those cases who are not receiving corticosteroid with bronchodilator in comparison to children receiving corticosteroids with/without bronchodilator. No specific adverse effect of drug SKCR was observed.

Key words: Ayurved, childhood bronchial asthma, SGOT, SGPT, Swas Kasa Chintamani Rasa

INTRODUCTION

Asthma is a problem worldwide, with an estimated 300 million affected individuals. The World Health Organization has estimated that 15 million disability-adjusted life years (DALYs) are lost annually due to asthma, representing 1% of the total global disease burden.^[1] It is a disease of the respiratory system, characterised by intermittent inflammation, constriction or obstruction of the airways leading to a temporary reduction in airflow and associated shortness of breath.^[2]

Asthma is the most common chronic childhood disease in nearly all industrialised countries. An attack is experienced when the asthmatic child's chronically inflamed bronchial airways, having become sensitised to certain environmental allergens (e.g., dust, smoke) and conditions (e.g., exercise,

cold weather, stressful emotions), begin to overproduce mucus in their presence. This leads to the swelling and muscle contraction that obstructs air flow and restricts breathing.^[3]

The prevalence of asthma is increasing in most countries, especially among children. Asthma is a significant burden, not only in terms of healthcare costs but also of lost productivity and reduced participation in family life.^[4]

Exposure to outdoor and especially indoor allergens is a significant risk factor for allergic asthma.^[5] In infancy, food allergy with manifestations in the skin, the gastrointestinal tract or respiratory tract is more common than inhalant allergy.^[6] The presence of food allergy is a risk factor for the development of symptoms of asthma in children aged >4 years.^[7,8] Respiratory viral infections are the single-most frequent asthma trigger in childhood.^[9,10] Respiratory syncytial virus is a common cause of severe respiratory symptoms in infants.^[10,11] Severe respiratory infections are associated with asthma persistence later in childhood.^[12]

Passive exposure to tobacco smoke is one of the strongest domestic and environmental risk factors for developing recurrent coughing/wheezing or asthma symptoms at any age during childhood.^[13] Pollutant,^[14,15]

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nutrition,^[16] irritant,^[17] exercise asthma,^[18,19] weather^[20] and stress^[21] are other causes for asthma.

In Ayurvedic classics, Tamak Swasa has almost similar clinical manifestation as in the bronchial asthma and can terminate the patient's life quickly.^[22]

Although asthma has been known for millennia, but even after century a root cure of asthma is not yet available. The modern medicines of asthma can control the acute asthma symptoms, but did not cure this disease significantly.

In Ayurveda, there are multiple drugs for treatment of Tamak Swasa (bronchial asthma), among them Swas-Kasa-Chintamani Rasa (SKCR) is considered one of the best drug to cure Tamak Swas. The trial drug is herbo-metallic in nature. In recent era, scientists have opinion that the herbo-metallic preparations of Indian system of Medicine should be used with precautions as these drugs may be toxic to the liver, kidney and brain. While the Ayurvedic scholars have justified the harmful effect of these drugs, only those drugs are toxic which are not properly prepared.

Therefore, on basis of textual reference, personal experience and previous work done on the SKCR drug on asthma,^[23] this drug was selected for further evaluation.

MATERIALS AND METHODS

Selection of Patients

Total 23 children (both male and female) were enrolled for the present study after getting written informed consent. The children with age group of 2-12 years having symptoms of cough, fever, breathlessness, running nose, restlessness, wheezing, etc., are selected and divided into subgroup 'A' having positive history of taking bronchodilator and corticosteroid and subgroup 'B' having positive history of taking bronchodilator only whereas subgroup 'C' patients having no history of taking steroid or bronchodilator prior to the registration.

The children having tonsillitis, pneumonia, bronchitis, pharyngitis, tubercular infection or any other systemic illness were excluded from study.

Diagnostic Criteria

Diagnosis of each case was made with the help of detailed history in respect to disease i.e., allergic history, family history, previous similar episode, physical and systemic examinations as well as the investigations.

Investigations

The following investigations were advised to make the diagnosis as well as to assess the effect of the SKCR drug during the subsequent follow-ups.

- Blood chemistry: Haemoglobin (Hb gm%), total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), absolute eosinophil count (AEC), liver function test (LFT): *SGOT, SGPT, alkaline phosphatase, serum bilirubin, serum protein and serum albumin*, blood urea and serum creatinine
- X-ray chest P.A. view
- Montoux test
- Urine (Routine and microscopic).

Selection of Drug

SKCR with garlic, ginger and honey (GGH) as Anupan (adjuvant) was selected for present study based on the effective response of the drug in bronchial asthma and its indication in Ayurvedic text^[24-30] as well as the drug is found effective in asthmatic cases in relation to subsidence of clinical features of asthma without showing any significant side effects except burning sensation in abdomen.^[23]

SKCR^[30] have following ingredients- Purified Parada (mercury)- 1 Part, Purified Gandhaka (Sulphur)- 2 part, Swarna Makshika Bhasma- 1 Part, Swarna Bhasma- 1 Part, Abhraka Bhasma- 2 Part, Loha Bhasma- 4 part, Mukta Bhasma- ½ part triturated with Bhavana Dravya such as Kantakari swaras (*Solanum xanthocarpum*), Yastimadhu (*Glycyrrhiza glabra*), Parna patra (*Piper betle*) and Goat milk.

Dose and Administration

Patients were advised to take SKCR drug (purchased from Market which is Manufactured by Dabur India Ltd., Plot No-22, Site 4, Sahibabad, Sahibabad Industrial Area, Sahibabad Industrial Area Ghaziabad, Uttar Pradesh, India) in a dose of 4 mg/kg/dose × 12 hrly (in powdered form) mixed in *Garlic: Ginger: Honey* (GGH) [in 1:2:4 ratio] to the patient and given for the 45 days.

There were three follow-up of the patient after registration at 7th, 15th and 45th day. The changes occurred during these days with the given treatment were recorded on the preformed case sheet. The investigations such as Hb gm%, TLC, DLC, ESR, LFT, urine R/M, and X-ray chest were carried out.

Parameters for Assessment of Bronchial Asthma

The clinical assessment of asthma was carried out on the basis of modified asthma scale No specific Significance of asterisk as given in Table 1.

Statistical Analysis

In the present study, SPSS software was used to get statistical data such as Mean (\bar{X}), Mean Difference (\bar{d}), Standard Deviation (SD) and Student's "t" test, etc.

Table 1: The scoring system (modified*): To assess the response of drug

Parameters	Scoring			
Breathlessness	Mild (1)	Moderate (2)	Severe (3)	Absent (0)
Talks in	May talk in sentences (1)	Phrases (2)	Words (3)	Talk normally (0)
Change in R/R (The R/R difference between the acute and normal state)	≤10/min (1)	11-20 (2)	>20 (3)	Normal (0)
Accessory muscles use	Nil or minimal (1)	Chest Indrawing (2)	Chest Indrawing, flaring up of alae nasi (3)	Absent (0)
Wheeze	Audible during expiratory phase with stethoscope (1)	Audible during both phase of respiration with stethoscope (2)	Audible in both phase of respiration without stethoscope (3)	Not audible or Absent with normal air entry (0)
Pulse/min	<100 (1)	100-120 (2)	> 120 (3)	Normal (0)
Sensorium	Anxious (1)	May be agitated (2)	Usually agitated (3)	Normal (0)
Symptoms (Episodes/week)	≤2/week (1)	>2/week (2)	Continues (3)	Absent (0)

*Modified scoring system (Gupta S et al., 2006). **Minimum – 0; while the maximum score is 24 (0=Normal; 1-8=mild; 9-16=moderate; 17-24=severe)

OBSERVATION

A total of 23 children divided into three groups such as Group 'A' (having positive history of taking bronchodilator/corticosteroids), Group 'B' (having positive history of taking bronchodilator only) and Group 'C' (patients having no history of taking steroids and bronchodilators in the past) The blood collection of asthmatic children was done for the investigations of metabolic markers viz. TLC, Hb gm%, AEC, serum protein, SGOT, SGPT, alkaline phosphatase, serum bilirubin, serum creatinine, blood urea and urine routine and microscopic at registration and on final follow-up to assess the hepatic and renal integrity. Other investigations were used to exclude the cases of other diseases from the study.

Maximum cases (86.95%) belong to the middle socioeconomic status and remaining to lower socioeconomic status (13.05%). Out of total 23 treated children with SKCR, the incidence of male children was 78.26%, while the maximum male asthmatic cases were observed in positive history of taking bronchodilator/steroid (Group A). Most of the cases were sensitive to cold (91.30%) and rhinitis (69.56%). Details of distribution of other provoking factors according to groups may be observed in Figure 1.

The cough, wheeze, breathlessness, decreased air entry in both lungs and frothy and mucoid sputum at the time of registration were the most common presenting features of disease and their incidence in children were 100%, 86.96%, 78.26%, 82.61% and 60.87%, respectively. These signs subside in maximum patients at first follow-up visit and almost all the clinical features were found absent on third follow-up visit except in one case (6.25%) having cough and wheeze as evident from Table 2.

In group A, all 11 cases had history of taking steroid and bronchodilator, seven cases (63.63%) were in mild grade

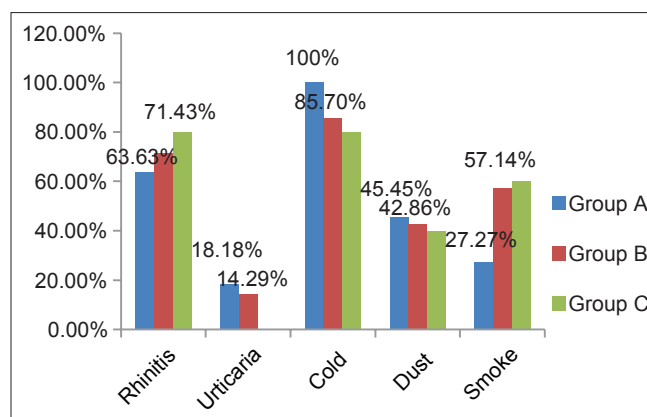


Figure 1: Details of distribution of other provoking factors according to Group

and four (36.36%) in moderate grade. The drug showing response in terms of improvement in grading of asthma on subsequent follow ups as shown in Table 3a. In Group B, all seven cases had history of taking only bronchodilator, four cases (57.14%) were in mild grade and three cases (42.8%) in moderate grade while no case in severe grade and drug shown response in subsequent follow-ups as shown in Table 3b. In group C, all five cases had no history of taking steroid and bronchodilator, three cases (60%) were in mild and two cases (40%) in moderate grade, drug showing effect on subsequent follow-ups evident from Table 3c.

On intra-group comparison, the effect of SKCR on the Hb gm%, TLC, was not found significant (>0.05) but AEC found significant as evident from the Table 4. Mean difference of Hb and TLC in the Groups A, B and C was not statistically significant as evident from paired-'t' test from the Table 5. But in (Groups A and C) AEC changes in terms of difference, mean and paired-'t' were found significant ($P < 0.05$).

Statistical difference among Groups A, B and C - In Groups A and B there is significant difference in all the values when mean difference of before treatment and after treatment

compared by using unpaired 't' test. In Groups A and C, there is significance in alkaline phosphatase (U/L) were observed when mean difference of before treatment and after treatment compared by using unpaired 't' test and other observations were not significant. In Groups B and C there is significance in AEC (/mm³) were observed when mean difference of before treatment and after treatment compared by using unpaired 't' test and other observations were not significant.

The mean of S. Protein, S. Albumin, SGOT, SGPT, S. Bilirubin and alkaline phosphatase before and after

treatment with SKCR in all groups were found insignificant. However, the mean of alkaline phosphatase after the treatment was observed higher (531.01 ± 177.45) than before treatment (497.65 ± 218.23) but again it was found statistically insignificant from the Tables 6 and 7.

To assess the integrity of liver, LFT was carried out before and after the treatment. Mean difference of S. Protein, S. Albumin, S. Bilirubin, SGOT, SGPT and Alkaline phosphatase in the Groups A, B and C (intra-group comparison) were not statistically significant except alkaline phosphatase which was found significant in Group A.

No adverse affect of the trial drugs on the kidneys was found after the urine analysis (routine and microscopic) in any form [Table 8]. The mean of urea and creatinine, before and after treatment were found insignificant. Details may be observed in Table 9.

Table 2: Incidence of clinical manifestations at registration and changes occurred during different follow ups in bronchial asthma

	Baseline (n=23) (%)	Follow-up visit (%)		
		1 st (n=23)	2 nd (n=19)	3 rd (n=16)
Clinical manifestations				
Breathlessness	18 (78.26)	6 (26.09)	4 (21.05)	0 (0)
Cough	23 (100)	6 (26.09)	5 (26.32)	1 (6.25)
Fever	11 (47.83)	0 (0.0)	2 (10.53)	0 (0.0)
Running nose	8 (34.78)	2 (8.69)	1 (5.26)	0 (0.0)
Restlessness	10 (43.48)	0 (0.0)	5 (26.32)	0 (0.0)
Expectoration (Frothy and mucoid)	14 (60.87)	3 (13.04)	2 (10.53)	0 (0.0)
Chest pain	10 (43.48)	0 (0.0)	1 (5.26)	0 (0.0)
Wheeze	20 (86.96)	7 (30.43)	2 (10.53)	1 (6.25)
B/L air entry				
Normal	4 (17.39)	20 (86.96)	15 (78.95)	15 (93.75)
Decreased (↓)	19 (82.61)	3 (13.04)	3 (15.79)	0 (0)
Crepitation	10 (43.48)	2 (8.69)	0 (0.0)	0 (0.0)
Use of accessory muscle	0 (0.0)	0 (0.0)	1 (5.26)	0 (0.0)

Table 3a: Effect of trial drug-SKCR with GGH at first, second and third follow-up on the basis of modified asthma scores-Group A

Grading of asthma	Initial (n=11) (%)	I st -FU visit (n=11) (%)	II nd -FU visit (n=11) (%)	III rd -FU visit (n=10) (%)
Mild (score-1-8)	7 (63.63)	10 (90.90)	8 (72.72)	3 (30)
Moderate (score-9-16)	4 (36.36)	0 (0.0)	0 (0.0)	0 (0.0)
Severe (score-17-24)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal (score-0)	0 (0.0)	1 (9.09)	3 (27.27)	7 (70)

SKCR – Swas-kasa-chintamani rasa; GGH – Ginger and honey

Table 3b: Effect of trial drug-SKCR with GGH at first, second and third follow-up on the basis of modified asthma scores-Group B

Grading of asthma	Initial (n=7) (%)	I st -FU visit (n=7) (%)	II nd -FU visit (n=5) (%)	III rd -FU visit (n=3) (%)
Mild (score-1-8)	4 (57.14)	5 (71.4)	2 (40)	0 (0.0)
Moderate (score-9-16)	3 (42.8)	0 (0.0)	0 (0.0)	0 (0.0)
Severe (score-17-24)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal (score-0)	0 (0.0)	2 (28.5)	3 (60)	7 (100)

SKCR – Swas-kasa-chintamani rasa; GGH – Ginger and honey

Table 3c: Effect of trial drug-SKCR with GGH at first, second and third follow-up on the basis of modified asthma scores-Group C

Grading of asthma	Initial (n=5) (%)	I st -FU visit (n=5) (%)	II nd -FU visit (n=3) (%)	III rd -FU visit (n=3) (%)
Mild (score-1-8)	3 (60)	4 (80)	1 (33.3)	0 (0.0)
Moderate (score-9-16)	2 (40)	0 (0.0)	0 (0.0)	0 (0.0)
Severe (score-17-24)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Normal (score-0)	0 (0.0)	1 (20)	2 (66.6)	3 (100)

SKCR – Swas-kasa-chintamani rasa; GGH – Ginger and honey

Table 4: Mean effect of SKCR drug in terms of Hb gm%, TLC and AEC before and after treatment of asthma

Mean difference between BT and AT	Hb%			TLC			AEC		
	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT
Mean	11.56	11.31	-0.30	8834.78	8475.00	-375.00	817.83	697.06	-264.18
± SD	1.49	1.16	1.36	2392.91	1957.38	2111.71	366.17	164.16	225.69
Paired 't' value			-0.88			-0.71			-4.68
'P' value			>0.05 NS			>0.05 NS			<0.05 S*

SKCR – Swas-kasa-chintamani rasa; TLC – Total leukocyte count; AEC – Absolute eosinophil count; Hb – Haemoglobin; AT – After treatment; BT – Before treatment; SD – Standard deviation

Table 5: Mean effect in terms of Hb gm/dl, TLC/mm³, AEC/mm³ before and after treatment of Bronchial asthma cases in Group A, B and C

Variables	Hb gm/dl			TLC/mm ³			AEC/mm ³		
	BT	AT	AT-BT	BT	AT	AT-BT	BT	AT	AT-BT
Group 'A'	11.88± 1.15	11.15± 1.20	-0.71± 1.49	8209.09± 2202.48	8410.00± 2429.20	-60.00± 1968.75	905.45± 336.49	705.50± 197.69	-242.50± 268.23
Mean±SD	(n=11)	(n=10)	(n=10)	(n=11)	(n=10)	(n=10)	(n=11)	(n=10)	(n=10)
Paired 't' and 'P' value	-1.51 >0.05 NS			-0.10 >0.05 NS			-2.86 <0.05 S*		
Group 'B'	10.66± 2.10	10.90± 1.21	0.33± 1.07	9685.71± 2722.39	9066.67± 923.76	633.33± 703.91	592.86± 297.81	682.67± 97.37	-184.00± 74.485
Mean±SD	(n=7)	(n=3)	(n=3)	(n=7)	(n=3)	(n=3)	(n=7)	(n=3)	(n=3)
Paired 't' and 'P' value	0.54 >0.05 NS			0.64 >0.05 NS			-4.28 >0.05 NS		
Group 'C'	12.10± 0.42	12.27± 0.65	0.43± 0.72	9020.00± 2421.16	8100.00± 754.98	-2433.33± 2173.32	940.00± 439.32	683.33± 125.83	-416.66± 76.37
Mean±SD	(n=5)	(n=3)	(n=3)	(n=5)	(n=3)	(n=3)	(n=5)	(n=3)	(n=3)
Paired 't' and 'P' value	1.04 >0.05 NS			-1.94 >0.05 NS			-9.45 <0.05 S*		

TLC – Total leukocyte count; AEC – Absolute eosinophil count; Hb – Haemoglobin; AT – After treatment; BT – Before treatment; SD – Standard deviation

Table 6: Effect of SKCR on SGOT, SGPT, alkaline phosphatase and showing mean effect in terms of laboratory findings before and after treatment of asthma

Mean difference between BT and AT	SGOT (U/L)			SGPT (U/L)			Phosphatase (U/L)		
	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT
Mean	36.57	34.44	-3.12	28.74	32.30	2.11	497.65	531.01	33.56
±SD	15.82	8.47	15.98	10.31	9.58	10.49	218.23	177.45	250.46
Paired 't' value	-0.78			0.81			0.54		
'P' value	>0.05 NS			>0.05 NS			>0.05 NS		

SKCR – Swas-kasa-chintamani rasa; SGPT – Serum glutamic pyruvic transaminase; SGOT – Serum glutamic oxaloacetic transaminase; AT – After treatment; BT – Before treatment; SD – Standard deviation

Table 7: Effect of SKCR on S. Protein, S. Albumin and S. bilirubin showing mean effect in terms of laboratory findings before and after treatment of asthma

Mean difference between BT and AT	S. Protein (g/dl)			S. Albumin (g/dl)			S. Bilirubin (g/dl)		
	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT
Mean	6.40	6.43	-0.08	3.93	3.89	-0.02	0.75	0.86	0.09
±SD	0.83	0.58	1.20	0.62	0.89	1.00	0.53	0.36	0.72
Paired 't' value	0.29			-0.09			0.52		
'P' value	>0.05 NS			>0.05 NS			>0.05 NS		

SKCR – Swas-kasa-chintamani rasa; AT – After treatment; BT – Before treatment; SD – Standard deviation

Table 8: Variables of urine-R/M Analysis before and after the treatment with SKCR

Variables	Urine (R and M)	
	Before treatment (n=23)	After treatment (n=16)
Pus cells	Absent	Absent
Epithelial cells	Absent	Occasional (0-1)
RBC	Absent	Absent
Albumin	Absent	Absent
Sugar	Absent	Absent
Crystal	Absent	Absent
Cast	Absent	Absent

SKCR – Swas-kasa-chintamani rasa; RBC – Red blood cells

Adverse Effect of Drug

In the present study, out of 23 patients, four developed mild problems after the ingestion of SKCR during the treatment.

Palatability (found for 1-2 minutes then subside) was a common problem faced by all patients. This is probably due to the Tikta-Katu-Kashaya rasa of the Anupana of the drug i.e., Garlic: Ginger: Honey [Table 10].

DISCUSSION

SKCR contains an inorganic mercurial preparation i.e., mercurous sulphide along with other herbomineral drugs which is not considered toxic in contrast to other studies carried out on various mercurial salts.

Many studies have been carried out on the effect of different salts of mercury. In one study, when children are exposed to mercury, including inorganic mercury, have been reported to develop a disorder called acrodynia,

Table 9: Effect of SKCR on urea and creatinine and showing mean effect in terms of laboratory findings before and after treatment of Asthma

Mean difference between BT and AT	S. Urea (g/dl)			S. Creatinine (g/dl)		
	n=23 BT	n=16 AT	n=16 AT-BT	n=23 BT	n=16 AT	n=16 AT-BT
Mean	29.37	44.12	14.57	0.80	0.86	0.03
±SD	6.23	63.48	64.97	0.16	0.19	0.245
Paired 't' value			0.90			0.50
'P' value			>0.05NS			>0.05 NS

SKCR – Swas-kasa-chintamani rasa; AT – After treatment; BT – Before treatment; SD – Standard deviation

Table 10: The adverse effect of drug during the treatment in bronchial asthma

Incidence of adverse effects	No. of patients (n=23)	
	Present	Absent
Loose stool	00	23
Burning abdominal pain or discomfort (epigastric) for 1-2 minutes	02 (8.69%)	21
Abnormal Taste (for 1-2 minutes)	23 (100%)	00
Loss of appetite	00	23
Headache	00	23
Vomiting	00	23
Defect in vision	00	23
Tics (uncontrollable muscle movement)	00	23

or “pink disease”.^[31] In patients, leg cramps, irritability, redness, peeling of the skin of hands, nose and soles of the feet. Itching, fever, sweating, salivating, rashes (including “baboon syndrome” rashes in the buttocks, anal and genital regions), sleeplessness and/or weakness,^[23] kidney damage, digestive tract problems including diarrhoea, nausea and ulcers,^[31] increased blood pressure and decreased heart rate,^[32-35] neurological effects including twitching, tics (uncontrollable muscle movements) and impaired gait have been reported in children following exposure to mercuric chloride.^[31,35,36]

Throughout the whole study no such symptoms have been reported that may be due to the processing of mercury with various herbal extracts like Kantakari swaras (*Solanum xanthocarpum*), Yastimadhu (*Glycyrrhiza glabra*), Parna patra (*Piper betel*) and Goat milk which may be nullifying its toxic impact on human health.

Therefore, the study was planned to evaluate the SKCR drug in terms to congregate more clinical data on the effect of SKCR drug in asthmatic children.

Reduction in number of patients having cough, wheeze, breathlessness, decreased air entry and achievement of normal air entry in both lungs in most of the cases ($n = 23$) are suggestive of clinical improvement during the follow ups, except in one case (6.25%) ($n = 21$) who had shown persistent cough and mild wheezing even on third follow-up while the relapse rate (as suggested by the onset of wheezing on auscultation) during the management on

second follow-up is 15.79%, as evident from Table 2. In a clinical study conducted by the Gupta *S et al.*, 2006^[23] 4.76% children ($n = 21$) had not responded to SKCR mixed with GGH on third follow-up and symptoms were persisting throughout the follow-ups while the relapse rate during the second follow-up was 11.54%.

In group ‘B’ and group ‘C’, incidence of most common features were subsided and all the patients had become asymptomatic on third follow-up. Out of seven mild and four moderate cases ($n = 11$) at registration in group-‘A’ had achieved the normal score in seven cases while the three cases has shown existence of mild score on third follow-up while in groups ‘B’ and ‘C’, all the cases ($n = 7$ and $n = 5$ respectively) have achieved normal score on third follow-up [Table 3a, 3b and 3c].

The findings suggest that the drug is more effective in those cases who are not receiving corticosteroid with bronchodilator in comparison to the patients receiving corticosteroids with or without bronchodilator.

On intra-group comparison, the effect of drug on the Hb gm% and TLC, was not found significant ($P > 0.005$) except significant improvement ($P < 0.05$) in Absolute Eosinophil Count (AEC) which was specific to ‘A’ and ‘C’ group after the treatment [Table 5] and on comparison of groups to each other (intergroup correlation), no significant hand, over the other group was observed.

After the treatment with SKCR in cases ($n = 25$), mean difference of S. protein, S. albumin, SGOT, SGPT and S. bilirubin were found insignificant ($P > 0.05$) on intra-group correlation except alkaline phosphatase in group ‘A’ ($P < 0.05$) [Tables 7 and 9].

Mean difference of S. Protein, S. Albumin, S. Bilirubin, SGOT, SGPT and Alkaline phosphatase in the subgroups A, B, and C were found statistically insignificant. On intergroup comparison among the ‘A’ vs ‘B’, ‘B’ vs ‘C’ and ‘A’ vs ‘C’ of all investigations, there was no significant change was observed except in alkaline phosphatase investigation of A vs C groups. The present study finding regarding the Liver Function Test suggest that when SKCR drug when given with GGH hepatotoxicity safe.

Acute renal failure has been observed in a number of case-studies in which mercuric chloride was ingested.^[23] But, in this study the mean blood urea and Sr. Creatinine were not altered significant when investigated after the complete course of SKCR treatment given with GGH and no findings were observed in urine R/M examination against SKCR renal safety. These findings suggest that the SKCR drug is nephrologically safe.

Vomiting, diarrhoea, severe abdominal pain, oropharyngeal pain, and ulceration and haemorrhages throughout the length of the gastro-intestinal tract have been reported in adults ingesting near lethal doses (20-30 mg/kg body weight) of mercuric chloride.^[37-39] In this study, only nausea and burning sensation in abdomen was observed and this was also due to the ingestion of garlic extract [Table 10].

CONCLUSIONS

The drug SKCR was given for a total of 45 days in a dose of 4 mg/kg/dose × 12 hourly with garlic, ginger and honey in ratio of 1:2:4. In most of the cases ($n = 23$) finding are suggestive of significant clinical improvement during the follow-ups. In present study, analysis of incidence of common features in group 'A' all the signs and symptoms were subsided except the cough and wheeze in one case (10%) on third follow-up while on second follow-up approximately 40% cases relapsed after getting fresh exposure to the trigger factors during the management. In group 'B' and group 'C', incidence of most common features were subsided and all the patients had become asymptomatic on third follow-up.

Group 'A' change in the alkaline phosphatase found significant while other metabolic markers were insignificant in all groups concludes the intact renal integrity and hepato safety.

The findings suggest that the drug is more effective in those cases who are not receiving corticosteroid with bronchodilator in comparison to children receiving corticosteroids with/without bronchodilator. SKCR is also effective in childhood bronchial asthma that has the history of steroid and bronchodilators. No specific adverse effect of drug SKCR was observed.

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