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Evaluating The Add-on Effect of Ardraka Arka with Standard Care in Managing Tamaka Shwasa (Bronchial Asthma) in Children

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ABSTRACT

Background: Tamaka Shwasa (Bronchial Asthma), a condition of Pranavaha Srotas (respiratory tract), arises from the vitiation of Vata and Kapha Doshas, impacting the Rasa Dhatu (lymph tissue). It is clinically characterized by Shwasa Kricchrata (breathing difficulty) and Kasa (cough), resembling bronchial asthma in modern medicine. Asthma, a prevalent chronic illness in children, continues to rise in India, necessitating alternative or complementary management strategies. This randomized clinical study investigates the efficacy of Ardraka Arka, a traditional herbal formulation, as an adjuvant to standard care in managing Tamaka Shwasa in children. The aim is to address the limitations of conventional asthma treatments while exploring the potential benefits of integrating complementary therapies.

Materials and Methods: Forty children aged 5-16 years, previously diagnosed with bronchial asthma and on standard care, were randomized into two groups: Group A received standard care alone, while Group B received standard care with Ardraka Arka. Subjects with other lung pathologies or severe asthma were excluded. Clinical assessments were conducted on Day 0 and Day 29.

Observations and Results: Both groups showed significant improvement in subjective parameters. However, Group B demonstrated marked improvement in objective parameters, notably forced vital capacity (FVC) and hemoglobin percentage (Hb%), compared to the control group. Statistical analysis validated the significance of these findings.

Conclusion: The study highlights the potential of Ardraka Arka as a complementary therapy, demonstrating improvements in both clinical and objective parameters. It underscores the value of integrating traditional formulations alongside standard care in managing Tamaka Shwasa in children.

Keywords: *Pediatric Asthma, Tamaka Shwasa, Ayurveda, Ardraka Arka.*

INTRODUCTION

Asthma, a condition affecting the airways, impacts 155 million people globally [Global Initiative for Asthma (2021)]. Over the past four decades, its prevalence and severity among children have risen significantly, with rates ranging from 5-30% across populations [Gupta et al. (2001)]. In India, respiratory disorders are the most common childhood ailments, with over 30% of children experiencing allergic conditions often leading to bronchial asthma—a rapidly growing concern [Kaur et al. (1998)]. Despite historical records and ongoing efforts, asthma remains inadequately controlled, with morbidity and mortality rates continuing to rise due to a lack of standardized population-based data.

Tamaka Shwasa, an illness of Pranavaha Srotas originating in the Pittasthana, is caused by the vitiation of Vata and Kapha Doshas, affecting the Rasa Dhatu. It manifests as Shwasa Kruchrata, Kasa, and Ghurghuraka and is described in Ayurveda as a Yapya Vyadhi [(Charaka Samhita, 2011)]. Its clinical symptomatology resembles bronchial asthma, a heterogeneous

disease defined by recurrent wheezing, breathlessness, chest tightness, and cough due to chronic airway inflammation and hyperresponsiveness, which are reversible and variable. [(Gohel et al., 2011)(Indian Academy of Paediatrics, n.d.)]

PREVALENCE: Bronchial asthma is the most common chronic disease in childhood, affecting 6% of children and 2% of adults in India. [(Global Asthma Network, 2018)] By 2025, an additional 100 million cases are expected globally [(Dharmage et al., 2019)]. A 2021 study in North Karnataka reported a 4% prevalence of asthma among children aged 5-16 years, while Mysore data showed a prevalence of 17.14% in children aged 6-14 years [Rashmi et al. (2021) Sanjana et al. (2014)]. Factors contributing to the increasing prevalence include atmospheric pollution (Rajodhuma), dietary changes, excessive exercise (Vyayama), and psychological stress [(Sri Madhavakara, 2017)]. Childhood asthma significantly impacts school attendance, family dynamics, and socio-economic conditions, often leading to complications like sinusitis, allergic rhinitis, and psychological issues [(Mrazek, 1992)]. Contemporary challenges in paediatric asthma management include growth delays, behavioural issues, and oral candidiasis due to inhaled corticosteroids [Indian Academy of Pediatrics (2022)]. Asthma is often misdiagnosed as bronchitis, resulting in repeated courses of inappropriate medication. While the adage "not all that wheezes is asthma" holds, it is critical to consider wheezing as asthma unless proven otherwise. Despite advances, asthma care often falls short, leaving patients without basic management. Studies on Tamaka Shwasa in children remain scarce, underscoring the need for standardized diagnostic and treatment protocols that address both parental concerns and child well-being.

Arka Kalpana, introduced in the 18th century, is a method of extracting essences from medicinal plants. Ardraka Arka is described in Arka Prakasha as effective for Shwasa Roga [Tripathi et al. (2008),Shaikh & Chondikar (2020)]. With its Ushna Virya and Vata Anulomana properties, Ardraka acts on Kapha to alleviate airway obstruction in Tamaka Shwasa. Studies confirm its anti-asthmatic properties [Gogte (2009)]. Arka is fast-acting (Shighrakari) and free from Dosha vitiation, making it ideal for managing this condition.

MATERIALS AND METHODS

A randomized, controlled pilot study was conducted to evaluate the efficacy of Ardraka Arka alongside standard care in children aged 6–15 years with Tamaka Shwasa.

2.1. Preparation of the drug

Raw drugs were sourced from the local market and authenticated by the Department of Dravya Guna, JSSAMC, Mysuru. The medicine was prepared at NKCA Pharmacy, a GMP-certified unit in Mysuru. Ardraka (1 part) was cleaned, crushed, and placed in a distillation apparatus with 10 parts of water. The mixture was heated, and the vapor was condensed, discarding the initial drops. The distillate was collected until the water volume was reduced by half and then stored in bottles.

2.2 Research Design:

The study was an interventional, randomized, standard-controlled pilot clinical study with a sample size of 20 participants in each group. This sample size was chosen due to the pilot nature of the research, accounting for potential dropouts. The selection criteria included subjects already diagnosed with Bronchial Asthma who met the inclusion criteria and provided informed written consent. The study was conducted at the Department of PG Studies in Kaumarabhritya, JSS Ayurvedic Medical College and Hospital, Mysuru, Karnataka.

2.3 Sample Size:

As the present is the pilot study 40 children were selected. Forty children diagnosed with mild to moderate Tamaka Shwasa were randomly assigned into two groups:
Group A (Trial): Ardraka Arka + standard care (n=20).
Group B (Control): Standard care only (n=20).

2.4 Ethical clearance and CTRI:

Ethical clearance was obtained from the Institutional Ethical Committee and the trial was registered.

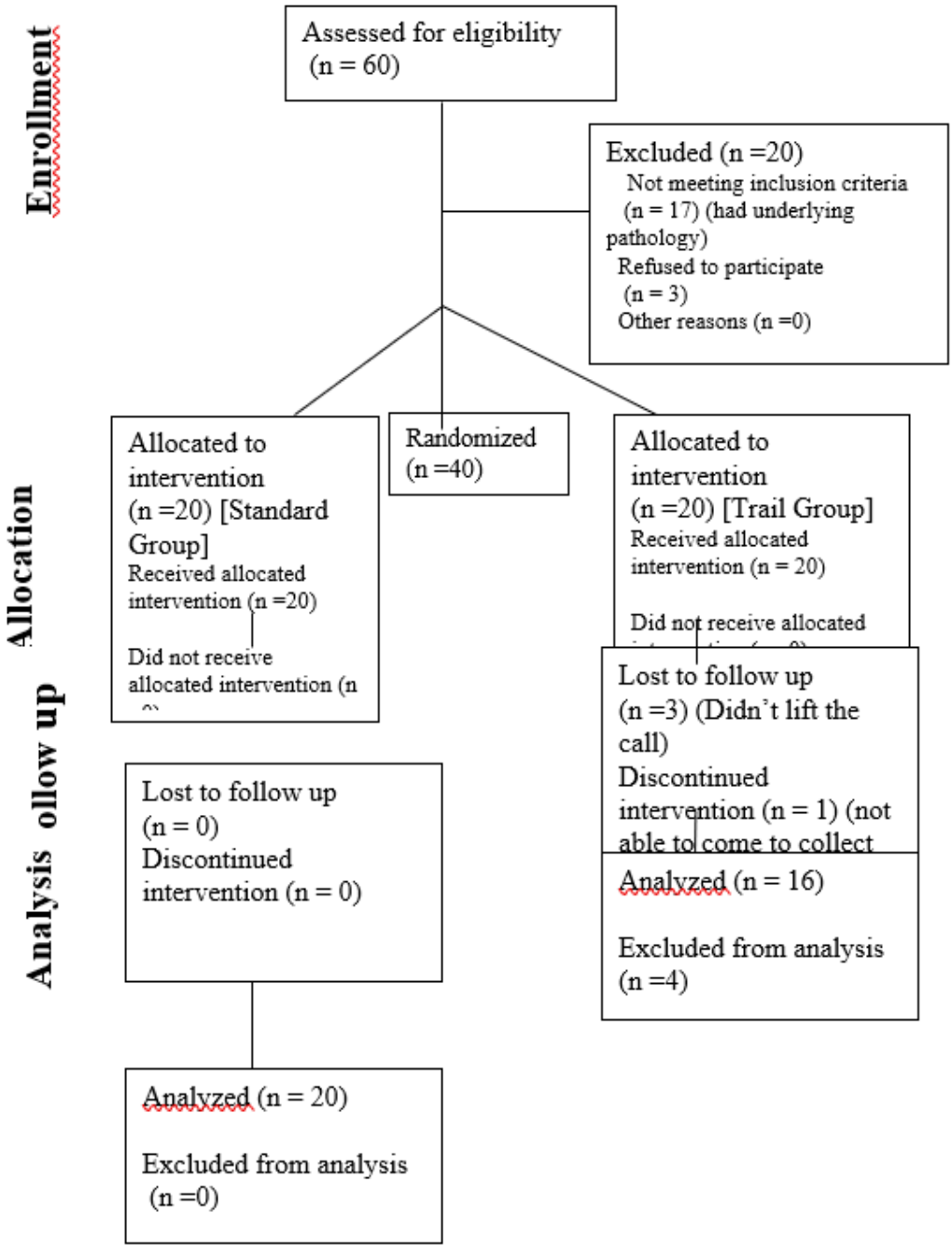
2.5 Participants:

Subjects of either gender diagnosed to be suffering from Tamaka Shwasa, coming under the inclusion criteria have been selected from the OPD and IPD of the Department of Kaumarabhritya, JSS Ayurveda Medical College and Hospital and JSS Medical College and Hospital, Mysuru, Medical camps and other referrals.

Inclusion Criteria:

The study included subjects diagnosed with Bronchial Asthma/Tamaka Shwasa who were already receiving modern medications. Participants aged 6-15 years, regardless of gender, religion, caste, or socio-economic status, were eligible. The subjects also needed to exhibit clinical symptoms of Tamaka Shwasa/Bronchial Asthma and fall under the mild persistent, mild intermittent, or moderate persistent types of asthma as classified by Nelson.

Exclusion Criteria:
The study will exclude subjects who were admitted to the hospital due to asthma exacerbation within 4 weeks before the visit, as well as individuals with any known uncontrolled systemic disease. Additionally, patients with severe persistent asthma will not be included, along with those who have a history of any other diagnosed lung pathology. Lastly, subjects who are incompatible with spirometry evaluation due to physical or other limitations will also be excluded from the study.



RESULTS:
3.1 Observations In this study of 40 participants (4 dropouts from the Trial Group), equal age representation (6-9 and 10-15 years) was observed. The Trial Group was male-dominant, while the Control Group had a balanced gender ratio. Socioeconomic status differed, with the Control Group predominantly middle class, while the Trial Group was evenly split between lower and middle classes. Both groups were mostly rural, Hindu, and mixed diet followers, with similar bowel habits and asthma triggers. Asthma severity improved more in the Trial Group, with moderate cases dropping significantly and mild cases increasing. Nebulization, inhaler, and oral drug use reduced more substantially in the Trial Group compared to the Control Group. These results suggest that Ardraka Arka may offer significant add-on benefits in managing Tamaka Shwasa (bronchial asthma) in children.

3.2 On subjective and Objective parameters:

Table No.1: Subjective parameter within the Trial group

Variables	N	Median	IQR	Z-Value	p-value	Remarks
BT Shwasa Kruchrata	16	2	(1-3)			
AT Shwasa Kruchrata	16	1	1(1)	2.7778	0.0054	S
BT Ghurghuraka Shabda	16	1.5	(1-2)			
AT Ghurghuraka Shabda	16	1	(0.75-1)	2.6058	0.00916	S
BT Kasa	16	1.5	(1-2)			
AT Kasa	16	1	(0-1)	2.602414	0.0092	S
BT Peenasa	16	2	(0.75-2)			
AT Peenasa	16	2	(0-1)	2.9178	0.003524	S
BT Anidra	16	2	(0.75-2)			
AT Anidra	16	1	(0-1)	2.341236	0.01922	S
BT Asino Labhate Sukam	16	1	(0-2)			
AT Asino Labhate Sukam	16	0	(0-.025)	2.917898	0.003524	S

The results demonstrated in Table No.1 shows a statistically significant improvement in the symptoms of Tamaka Shwasa (bronchial asthma) following treatment. Key symptoms such as Shwasa Kruchrata (difficulty in breathing), Ghurghuraka Shabda (wheezing sounds), Kasa (cough), Peenasa (nasal discharge), Anidra (sleeplessness), and Asino Labhate Sukam (difficulty sleeping lying down) showed a notable reduction in their median scores from the "Before Treatment" (BT) phase to the "After Treatment" (AT) phase. The reductions were supported by significant Z-values and p-values (all below 0.05), indicating the efficacy of the intervention. These findings suggest that the treatment was effective in alleviating the severity of symptoms in the study population. In both the groups, parameters kashtena sleshma moksha, vishushkasya and ushnaabhinandthi couldn't be assessed due tied valves.

Table No.2: Subjective parameter within the Control group

Variables	N	Median	IQR	Z-Value	p-value	Remarks
BT Shwasa Kruchrata	20	2	1.75-2			
AT Shwasa Kruchrata	20	1	1-1.25	3.22	0.001	S
BT Ghurghuraka Shabda	20	1	1-2			
AT Ghurghuraka Shabda	20	1	0-1	2.22	0.02	S
BT Kasa	20	2	2			
AT Kasa	20	1	0-1	3.24	0.001	S
BT Peenasa	20	1	0-2			
AT Peenasa	20	0	0-1	2.74	0.006	S
BT Anidra	20	2	1-2			
AT Anidra	20	1	0.75-1.25	3.17	0.001	S
BT Asino Labhate Sukam	20	1	0.75-2			
AT Asino Labhate Sukam	20	0	0-1	2.07	0.03	S

Table No.2 shows the study showed significant improvement in Tamaka Shwasa (bronchial asthma) symptoms post-treatment. Median scores for Shwasa Kruchrata, Ghurghuraka Shabda, Kasa, Peenasa, Anidra, and Asino Labhate Sukam all decreased significantly ($p < 0.05$), with Z-values ranging from 2.07 to 3.24. These results highlight the treatment's effectiveness in reducing asthma severity.

Table No.3: Objective parameter within the Trial group

Variables	N	Mean	SD	t value	p-value	Remarks
BT Hb gm/dl	16	11.97	1.06			
AT Hb gm/dl	16	12.96	1.13	6.5247	0.0000	S
BT ESR mm/hr	16	29.75	21.87			
AT ESR mm/hr	16	20.06	11.78	2.1314	0.051583	NS
BT AEC cells/cumm	16	652.8	324.80			
AT AEC cells/cumm	16	373.7	152.11	5.1833	0.0001113	S
BT FVC	16	84.111	14.45			
AT FVC	16	96.00	9.77	3.3365	0.004508	S
BT FEV1	16	73.231	19.98			
AT FEV1	16	89.5132	11.17	3.2781	0.0050	S
BT ACQT	16	13.93	3.55			
AT ACQT	16	20.00	3.74	-8.2078	0.00000063	S
BT Neutrophils	16	62.0	11.51			
AT Neutrophils	16	59.57	5.63	0.7319	0.4755	NS
BT Lymphocytes	16	28.06	11.62			
AT Lymphocytes	16	31.38	5.24	1.0834	0.2957	NS
BT Eosinophils	16	5.612	2.93			
AT Eosinophils	16	4.625	1.36	1.9586	0.050	NS
BT Monocytes	16	3.881	1.86			
AT Monocytes	16	4.438	2.36	0.92082	0.3717	NS
BT WBC(TC) cells/cumm	16	11109	2552.12			
AT WBC(TC) cells/cumm	16	8402	1664.32	5.2803	0.000092	S

Table No.3 shows analysis demonstrated significant post-treatment improvements in several parameters, including an increase in hemoglobin (11.97 ± 1.06 to 12.96 ± 1.13, $p < 0.0001$) and reductions in Absolute Eosinophil Count (652.8 ± 324.80 to 373.7 ± 152.11, $p < 0.0001$) and White Blood Cell count (11,109 ± 2,552.12 to 8,402 ± 1,664.32, $p < 0.0001$). Pulmonary function improved significantly, with increases in FVC (84.11 ± 14.45 to 96.00 ± 9.77, $p = 0.0045$) and FEV1 (73.23 ± 19.98 to 89.51 ± 11.17, $p = 0.005$). Asthma Control Questionnaire scores also improved notably (13.93 ± 3.55 to 20.00 ± 3.74, $p < 0.0001$). While ESR and Eosinophil percentage showed trends toward improvement, they were not statistically significant ($p = 0.051583$ and $p = 0.050$). Changes in Neutrophils, Lymphocytes, and Monocytes were minimal. These results suggest substantial improvements in hemoglobin, pulmonary function, and inflammatory markers, with less pronounced effects on other hematological parameters.

Table No.4: Objective parameter within the Control group

Variables	N	Mean	SD	t value	p-value	Remarks
BT Hb gm/dl	20	12.79	0.89			
AT Hb gm/dl	20	12.88	1.02	0.42061	0.6788	NS
BT ESR mm/hr	20	31.85	21.72			
AT ESR mm/hr	20	21.9	13.24	2.0930	0.003404	S
BT AEC cells/cumm	20	563.4	407.99			
AT AEC cells/cumm	20	392.75	204.89	2.093024	0.006246	S
BT FVC	20	94.77	15.16			
AT FVC	20	106.05	10.33	4.285	0.0003	S
BT FEV1	20	86.431	19.43			
AT FEV1	20	97.037	14.27	3.3749	0.003985	S
BT ACQT	20	14.30	4.17			
AT ACQT	20	21.05	4.26	7.0764	0.0000098	S
BT Neutrophils	20	59.30	9.62			
AT Neutrophils	20	57.25	11.13	0.9214	0.384	NS
BT Lymphocytes	20	29.9	8.04			
AT Lymphocytes	20	32.20	10.27	1.364	0.1885	NS
BT Eosinphils	20	6.06	2.93	2.09302	0.04378	S

AT Eosinphils	20	4.335	1.36			
BT Monocytes	20	4.71	2.40			
AT Monocytes	20	6	2.15	2.5833	0.018	S
BT WBC(TC) cells/cumm	20	11549	2912.28			
AT WBC(TC) cells/cumm	20	9572	2765.37	3.436	0.003	S

Table No.4 shows the analysis indicates significant improvements in several hematological and pulmonary parameters after treatment. Erythrocyte Sedimentation Rate (ESR) showed a notable reduction, with the mean decreasing from 31.85 ± 21.72 to 21.9 ± 13.24 ($t = 2.093$, $p = 0.0034$). Similarly, Absolute Eosinophil Count (AEC) decreased significantly from 563.4 ± 407.99 to 392.75 ± 204.89 ($t = 2.093$, $p = 0.0062$). Pulmonary function parameters also improved, with Forced Vital Capacity (FVC) increasing from 94.77 ± 15.16 to 106.05 ± 10.33 ($t = 4.285$, $p = 0.0003$) and Forced Expiratory Volume in 1 second (FEV1) rising from 86.43 ± 19.43 to 97.04 ± 14.27 ($t = 3.3749$, $p = 0.004$). Furthermore, Asthma Control Questionnaire (ACQT) scores improved significantly, with a mean increase from 14.30 ± 4.17 to 21.05 ± 4.26 ($t = 7.0764$, $p < 0.0001$).

Additionally, Eosinophil percentage showed a reduction from 6.06 ± 2.93 to 4.34 ± 1.36 ($t = 2.093$, $p = 0.0438$), and Monocyte percentage increased from 4.71 ± 2.40 to 6 ± 2.15 ($t = 2.5833$, $p = 0.018$). White Blood Cell (WBC) count also reduced significantly from 11,549 ± 2,912.28 to 9,572 ± 2,765.37 ($t = 3.436$, $p = 0.003$). However, changes in Hemoglobin (Hb) levels, Neutrophils, and Lymphocytes were not statistically significant ($p > 0.05$). These findings demonstrate the efficacy of the treatment in reducing inflammation, improving pulmonary function, and alleviating asthma symptoms, with less impact on other hematological parameters.

Table No.5: Subjective parameters- Between the group

Variable	AT	Group	N	Median	IQR	Z value	p-value
Shwasa Kruchrata	AT	Control	20	1	(1-1.25)	0.7092	0.4782
		Trial	16	1	-1		
Ghurghurak Shabda	AT	Control	20	1	(0-1)	0.324786	0.7455
		Trial	16	1	(0.75-1)		
Kasa	AT	Control	20	1	(0-1)	1.0848	0.278
		Trial	16	1	(0-1)		
Peenasa	AT	Control	20	0	(0-1)	0.61009	0.5418
		Trial	16	1	(0-1)		
Kashtena shlesma Moksha	AT	Control	20	0	(0-1)	1.03944	0.2986
		Trial	16	0	(0-0.25)		
Anidra	AT	Control	20	1	(0.75-1.25)	0.40878	0.6827
		Trial	16	1	(0-1)		
Asino Labhate sukam	AT	Control	20	0	(0-1)	1.205009	0.2282
		Trial	16	0	(0-0.25)		
Ushnabhinandathi	AT	Control	20	0	(0-1)	0.1318537	0.8951
		Trial	16	0	(0-1)		
Vishushkasya	AT	Control	20	0	(0-1)	1.3355	0.1817
		Trial	16	0	(0-0.25)		

The comparative analysis of post-treatment outcomes in table No.5 between the Control and Trial groups reveals no statistically significant differences in the assessed variables, as all p-values exceed the threshold of 0.05. Shwasa Kruchrata (difficulty in breathing) had a median of 1 in both groups, with an IQR of (1–1.25) in the Control group and (-1) in the Trial group ($Z = 0.7092$, $p = 0.4782$). Ghurghuraka Shabda (wheezing sounds) also showed no significant difference, with medians of 1 and IQRs of (0–1) for the Control group and (0.75–1) for the Trial group ($Z = 0.3248$, $p = 0.7455$).

Similarly, variables such as Kasa (cough), Peenasa (nasal discharge), Kashtena Shlesma Moksha (difficulty expelling phlegm), Anidra (sleeplessness), and Asino Labhate Sukam (difficulty sleeping lying down) demonstrated comparable medians and overlapping IQRs between the groups, with p-values ranging from 0.2282 to 0.6827. Other parameters like Ushnabhinandathi and Vishushkasya also showed no significant differences, with Z-values of 0.1319 ($p = 0.8951$) and 1.3355 ($p = 0.1817$), respectively.

These results suggest that both the Control and Trial groups experienced similar improvements post-treatment, with no significant advantage observed in the Trial group for these specific variables.

Table No.6: Objective parameters- Between the group

Variable	BT/AT	Groups	N	Mean	Difference	%	SD	t-value	P-value	Remarks
		control	20	12.79			0.89			
	BT	Trial	16	11.97	0.82	6.411259	1.06	2.4549	0.0202	S
		control	20	12.88			1.02			
Hb	AT	Trial	16	12.96	-0.08	-0.61728	1.13	0.19625	0.8457	NS
		control	20	57.25			11.13			
Neutrophils	AT	Trial	16	59.56	-2.31	-3.87844	5.63	0.80845	0.4254	NS
		control	20	32.2			10.27			
Lymphocyte	AT	Trial	16	31.38	0.82	2.546584	5.24	0.31211	0.75572	NS
		control	20	4.335			1.36			
Eosinophils	AT	Trial	16	4.625	-0.29	-6.27027	1.36	0.46885	0.6424	NS
		control	20	4.71			2.4			
	BT	Trial	16	3.881	0.829	17.60085	1.86	1.1677	0.2511	NS
		control	20	6			2.15			
Monocytes	AT	Trial	16	4.438	1.562	26.03333	2.36	2.0493	0.04903	S
WBC		control	20	9572			2765.37			
AT		Trial	16	8402	1170	12.22315	1664.32	1.5691	0.1265	NS

Table No.7: Objective parameters- Between the group

Variable	BT/AT	Groups	N	Mean	Difference	%	SD	t-value	P-value	Remarks
ESR		control	20	21.9			13.29			
AT		Trial	16	20.0625	1.8375	8.390411	11.78	0.4332	0.6676	NS
AEC		control	20	392.75			204.89			
AT		Trial	16	373	19.75	5.294906	152.11	0.32016	0.7508	NS
FEV1		control	20	99.15			19.48			
AT		Trial	16	90.81	8.34	8.411498	11.18	1.9651	0.05782	NS
FVC		control	20	94.77			15.76			
BT		Trial	16	84.111	10.66	11.17405	14.45	2.1902	0.0357	S
FVC		control	20	106.05			10.33			
AT		Trial	16	96.008	10.042	9.28972	9.77	2.9698	0.00555	S
ACQT		control	20	21.05			4.26			
AT		Trial	16	20.88	0.17	0.807601	3.74	0.7864	0.4371	NS

Table No.6 the analysis of hematological parameters revealed significant differences in baseline hemoglobin (Hb) levels, with the Trial group (11.97 ± 1.06) showing lower values than the Control group (12.79 ± 0.89, p = 0.0202). Post-treatment, Hb levels improved in both groups without significant differences (p = 0.8457). Neutrophil, Lymphocyte, and Eosinophil percentages showed no significant differences post-treatment (p > 0.05), but Monocyte percentage improved significantly in the Control group (p = 0.049), while the Trial group showed no change. WBC counts were lower in the Trial group post-treatment but not significantly different (p = 0.1265). Overall, both groups showed improvements, with notable differences favoring the Control group in Monocyte percentage and baseline Hb levels.

Table No.7 shows Post-treatment analysis revealed no statistically significant differences between the Control and Trial groups for ESR (21.9 ± 13.29 vs. 20.06 ± 11.78, p = 0.6676), Absolute Eosinophil Count (392.75 ± 204.89 vs. 373 ± 152.11, p = 0.7508), and Asthma Control Questionnaire Tool scores (21.05 ± 4.26 vs. 20.88 ± 3.74, p = 0.4371). While FEV1 showed improvement in both groups, the difference (8.34, p = 0.05782) approached but did not reach statistical significance. However, Forced Vital Capacity (FVC) demonstrated significant differences both at baseline and post-treatment, with the Control group consistently outperforming the Trial group (baseline: p = 0.0357, post-treatment: p = 0.00555), indicating a notable improvement in lung function for the Control group.

DISCUSSION

Discussion on the Trial Drug:

Ardraka Arka recognized as the most potent among various formulations like Kalka, Churna, Swarasa, and Taila, Arka is Dosha Rahitam and Sheeghrakari (fast-acting), making it Gunasanghprakashkam.[Pujari et al. (2014a)] Its extended shelf life enhances compliance, reduces the dosage of other medications, and serves both preventive and curative purposes. The trial drug, Ardraka Arka, as described in Panchashatakam of Arka Prakasha, is an add-on therapy that improves bioavailability of standard treatments. With its Ushna Virya and Vataanulomana properties, it targets Kapha Dosha in Tamaka Shwasa, clearing obstructions in Pranavaha Srotas caused by Kapha.

The distillation process concentrates essential oils and bioactive compounds (e.g., gingerols, shogaols), enhancing the extract's potency.[springer.com] Ginger inhibits P-glycoprotein, improving drug absorption and bioavailability of asthma drugs.[Oxford Academic (oup.com)] Additionally, it inhibits CYP3A4 enzymes, increasing plasma concentrations and therapeutic effects.[researchgate.net] Distillation also removes impurities, enhances stability, and improves solubility of bioactive compounds, converting gingerols into shogaols for better bioavailability and anti-inflammatory effects.

As an Anupana, Madhu acts as a Yogavahi, enhancing drug delivery, absorption, bioavailability, and tissue penetration (Sookshma marga anusari). It possesses Rasayana properties [(MedlinePlus, 2023)] and Lekhaniya Guna, aiding in Kapha Vilayana and improving palatability for synergistic therapeutic effects.

Discussion on observations:
Before the use of the trial drug, nebulization was used by 75% of participants, but after the intervention of Ardraka Arka, this reduced to 35%. Similarly, inhaler use dropped significantly in the trial group, from 100% to 43%, compared to 80% in the control group. The usage of oral drug like anti-histamine and Montelukast led to a 52.5% reduction in the trial group, while the control group saw only a 25% reduction, highlighting the superior effectiveness of the trial drug. This can be explained by ginger's known anti-inflammatory and bronchodilator.[(Seki et al., 2011)] effects. Ginger contains bioactive compounds like gingerol and shogaol, which inhibit pro-inflammatory enzymes and cytokines, reducing airway inflammation commonly seen in asthma. Additionally, ginger helps relax bronchial smooth muscles by modulating calcium uptake, improving airflow and reducing bronchospasm. The ability of Ardraka Arka to reduce airway resistance and inflammation provides evidence for its beneficial role in managing asthma symptoms alongside conventional treatments.

DISCUSSION ON RESULTS:
Ginger's active compounds, gingerols, and shogaols help relax airway smooth muscles, aiding in bronchodilation and easing airflow, especially when combined with beta-agonists like Salbutamol. Ginger also reduces inflammation by inhibiting pro-inflammatory cytokines (TNF-α, IL-1β, IL-6) and NF-κB activation, complementing Budesonide's effects. It further, modulates eicosanoid pathways,[(Zick et al., 2015)] decreases leukotriene and prostaglandin production, and stabilizes mast cells, reducing histamine release. Ginger lowers eosinophil activity, enhancing Budesonide's impact in reducing airway inflammation. Ardraka Arka when combined, might have provided a synergistic, multi-faceted approach to improving asthma control in children.

The Mucolytic Action of Ginger might have helped reduce mucus viscosity, facilitating its clearance from airways and mitigating cough. This supports the action of leukotriene receptor antagonists (e.g., Montelukast).[(Ayustaningwarno et al., 2024)] Also, Studies have shown that Ginger neutralizes reactive oxygen species (ROS), reducing oxidative stress in the lungs, which contributes to airway inflammation and cough.

Ginger's bioactive compounds, including gingerols, shogaols, and zingerone, have antiviral and antimicrobial properties that help mitigate respiratory infections linked to colds and asthma exacerbations. Ginger inhibits viral replication, particularly in respiratory syncytial virus (RSV) and human rhinovirus, blocking viral entry into cells.[onlinelibrary.wiley.com] which are the most common causes of cold. It also targets bacteria like Streptococcus pneumoniae and Haemophilus influenzae, reducing secondary infections by disrupting bacterial cell walls.

This specific antiviral and antibacterial [mdpi.com] actions of ginger prevent or mitigate respiratory infections that can lead to cold symptoms and asthma exacerbations, supporting the standard management of asthma by reducing infection-related complications.

Ginger and its bioactive constituents, including 6-gingerol, 8-gingerol, 6-shogaol, citral, and eucalyptol, these compounds may help alleviate wheezing by mediating them through the induction of relaxation in airway smooth muscle and the attenuation of airway resistance and inflammation. [(Gholamnezhad et al., 2019)]

Studies have demonstrated that ginger possesses strong anti-inflammatory properties, [(Townsend & Emala, 2013)] primarily by inhibiting pro-inflammatory cytokines and the NF-κB pathway, which leads to reduced airway swelling and mucus production. It also blocks the 5-lipoxygenase enzyme, lowering leukotriene levels and thereby preventing bronchoconstriction and mucus accumulation. Furthermore, ginger stabilizes mast cells, minimizing histamine release and airway inflammation, and also reducing the eosinophil activity to decrease airway hyperresponsiveness. [(Li et al., 2020)] These combined effects might have made Ardraka Arka an effective adjunctive therapy for alleviating breathing difficulties during pediatric asthma exacerbations.

On Objective Parameters:
The trial group showed notable improvement in Forced Vital Capacity (FVC), indicating that Ardraka Arka positively impacted lung function. The gingerols and shogaols in Ardraka Arka promote bronchodilation by relaxing airway smooth muscles, relieving breathlessness and wheezing, especially when combined with beta-agonists like Salbutamol. Ginger also reduces pro-inflammatory cytokines (TNF-α, IL-1β, IL-6) and stabilizes mast cells, decreasing leukotrienes and

prostaglandins, which improves airway function and reduces asthma symptoms. Studies have shown a direct correlation between ginger intake, increased FVC, and reduced asthma symptoms. [(Usmani et al., 2019)]

In the trial group, Hb% increased significantly from 11.96% to 12.96%. This may be due to the add-on effect of Ardraka Arka, rich in gingerols (6-gingerol, 8-gingerol, 10-gingerol), which enhance iron absorption and support erythropoiesis. Ginger's antioxidant and anti-inflammatory properties mitigate oxidative stress, promoting healthier blood parameters and optimizing haemoglobin levels through improved iron metabolism and red blood cell production. [(Fogliano et al., 2019)]

The trial group showed an increase in monocytes, a type of white blood cell that enhances immunity. Ginger's bioactive compounds like 6-gingerol can inhibit pro-inflammatory cytokines (TNF-α, IL-6), reduce oxidative stress, and suppress monocyte-driven inflammation, thus boosting immune function and controlling inflammation.[(Tripathi et al., 2008)]

Before treatment, nine children were classified as having moderate asthma. After Ardraka Arka, six transitioned to mild persistent asthma, while two moved to mild intermittent asthma. One child showed progress but remained in the moderate category. This change had a positive impact on various quality-of-life aspects, as measured by the Asthma Control Questionnaire (ACQ). Children experienced fewer symptoms, better sleep, more energy, reduced activity limitations, and less need for emergency medication, leading to improved emotional well-being, lung function, and a more active lifestyle.

Discussion on the Mode of Action of the Drug: In Ayurveda, the main causes of Tamaka Shwasa are the vitiation of Vata and Kapha Dosha, along with the formation of Ama. Drugs with properties like Deepana, Pachana, Vatanulomana, Shwasahara, and Kasahara can break the Samprapti of Tamaka Shwasa. In children, where Kapha Dosha is physiologically dominant, Ardraka Arka demonstrates significant effectiveness due to its Vatakaphahara and Ushna Veerya properties. [(Pujari et al., 2014)] Its Bhedana action breaks down Kapha, clears airway obstructions, and facilitates smooth Vayu movement.

The essential oils in ginger, including Gingerol, Shogaol, and Zingerone, have antitussive, anti-inflammatory, antibacterial, antihistaminic, and prostaglandin-inhibiting effects. These compounds reduce airway inflammation, liquefy and expel mucus, stabilize mast cells, and regulate lung muscle contraction and relaxation. Additionally, ginger's antioxidant properties help reduce systemic inflammation and neutralize free radicals, supporting respiratory health. [(Healthline, 2025)]

CONCLUSION:

In both subjective and objective parameters, the trial demonstrated promising results. Whsile both groups showed similar effects in subjective measures, the trial group exhibited a noticeable improvement in objective parameters, particularly in Forced Vital Capacity (FVC). This suggests that Ardraka Arka positively impacted lung function, ultimately enhancing the quality of life for the children. Therefore, the add-on effect of Ardraka Arka, when used alongside standard care, proved beneficial in the management of Tamaka Shwasa, or bronchial asthma, in children.

6. Limitations and recommendations

- Long term follow-up was not done as it was a time bound study.
- The sample size was not adequate to draw solid conclusions.

Author Contributions:

MS and Srihari were instrumental in developing the concept and design of the study. They were actively involved in acquiring, analyzing, and interpreting the data, and were also responsible for drafting the manuscript. Both authors contributed through the critical revision of the manuscript, refining its intellectual content, and provided final approval for the version to be published.

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The authors declare that generative AI tools were utilized in the preparation of this thesis. Specifically, AI was used for drafting and editing sections of the manuscript to enhance clarity, coherence, and overall quality. The final content was thoroughly reviewed and revised by the authors to ensure accuracy and adherence to scientific standards.

Conflict of Interest:

None

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