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COMPARATIVE CLINICAL TRIAL OF BHARANGIMOOLA ARKA AND SALBUTAMOL NEBULIZATION IN TAMAKA SHWASA (ACUTE EXACERBATION OF BRONCHIAL ASThma): A CASE SERIES STUDY

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ABSTRACT

Tamaka Shwasa (Bronchial asthma) is a disease occurring due to involvement of Vata and Kapha which presents in two forms – Vaigika (Acute exacerbated) or Avaigika (under control). An emergency management is required during acute exacerbation. Pilot study has proved a statistically highly significant difference in symptoms like breathlessness (Z = -4.820, p< 0.000) after treatment with Nebulization of Bharangimoola Arka (5ml administered 6th hourly for 3 times) and also FVC% and FEV1% have improved significantly with a t value equal to -5.857 and -5.090 respectively with p<0.05. Hence an effort is put forth to compare Bharangimoola Arka with standard drug salbutamol Nebulization in controlling the acute exacerbation state in six episodes of administration. The main aim of the study was to compare the efficacy of Bharangimoola Arka Nebulization with standard drug Salbutamol in reducing the symptoms of Vegavasta (Acute exacerbated) of Tamaka Shwasa (Acute exacerbation of Bronchial Asthma). It was an open label, single center, prospective, double arm clinical study conducted in 100 patients of acute exacerbation of Bronchial Asthma. The patients falling under the inclusion criteria were taken for the study and pre and post spirometry was done to evaluate the broncho dilation effect. The patients were hospitalized for 2 days, and nebulization was done 6th hourly with a fixed dose of 5 ml of Bharangimoola Arka and 2.5 ml of Salbutamol sulphate in two groups. Before and after each episode of nebulization, Peak Expiratory Flow Test was done. This study provides evidence for the significant effect of 5 ml of Bharangimoola Arka in reducing the symptoms like Breathlessness, Wheeze and Cough in Acute exacerbation of Bronchial asthma which is on par with the standard drug Salbutamol Sulphate - 2.5ml when administered six doses 6th hourly without inducing tremors.

Keywords: Arka, Ayurveda, Bharangimoola, Bronchial asthma, Salbutamol, Clerodendrum serratum (Linn.), Nebulization, Tamaka Shwasa.

INTRODUCTION

Tamaka Shwasa can manifest either in Vaigika or Avaigika state due to predominance of Kapha –Vata Doshas.1 The name of the disease is due to the feeling of entering into darkness during the state of attack, when condition reaches to an acute state. As per the statistics, the prevalence of the same has increased in past two decades due to pollution, rapid environment changes, adaptation of newer dietary preparation and tremendous psychological stress.2 It is estimated that around 15-20 million people are asthmatics and it was seen as one of the leading causes of morbidity and mortality in rural India.3

In present day the management of acute stage is done by Nebulization, which involves a process administration of suspension of fine vaporized liquid droplets in air (aerosol).4 This study is carried out with the same aspire to establish the efficacy of herbal preparation in acute exacerbation of Bronchial Asthma based on the pilot study.

In pilot study Patients with acute exacerbation were given with 5ml Bharangimoola Arka in the form of Nebulization 6th hourly for 2 days. Pre and post Spirometry and peak expiratory flow rates were measured. The Bharangimoola Arka Nebulization has shown significant effect on symptoms like breathlessness and wheeze, & moderate effect on symptoms like cough, chest tightness and speech. The administration of Bharangimoola Arka is proven to be safe as it didn’t show any side effects for any patients during the study.5

This study was carried out to compare the efficacy of Bharangimoola Arka with salbutamol as nebulization in acute exacerbation of Bronchial Asthma.

MATERIALS AND METHODS

This study design was cleared from institutional ethics committee SDM/IEC/104/2016-2017and registered with CTRI No. 2016/10/012476. Written consent was procured from the subjects with acute presentation. Patients were recruited from In – Patient Department of general medicine of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan through purposive sampling. The self-structured proforma consisting of clinical symptoms of Tamaka Shwasa and Acute Exacerbation in Bronchial Asthma as per criteria mentioned in GINA-Global Initiation for Asthma were administered to the patients to include into the study.6Subjects who are fulfilling inclusion criteria were allocated to Group A – administered with Bharangimoola Arka and Group B – Salbutamol Sulphate.
Assessment criteria

Clinical features of patients were assessed before and after six episodes of Nebulization. Grading for the signs and symptoms is as follows:

0– No symptoms
1 – Mild – while walking, can lie down
2 – Moderate- while at rest, prefers sitting
3 – Severe –while at rest, sits upright

Spirometry parameters were observed before and after the 1st dose and 6th Dose of nebulization. Peak Expiratory Flow Rate (PEFR) were observed before and after all the dose of nebulization.

Inclusion & Exclusion criteria

Patients of both gender aged between 16 – 60 years with mild to moderate acute exacerbation, who are conscious and well oriented were included for the study. The patients with severe exacerbation, emphysema, chronic airway limitation, with history of tuberculosis and cardiac involvement, other complicated respiratory diseases having any organic lesion such as tumor or any anatomical defect in airway, cyanosis and uncontrolled hypertension, diabetes mellitus and suffering with other systemic illness were not included for the study.

Method of Drug Preparation

Required quantity of water was added to the root of Bharangi for soaking and kept overnight. Next day it was poured into the Arka Yantra (distillation apparatus) and boiled after adding remaining water. The vapors generated was condensed and collected in a receiver, which was stored in amber color bottle.

Intervention

The patient falling under the inclusion criteria are taken for the study and pre and post spirometry was done to evaluate the effect of bronco dilation. The patients were hospitalized for 2 days, nebulization was done 8th hourly with a fixed dose of 5 ml of Bharangimoola Arka and 2.5ml/5mg of salbutamol sulphate. Before and after each episodes of nebulization, Peak Expiratory Flow Test was done. In between if the patients got the attack then same medicine was repeated. After the treatment if notable effect is not elicited then co-current medication will be advised as per expert opinion.

Table 1: Effect of Bharangimoola Arka and Salbutamol on Symptoms of Tamaka Shwasa

| Symptoms            | GROUP                              | Mean Rank | Sum of Ranks | Mann– Whitney U & Wilcoxon W | Z       | Asymp. Sig. (2-tailed) | Significance |
|---------------------|------------------------------------|-----------|--------------|------------------------------|---------|------------------------|-------------|
| Breathlessness BT   | Bharangimoola Arka                 | 60.10     | 3005.00      | 770.0 2045                   | -3.513  | .000                   | HS          |
|                     | Salbutanol                         | 40.90     | 2045.00      |                              |         |                        |             |
| Breathlessness AT   | Bharangimoola Arka                 | 50.50     | 2525.00      | 1250 2525                    | .000    | 1.000                  | NS          |
|                     | Salbutanol                         | 50.50     | 2525.00      |                              |         |                        |             |
| Wheeze BT           | Bharangimoola Arka                 | 63.60     | 3318.00      | 595 1870                     | -4.819  | .000                   | HS          |
|                     | Salbutanol                         | 37.40     | 1870.00      |                              |         |                        |             |
| Wheeze AT           | Bharangimoola Arka                 | 54.00     | 2700.00      | 1075 2350                    | -1.951  | .051                   | S           |
|                     | Salbutanol                         | 47.00     | 2350.00      |                              |         |                        |             |
| Talks in BT         | Bharangimoola Arka                 | 55.09     | 2754.50      | 1020.0 2295.50               | -1.686  | .122                   | NS          |
|                     | Salbutanol                         | 45.91     | 2295.50      |                              |         |                        |             |
| Talks in AT         | Bharangimoola Arka                 | 53.00     | 2650.00      | 1125 2400                    | -2.283  | .022                   | S           |
|                     | Salbutanol                         | 48.00     | 2400.00      |                              |         |                        |             |
| Cough BT            | Bharangimoola Arka                 | 59.69     | 2984.50      | 790.5 2065.50                | -3.433  | .001                   | HS          |
|                     | Salbutanol                         | 41.31     | 2065.50      |                              |         |                        |             |
| Cough AT            | Bharangimoola Arka                 | 54.54     | 2727.00      | 1048 2323                    | -2.191  | .028                   | HS          |
|                     | Salbutanol                         | 46.46     | 2323.00      |                              |         |                        |             |
| Sputum production BT| Bharangimoola Arka                 | 60.04     | 3002.00      | 773 2048                     | -3.433  | .001                   | HS          |
|                     | Salbutanol                         | 40.96     | 2048.00      |                              |         |                        |             |
| Sputum production AT| Bharangimoola Arka                 | 56.01     | 2800.50      | 974.5 2249.50                | -3.258  | .001                   | HS          |
|                     | Salbutanol                         | 44.99     | 2249.50      |                              |         |                        |             |
| Chest tightness BT  | Bharangimoola Arka                 | 62.01     | 3100.50      | 674.5 1949.50                | -4.158  | .000                   | HS          |
|                     | Salbutanol                         | 38.99     | 1949.50      |                              |         |                        |             |
| Chest tightness AT  | Bharangimoola Arka                 | 56.98     | 2849.00      | 926 2201                     | -2.506  | .012                   | S           |
|                     | Salbutanol                         | 44.02     | 2201.00      |                              |         |                        |             |

HS – highly significant b) NS – not significant c) BT – before treatment d) AT – after treatment e) SD – standard deviation f) SE – standard error
OBSERVATIONS AND RESULTS

In this study 43.3% of patients were in the age group of 16-26 years. The sample included 33.3% labor workers, 26.7% students, 23.3% housewives, and 10% and 6.7% are professionals and business men respectively. Statistically significant result was observed in following symptoms of breathlessness (Z = -3.513, p = 0.000), cough (Z = -3.433, p = 0.002), sputum production (Z = -2.191, p = 0.001) and chest tightness (Z = 4.158, p = 0.000) in the group and difficulty in speech (Z = 2.283, p = 0.022) in Group B. (Table 1)

Repeated measures ANOVA determined that mean PEFR has increased significantly after treatment. Post hoc tests using the Bonferroni correction 0.008 revealed that treatment elicited an increase in PEFR from 1st dose BT to 6th dose AT was statistically highly significant. On comparing the effect of treatment in between treatments it was found that treatment was statistically significant after each episode of nebulization. (Table 2, 3)

Statistically highly significant improvement was observed in all the parameters of Spirometry (Pulmonary Function Test). FVC% and FEV1% improvement was recorded which is significant in both the groups. (Table 4)

Table 2: Effect of Bharangimoola Arka and Salbutamol on PEFR with repeated measure ANOVA

| (I) factor1pefr | (J) factor1pefr | Mean Difference (I-J) | Std. Error | Sig.* | 95% Confidence Interval for Difference |
|----------------|----------------|-----------------------|------------|-------|---------------------------------------|
|                | 1st dose       |                       |            |       |                                       |
| 2nd dose       | -70.500*       | 5.796                 | .000       | -82.000 | -59.000                              |
| 3rd dose       | -132.150       | 6.068                 | .000       | -144.190 | -120.110                             |
| 4th dose       | -196.150       | 7.186                 | .000       | -210.409 | -181.891                             |
| 5th dose       | -264.650       | 7.159                 | .000       | -278.854 | -250.446                             |
| 6th dose       | -305.050       | 6.473                 | .000       | -317.894 | -292.206                             |
|                | 2nd dose       |                       |            |       |                                       |
| 1st dose       | 70.500*        | 5.796                 | .000       | 59.000  | 82.000                                |
| 3rd dose       | -61.650        | 4.966                 | .000       | -71.504 | -51.796                              |
| 4th dose       | -125.650       | 6.007                 | .000       | -137.570 | -113.730                             |
| 5th dose       | -194.150       | 7.462                 | .000       | -208.957 | -179.343                             |
| 6th dose       | -234.550       | 6.958                 | .000       | -248.356 | -220.744                             |
|                | 3rd dose       |                       |            |       |                                       |
| 1st dose       | 132.150        | 6.068                 | .000       | 120.110 | 144.190                              |
| 2nd dose       | 61.650         | 4.966                 | .000       | 51.796  | 71.504                               |
| 4th dose       | -64.000        | 2.902                 | .000       | -69.759 | -58.241                              |
| 5th dose       | -132.500       | 4.216                 | .000       | -140.866 | -124.134                             |
| 6th dose       | -172.900       | 4.115                 | .000       | -181.066 | -164.734                             |
|                | 4th dose       |                       |            |       |                                       |
| 1st dose       | 196.150        | 7.186                 | .000       | 181.891 | 210.409                              |
| 2nd dose       | 125.650        | 6.007                 | .000       | 113.730 | 137.570                              |
| 3rd dose       | 64.000         | 2.902                 | .000       | 58.241  | 69.759                               |
| 5th dose       | -68.500        | 4.353                 | .000       | -77.137 | -59.863                              |
| 6th dose       | -108.900       | 5.013                 | .000       | -118.847 | -98.953                              |
|                | 5th dose       |                       |            |       |                                       |
| 1st dose       | 264.650        | 7.159                 | .000       | 250.446 | 278.854                              |
| 2nd dose       | 194.150        | 7.462                 | .000       | 179.343 | 208.957                              |
| 3rd dose       | 132.500        | 4.216                 | .000       | 124.134 | 140.866                              |
| 4th dose       | 68.500         | 4.353                 | .000       | 59.863  | 77.137                               |
| 6th dose       | -40.400        | 2.699                 | .000       | -45.755 | -35.045                              |
|                | 6th dose       |                       |            |       |                                       |
| 1st dose       | 305.050        | 6.473                 | .000       | 292.206 | 317.894                              |
| 2nd dose       | 234.550        | 6.958                 | .000       | 220.744 | 248.356                              |
| 3rd dose       | 172.900        | 4.115                 | .000       | 164.734 | 181.066                              |
| 4th dose       | 108.900        | 5.013                 | .000       | 98.953  | 118.847                              |
| 5th dose       | 40.400         | 2.699                 | .000       | 35.045  | 45.755                                |

Based on estimated marginal means

* The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).
antagonism cardiac arrhythmias and seizures due to adenosine complications like nausea, vomiting, and headache; it effects related to plasma concentrations of theophylline are feels tiredness with more due to larger surface area which 

Nebulization sulphate. 

comparison of its efficacy with th acute exacerbation in six episodes of the administration and been taken with the aim of evaluating the efficacy of the same can be become fatal like the deadly snake venom. The manifestation of 

If Tamaka Shwasa is not managed timely or if the patient indulges in unwholesome regimens during the disease being exacerbated can lead to also the residual Dosha which are still remaining in channels can be eliminated by the administering medicated fumes. 

Bharangimoola Arka Nebulization with the dose of 5ml of was administered 8 hourly for 6 times. On the basis of observations in pilot study the interval period between the dose was fixed to 8 hours considering the time of medication for Tamaka Shwasa as Muhur Muhu (Repeated administration of Medicine).The symptom breathlessness, tightness of chest, wheeze and cough was reduced significantly (p value =.000. (P value .002) (Table 1, 2& 3) respectively after nebulization. This facilitates the movement of Prana vayo (Type of Vata) by liquefying the tenacious sputum in the Srotas (channels).

In this disease Vata moves in the reverse order and pervades the channels afflicting the neck and head, and stimulates Kapha to cause signs and symptoms due to obstruction. Hence the therapies will be beneficial which induce downward movement of Vata just like the snow melts on account of the hot rays of the sun, the stable Kapha in the body gets dissolved on account of the heat generated by oleation and fomentation therapies. That liquefied Kapha should be eliminated by administering emesis therapy 16.

And also the residual Doshas which are still remaining in channels can be eliminated by the administering medicated fumes. 

**DISCUSSION**

If Tamaka Shwasa is not managed timely or if the patient indulges in unwholesome regimens during the disease being exacerbated become fatal like the deadly snake-venom. The manifestation of the same can be either in Vega or Avega Avastha, the study has been taken with the aim of evaluating the efficacy of Bharangimoola Arka Nebulization in reducing the symptoms of acute exacerbation in six episodes of the administration and comparison of its efficacy with the standard drug salbutamol sulphate.

Nebulization therapy in acute stage of asthma is more beneficial due to larger surface area which increases the rate of absorption, there by delivery of proteins derivative in lung tissue will become more active. However on regular usage of nebulization patient feels tiredness with loss of appetite and tremors. Also The side effects related to plasma concentrations of theophylline are minor complications like nausea, vomiting, and headache; it can lead to cardiac arrhythmias and seizures due to adenosine A1-receptor antagonism. 5

| GROUP | Parameter | N | Mean | SD | SE | \( t' \) value | \( \beta \) value | Remark |
|-------|-----------|---|------|----|----|----------------|----------------|--------|
| PEFR 1st dose BT in l/sec | Bharangimoola Arka | 50 | 1.3436E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 1st dose AT in l/sec | Salbutamol | 50 | 1.5234E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 2nd dose BT in l/sec | Bharangimoola Arka | 50 | 2.1788E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 2nd dose AT in l/sec | Salbutamol | 50 | 2.3372E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 3rd dose BT in l/sec | Bharangimoola Arka | 50 | 2.0478E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 3rd dose AT in l/sec | Salbutamol | 50 | 2.2292E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 4D_BT_SEC | Bharangimoola Arka | 50 | 3.3780E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 4D_BT_SEC | Salbutamol | 50 | 3.5560E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 5D_BT_SEC | Bharangimoola Arka | 50 | 4.0660E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 5D_BT_SEC | Salbutamol | 50 | 4.2040E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 6D_BT_SEC | Bharangimoola Arka | 50 | 4.3920E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 6D_BT_SEC | Salbutamol | 50 | 4.5760E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 7D_BT_SEC | Bharangimoola Arka | 50 | 4.9500E2 | 1 | 0.066 | -5.857 | .000 | HS |
| PEFR 7D_BT_SEC | Salbutamol | 50 | 5.1720E2 | 1 | 0.066 | -5.857 | .000 | HS |

HS – highly significant b) NS – not significant c) BT – before treatment d) AT – after treatment e) SD – standard deviation f) SE – standard error g) FVC- forced vital capacity h) FEV1- forced expiratory volume in 1 second

**Table 3: Effect of Bharangimoola Arka and Salbutamol on PEFR of Tamaka Shwasa**

**Table 4: Effect of therapy on Spirometry parameters in Tamaka Shwasa Patients**
Significant improvement in initial mean score of PEFR, FVC & FEV1 was observed from 1st dose to the 6th doses in both the group. It suggests significant reduction in airway obstruction.

The phyto chemical of Bharangimoola Arka (root of Clerodendrum serratum (Linn.)) on preliminary test have proven to be positive for Carbohydrates, Phenolic, Tannins and Terpenoids. Generally, previous researches on phytochemical among carbohydrates components D-mannitol was found.9

The components of Bharangimoola Arka - phenolic compound, Tannins and Terpenoids are found to be anti-inflammatory in Asthma.10 The Bharangimoola (Clerodendrum serratum (Linn.)), due to its anti-inflammatory action succeed to restrict the underlying pathology instantly. The anti-inflammatory effects of phenolic compounds are related in previous research are; due to modulation of the expression of pro-inflammatory genes, like NOS, cyclooxygenase, lipoxygenase; acting throughout nuclear factor (NF-kB) signaling; and mitogen-activated protein kinase and activating the Nrf2/Keap1 pathway.11

In another way the role play of any particular phenolic antioxidant is directly associated with the capacity of the hydrogen radical donation from the phenolic group and the presence of an unpaired electron in the aromatic ring.

A study is evident that the ethanolic root extract of Clerodendrum serratum (Linn.) showed significant anti-inflammatory activity in carrageenan-induced oedema in the cotton pellet model in experimental mice, rats and rabbits at concentrations of 50, 100 and 200 mg/kg.12

The Ices hydropicenic Acid (IHPA) pent acyclic triterpenoid saponin, first isolated component from roots of Bharangi, at the dose of 100mg/kg provides protection of mast cell degeneration (59.62%) in comparison to standard sodium cromoglycate (64.48%).13 Another components of Bharangimoola Saponin and D mannitol possesses antihistamine and anti-allergic effect respectively. Apigenin-7-glucoside (flavonoid) acts as anti-inflammatory and antimicrobial agent.14

CONCLUSION

Hence with the evidence of present clinical trial and other research updates the Bharangimoola Arka is found to have more sustained effect in reduction of Tamaka Shwasa in acute stage in comparison with Salbutamol Sulphate. No adverse effects like tremor, dryness of mouth was not observed among the subjects treated with Bharangimoola Arka.

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