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EXPERIMENTAL EVALUATION OF KULATHAGUDA IN THE MANAGEMENT OF TAMAKASWASA W.S.R TO BRONCHIAL ASTHMA IN GUINEA PIG

Dr. Subham Pradhan[1], Mr. Choudhury Pratyush Kumar Baral[2], Ms. Kiran Anjum Jew[3], Dr. Shakti Ketan Prusty[4]

[1]PG Scholar, PG Department of Rasashastra & Bhaishajya Kalpana, Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India

[2]M.Pharm Scholar, Department of Pharmacology, School of Pharmaceutical Sciences, SOA Deemed to be University, Bhubaneswar, Odisha, India

[3] M.Pharm Scholar, Department of Pharmacology, School of Pharmaceutical Sciences, SOA Deemed to be University, Bhubaneswar, Odisha, India

[4]Associate Professor, Department of Pharmacology, School of Pharmaceutical Sciences, SOA Deemed to be University, Bhubaneswar, Odisha, India

Corresponding Author: Dr. Subham Pradhan

ABSTRACT

Bronchial asthma is a chronic inflammatory disorder of the airways characterized by reversible airway obstruction, bronchial hyper-responsiveness and recurrent episodes of wheeze and dyspnoea. In Ayurveda, it is correlated with Tamaka Swasa, caused by vitiation of Vata and Kapha in the Pranavaha Srotas. Kulathaguda is a classical Avaleha formulation described in Chakradatta under Hikka-Swasa Adhikara, indicated in Tamaka Swasa, Kasa, Jwara and Hikka.

In the present study, Kulathaguda was prepared by classical methods and its broncho-protective activity was evaluated on histamine-induced bronchospasm in guinea pigs. Eighteen healthy guinea pigs were divided into three groups (n=6): Group I – Control (normal saline), Group II – Standard (Cetirizine 1 mg/kg p.o.) and Group III – Trial (Kulathaguda 1000 mg/kg p.o.). Drugs were administered for 14 days; on day 14, animals were exposed to 1% histamine aerosol and pre-convulsive time (PCT) was recorded before and after treatment.

Kulathaguda produced significant delay in onset of pre-convulsive dyspnoea compared to control, with 48.49% protection, which was comparable to Cetirizine (46.33%). The increase in PCT in trial and standard groups was highly significant ($p<0.001$) versus control. No toxicity or abnormal behaviour was observed during acute toxicity and treatment period. Thus, Kulathaguda shows promising broncho-protective activity in histamine-induced bronchospasm in guinea pig and may be beneficial in the management of Tamaka Swasa (bronchial asthma).

KEYWORDS: *Tamaka Swasa, Kulathaguda, Bronchial asthma, Histamine induced bronchospasm, Guinea pig, Experimental Study.*

INTRODUCTION

Bronchial asthma is a chronic inflammatory condition of the airway characterized by variable airflow obstruction, bronchial hyper-responsiveness and airway inflammation, presenting clinically with episodic cough, wheeze, chest tightness and dyspnoea. In Ayurveda it can be correlated with Tamaka Swasa, wherein vitiated Vata gets obstructed by Kapha in the Pranavaha Srotas leading to difficulty in breathing and paroxysmal attacks of Swasa.

Worldwide, asthma affects nearly 300 million individuals and causes approximately 2,50,000 deaths annually. In India, an estimated 15–20 million people suffer from asthma, with a prevalence of 4–20% among school-going children in different regions and one in six children under 16 years being affected. The incidence is high in the first two years of life with peak incidence between 5–10 years, and boys are affected about twice as often as girls.

Modern management includes bronchodilators and corticosteroids, which provide symptomatic relief but are

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associated with adverse effects and do not always correct the underlying hyper-responsiveness. Ayurveda offers various Shodhana and Shamana measures for Tamaka Swasa. Among Shamana measures, Avaleha Kalpana occupies an important place due to its palatability, stability and better patient compliance. Kulathaguda, described in Chakradatta (Hikka-Swasa Adhikara 12/31–34), is indicated in Swasa, Kasa, Jwara, Hikka and Tamakaswasa. Yet, experimental validation of this formulation in bronchial asthma is limited, hence this study was undertaken.

Experimental Animals

Eighteen healthy adult guinea pigs (Cavia porcellus) of either sex, weighing 350–450 g, were used. Animals were procured from the Animal House Facility, School of Pharmaceutical Sciences, SOA Deemed to be University, Bhubaneswar. They were housed in polypropylene cages with autoclaved paddy husk bedding, under controlled conditions of 25 ± 2 °C temperature, 45–55% relative humidity and 12 h light/dark cycle. Standard pellet diet and filtered water were provided ad libitum. Animals were acclimatized for seven days prior to experimentation.

The experimental protocol was approved by the Institutional Animal Ethics Committee and all procedures followed CPCSEA guidelines for the care and use of laboratory animals.

Drugs and Chemicals

- Histamine dihydrochloride 1% solution in distilled water for aerosol induction of bronchospasm.
- Standard drug: Cetirizine 1 mg/kg body weight, prepared freshly in distilled water.
- Trial drug: Kulathaguda 1000 mg/kg body weight, suspended in warm distilled water.
- Normal saline as vehicle for control group.

All chemicals used were of analytical grade.

Dose Selection

Human therapeutic dose of Kulathaguda was converted to animal dose based on body surface area conversion, and a dose of 1000 mg/kg p.o. was selected for the trial group considering safety observed in acute toxicity study. Cetirizine dose 1 mg/kg p.o. (per os = by mouth, i.e. oral administration) . was selected as standard H1-antihistaminic reference.

Grouping of Animals

The animals were randomly divided into three groups, six animals in each:

- Group I – Control: **Normal saline** p.o.
- Group II – Standard: **Cetirizine 1 mg/kg** p.o.
- Group III – Trial: **Kulathaguda 1000 mg/kg** p.o.

All drugs were administered once daily by oral gavage for 14 consecutive days.

Acute Toxicity Study

Acute oral toxicity of Kulathaguda was carried out as per OECD guideline 423. Healthy guinea pigs were administered increasing doses of Kulathaguda and observed continuously for 4 hours and daily for 14 days for morbidity, mortality and behavioural changes such as locomotor activity, respiration, salivation, convulsions, piloerection and food and water intake. No mortality or toxic signs were observed, indicating safety of the formulation at and above the experimental dose.

Experimental procedure

Day 0 (Baseline): Each guinea pig placed individually in a transparent histamine exposure chamber (dimensions suitable for animal movement). 1% Histamine dihydrochloride solution aerosolized using calibrated nebulizer positioned outside chamber. Animals observed continuously for sequence of bronchospasm symptoms:

- Increased respiratory rate
- Sneezing/cough reflex
- Labored abdominal breathing
- Gasping
- Pre-convulsive dyspnoea (PCD) – marked gasping with outstretched neck and raised hind limbs

PCT_1 recorded as time (minutes) from histamine exposure start to PCD onset.

Day 1–14: Daily oral administration of trial and standard drugs 1 hour before same time each day. Animals monitored daily for behaviour: general activity, grooming, feeding, cage mate interaction, handling response. No abnormalities noted.

Day 14 (Post-treatment): 1 hour after final drug dose, animals exposed to 1% histamine aerosol exactly same procedure as Day 0. PCT_2 recorded. Animals immediately removed from chamber post-PCD and placed in fresh air.

Calculation of percentage protection

Percentage protection against histamine-induced bronchospasm was calculated as:

where T_1 = mean of PCT of before treatment group and T_2 = mean of PCT of after treatment group. Higher percentage indicates better broncho-protection.

Statistical Analysis

All values were expressed as Mean ± SEM (n=6). Data were analysed by one way ANOVA followed by Tukey HSD test. A p-value less than 0.05 was considered statistically significant; $p<0.01$ and $p<0.001$ were taken as highly significant.

Results

Effect on pre-convulsive time (PCT)

- **Control group** displayed **rapid onset of bronchospasm** (5.21 ± 0.18 min).
- **Cetirizine-treated animals** showed significantly delayed onset (10.47 ± 0.29 min).
- **Kulathaguda-treated animals** demonstrated comparable protection (10.56 ± 1.52 min).

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Both treatment groups exhibited **highly significant protection** **($p < 0.01$)** compared to the control.

Table no. 1 showing effect of the Kulathaguda on histamine induced Bronchoconstriction

Group	No of animals	Drugs and Dose (P.O.)	Preconvulsive time		% of protection
			PCT T1 Before Treatment	PCT T2 After treatment	
GI Control	6	Saline water	**5.78±0.48**	**5.21±0.18**	----
G II Standard drug Cetirizine	6	Cetirizine 10 mg/kg	**5.62±0.59**	**10.47±0.29**	46.33%
G III Trial drug Treated with *Kulathaguda*	6	*KulathaGuda* 1000 mg/kg	**5.44±0.71**	**10.56±1.52**	48.49%

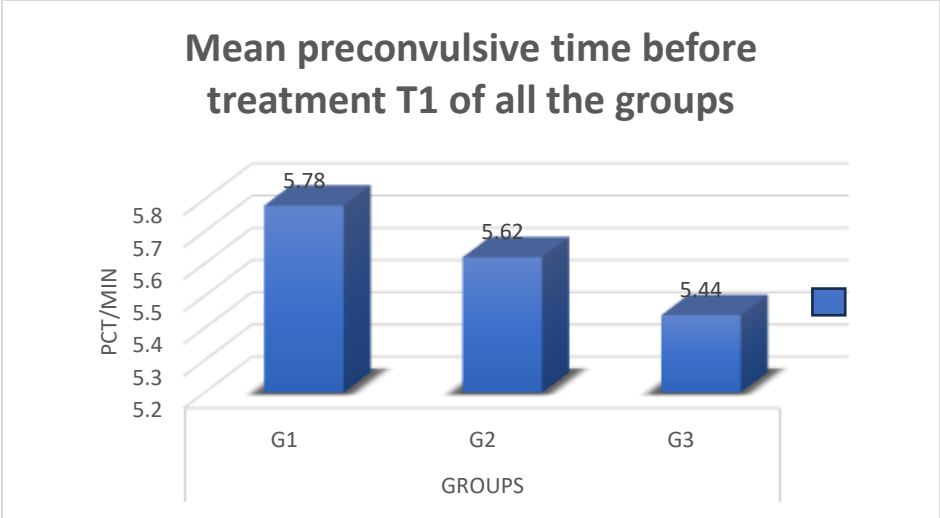
All values are Mean ± SEM, n=6. $p<0.001$ when standard and test groups were compared with control (ANOVA followed by Tukey HSD).

Before treatment (T1), there was no statistically significant difference between groups, indicating uniform baseline sensitivity to histamine. After 14 days treatment (T2), both Cetirizine and Kulathaguda significantly increased PCT compared to control ($p<0.001$).

Tukey HSD after treatment showed highly significant differences between control vs standard and control vs test ($p<0.01$), whereas the difference between standard vs test was statistically insignificant, suggesting comparable efficacy of Kulathaguda and Cetirizine.

No mortality or abnormal behaviour was observed in any group during the treatment period.

Graph No. 1



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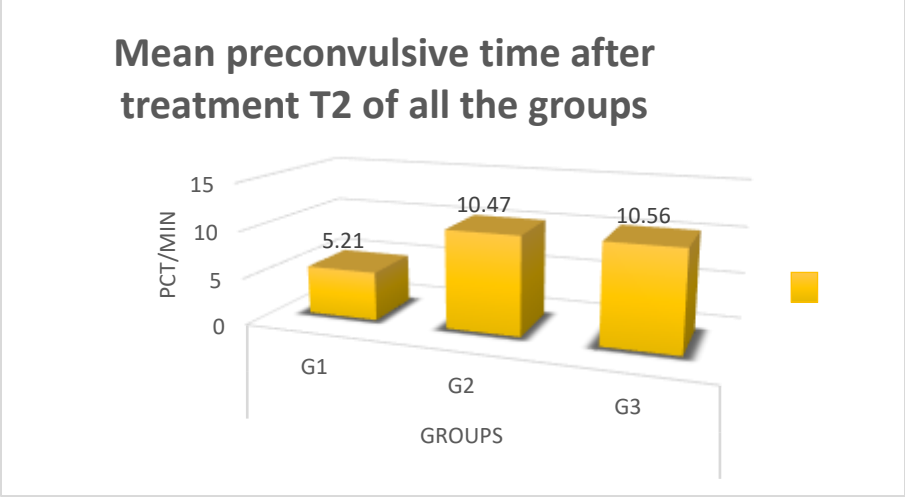
Graph No. 2



Interpretation

Kulathaguda exerts a **broncho-protective effect equivalent** to that of the standard drug Cetirizine.

Table no. 2 Preconvulsive Time Before Treatment

Control Group in minute	Standard Group in minute	Trial Group in minute
5.2	6.1	5.35
6.1	5.13	6.13
5.55	5.07	4.18
6.41	6.28	5.37
6.1	6.13	6.12
5.35	5.05	5.49

Table no. 3 Intermediate calculations ANOVA table PCT T1

Source of Variation	Degree of Freedom	Sum of Sqare	Mean Sqare
Treatments	2	0.358	0.1789
Residuals	15	5.511	0.3674
Total	17	5.869	

F =0.4871

Table no. 4 Summary of data

Group	No of Animals	Mean	Standard Deviation	Standard Error of Mean	Median
Control	6	5.78	0.48	0.198	6.10
Standard	6	5.62	0.59	0.244	6.10
Trial	6	5.44	0.71	0.291	5.49

Table no. 5 Preconvulsive time after treatment T2

Control Group in minute	Standard Group in minute	Trial Group in minute
5.22	10.33	10.39
5.55	10.4	10.12
5.14	11	13.56
5.11	10.55	9.57
5.03	10.45	9.42
5.22	10.11	10.33

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Table no. 6 Intermediate Calculations ANOVA table PCT T2

Source of Variation	Degree of freedom	Sum of sqare	Mean sqare
Treatments	2	112.74	56.37
Residuals	15	12.13	0.81
Total	17	124.87	

F = 69.58

Table no.7 Summary of data

Group	No of animals	Mean	Standard deviation	Standard error of mean	Median
Control	6	5.21	0.18	0.073	5.18
Standard	6	10.47	0.29	0.118	10.43
Trial	6	10.56	1.52	0.620	10.23

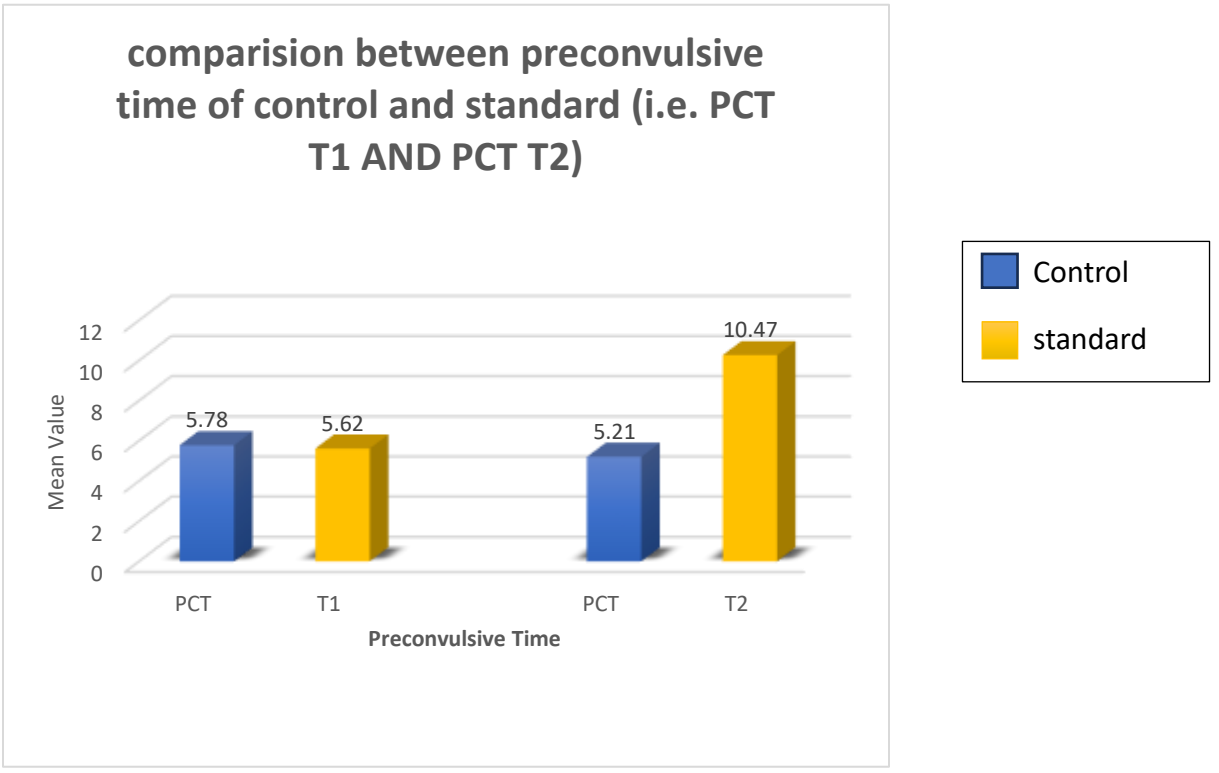
Table no. 8 Tukey HSD Analysis – Before Treatment

Treatment pair	Mean difference	Tukey HSD Q statistic	Tukey HSD P Value	Tukey HSD Interfence
Control vs standard	**0.158**	0.6399	0.8929804	Insignificant
Control vs test	**0.345**	1.3942	0.5928949	Insignificant
Standard vs test	**0.187**	0.7544	0.8474294	Insignificant

Table no. 9 Tukey HSD Analysis – After Treatment

Treatment pair	Mean difference	Tukey HSD Q statistic	Tukey HSD P Value	Tukey HSD interfence
Control vs standard	**5.26**	14.3147	0.0010053	** p<0.01
Control vs test	**5.35**	14.5641	0.0010053	** p<0.01
Standard vs test	**0.09**	0.2494	0.8999947	insignificant

Graph No. – 3



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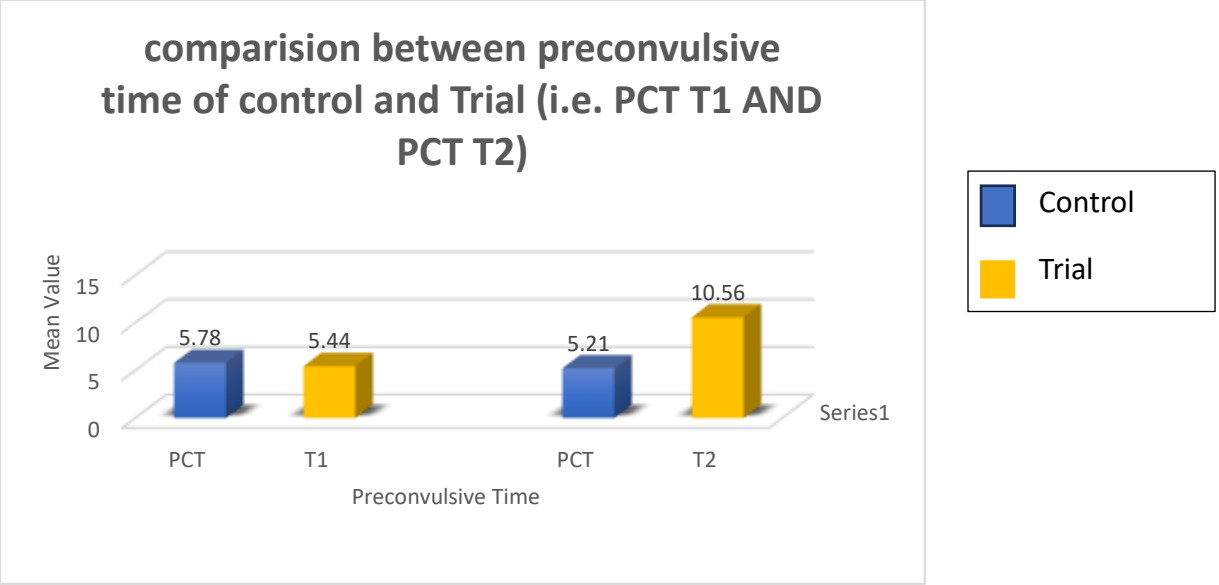
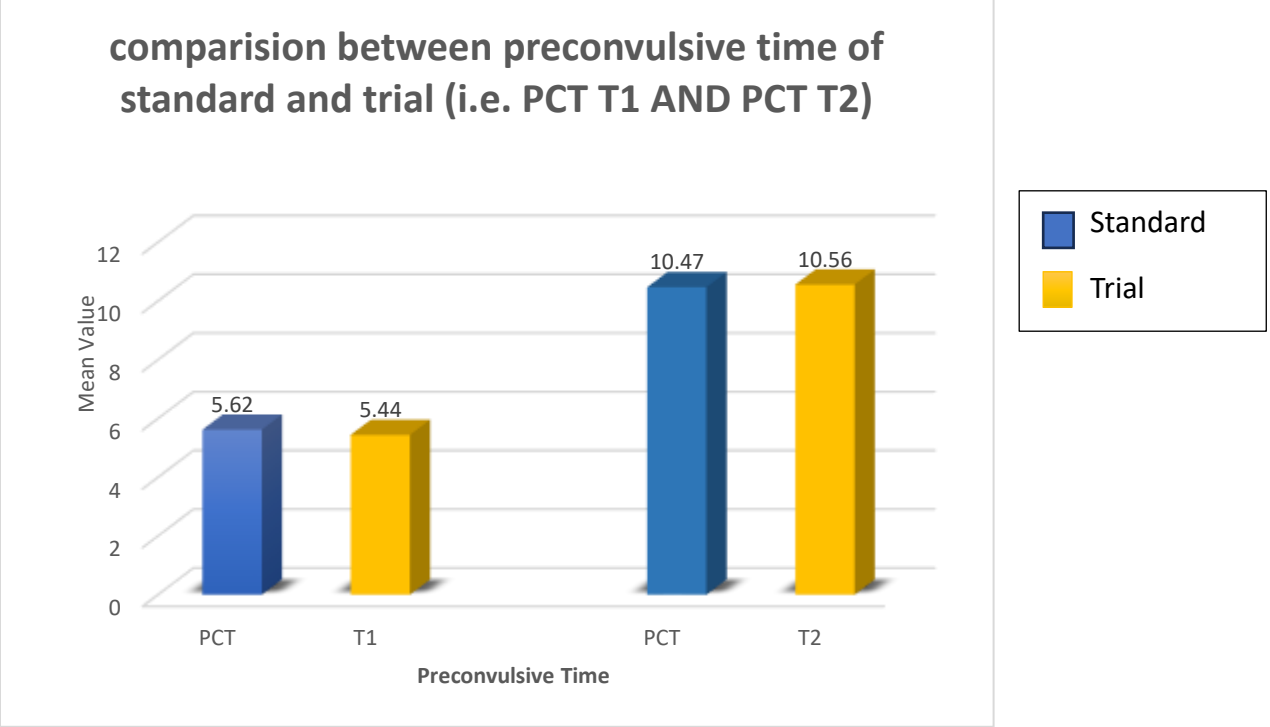
Graph no. -4



Graph No. -5



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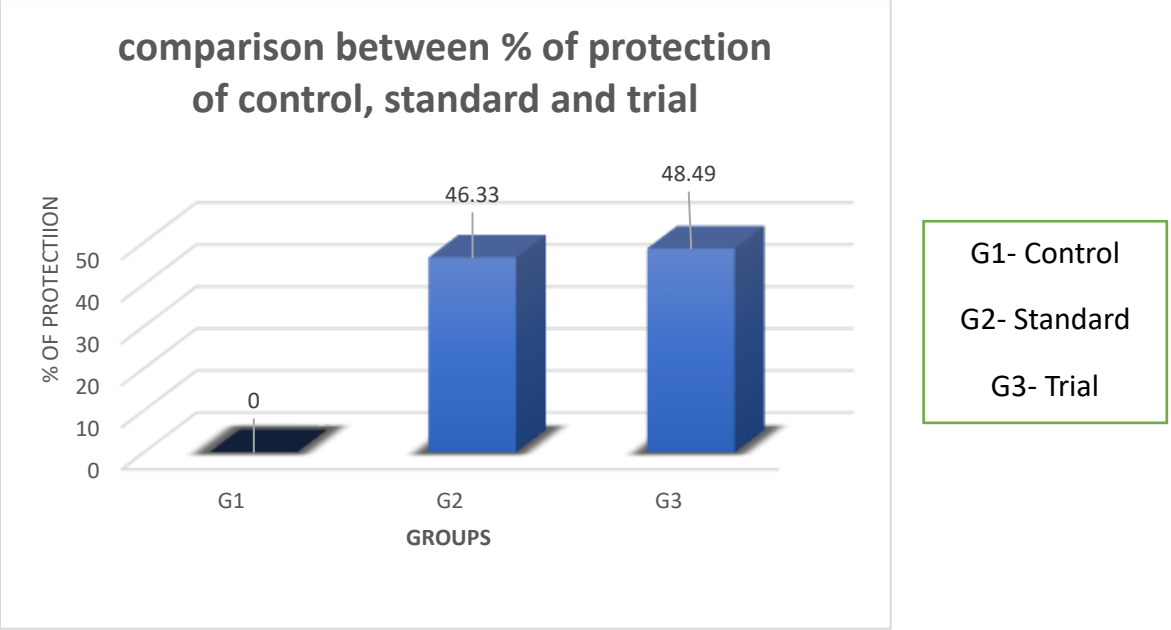
Graph No. -6



Statistical Analysis

In the **Control group (G1),** the mean pre-convulsive time was 5.21 seconds, corresponding to 0% protection, indicating rapid onset of bronchospasm after histamine exposure.

In the **Standard group (G2)** treated with **Cetirizine**, the mean pre-convulsive time increased markedly to 10.47 seconds, providing 46.33% protection compared to the control.

In the **Trial group (G3)** treated with ***Kulathaguda***, the mean pre-convulsive time further increased to 10.56 seconds, corresponding to 48.49% protection.

Among the treated groups, ***KulathaGuda*** exhibited the highest percentage protection (48.49%), which is comparable to the standard drug **Cetirizine** (46.33%), demonstrating its notable broncho-dilatory potential.

The increase in post-treatment latency time was found to be highly significant ($P < 0.001$) when compared with the control group, indicating a statistically robust therapeutic effect.

DISCUSSION

Histamine-induced bronchospasm in guinea pigs is a well-established experimental model for bronchial asthma, as guinea pig airways closely resemble human bronchi in terms of histamine sensitivity and H1 receptor distribution. Inhaled histamine produces intense bronchoconstriction, hypoxia and pre-convulsive dyspnoea, and drugs with broncho-protective activity delay the onset of these symptoms, reflected as increase in PCT.

In the present study, Kulathaguda produced a significant increase in PCT after 14 days of oral administration, with 48.49% protection against histamine-induced bronchospasm, which was comparable to Cetirizine (46.33%). The insignificant difference between standard and trial groups on tukey HSD analysis indicates that Kulathaguda exerts broncho-protective action equivalent to the standard antihistaminic drug.

The effect of Kulathaguda may be attributed to the combined pharmacological actions of its ingredients. Kulatha is described as Kapha-Vatahara with Lekhana and Medohara properties, possibly reducing airway obstruction by Kapha. Dashamoola is known for its anti-inflammatory and bronchodilatory effects, reducing airway inflammation and hyper-responsiveness. Bharangi is a well-known Swasa-Kasa hara drug having expectorant and bronchodilator actions. Pippali is documented to possess bronchodilatory, bio-availability-enhancing and anti-inflammatory properties. Twak, Ela and Patra contribute additional anti-inflammatory, carminative and mucolytic actions. Guda and Madhu facilitate drug delivery, improve palatability and act as demulcents for respiratory mucosa.

From an Ayurvedic perspective, Tamaka Swasa involves Avarana of Vata by Kapha in Pranavaha Srotas. Due to its Ushna, Tikshna, Laghu and Ruksha Gunas, Kulathaguda helps in Kapha Vilayana, removes Avarana and normalizes the Gati of Vata. Improvement in PCT in the experimental model reflects restoration of free Prana Vayu movement and reduction of bronchial obstruction.

The absence of toxic signs in acute toxicity study and during treatment indicates a wide safety margin for Kulathaguda at therapeutic doses. This is an added advantage over some modern

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anti-asthmatic drugs which may cause sedation, tachycardia or other adverse effects.

CONCLUSION

Kulathaguda Avaleha, a classical Ayurvedic formulation described in Chakradatta for Swasa-Kasa, was successfully prepared as per traditional guidelines and evaluated in histamine-induced bronchospasm in guinea pigs. The study showed that Kulathaguda significantly delayed the onset of pre-convulsive dyspnoea and provided 48.49% protection, comparable to standard drug Cetirizine.

The formulation was found to be safe in acute toxicity study and did not produce any observable behavioural or systemic adverse effects. These findings suggest that Kulathaguda possesses promising broncho-protective activity and can be considered as a potential supportive remedy in the management of Tamaka Swasa (bronchial asthma). Further clinical studies are required to validate these results in human subjects and to establish dosage, duration and therapeutic indications.

Photographic Documentation of Experimental Study in Animal Laboratory

Animal house


Housing & feeding of Guinea pig


Prep. Of 1%histamine

Trial drug solution


Cetirizine solution


Histamine solution


Histamine chamber


Feeding of trial drug


Histamine aerosol


PCT observation

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