Research Article

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EVALUATION OF BRONCHODILATOR EFFECT OF KANTAKARI EXTRACT NEBULISATION IN WHEEZING CHILDREN: A RANDOMIZED CLINICAL STUDY

Patil Amol^{1*}, Aziz Arbar², Deepti A.K.¹

¹PG Scholar, Department of Kaumarabhritya, KLEU's Shri BMK Ayurved Mahavidyalaya and Research Centre, Belgaum, Karnataka, India

²Reader, Department of Kaumarabhritya, KLEU's Shri BMK Ayurved Mahavidyalaya and Research Centre, Belgaum, Karnataka, India

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*Corresponding author

Dr. Amol Patil, PG Scholar, Department of Kaumarabhritya, KLEU'S, Shri BMK Ayurved Mahavidyalaya and Research Centre, Belgaum, Karnataka, India E-mail: dr.amolp234@gmail.com

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ABSTRACT

The aim of this study was to evaluate the bronchodilator effect of Kantakari extract Nebulisation in wheezing children. Around 30 % of all children suffer from recurrent episodes of respiratory symptoms, such as wheezing, in early life. Wheezing places an important burden in terms of morbidity, quality of life, use of the health care system and health care costs. In Ayurvedic system of medicine, treatment of respiratory disorders has advantages like safety, economy, effectiveness and easy availability. The inhaled route of administration is preferable to the oral route because the adverse effects are comparatively less and this route is more effective. In the present study it was found that the trial drug and standard drug were statistically highly significant (p 0.001) on the (Forced Peak Expiratory Volume) FPEV and Wheezing. Percentage of improvement in PEFR among standard group and trial group was 37.66 % and 23.56 % respectively. There was 88 % of reduction in wheezing in standard Group, whereas in trial Group 60.71 % reductions in wheezing was seen. It can be concluded that Kantakari extract has mild to moderate bronchodilator effect. Kantakari extract shows marked improvement in FPEV and significant result in reduction in wheezing after 30 minutes, this can be concluded as effectiveness of Ayurvedic drug with new route of administration.

Keywords: Wheezing, Kantakari, Nebulisation, Bronchodilator.

INTRODUCTION

Wheezing is the major sign and symptom of bronchial asthma. 'Wheezing' refers to high - pitch whistling sounds audible on auscultation by the stethoscope. A partial obstruction of the bronchi and bronchioles leading to narrowing produces wheezing. Wheezing is most often due to heightened sensitivity of respiratory tract. Infection of lower respiratory passage may often cause bronchospasm.¹ A cold or acute respiratory disease always precedes attacks of wheezing, most frequent between 1-8 years of age. However, although 20 % of all children will have had at least one wheezing illness by 1 year of age, almost 33 % by 3 years of age, and nearly 50 % by 6 years.² Herbal approaches have regained their popularity for the treatment of respiratory disorders with their efficacy and safety aspect being supported by controlled clinical studies.³ Kantakari, which contains several steroidal alkaloids like solanacarpine⁴, solanacarpidine, solasonine and solamargine, has been reported very useful in respiratory diseases like kasa roga (cough) and also in Tamakswasa (bronchial asthma).⁵ The plant is also found to have anti-inflammatory and anti-asthmatic activities in clinical trials.⁶ Several routes of administration of drug have not only been described in Ayurvedic text but also practiced for several millennia. Administration of drugs through nasal route is highly prevalent in Ayurveda.⁷ The inhaled route of administration is preferable to the oral route because the

adverse effects caused by systemic action of the drugs are comparatively less and also because this route is more effective.⁸ This mode of administration proves to be highly beneficial in saving life in acute life- threatening conditions such as status Asthmatic. But wide range of toxic side effects of modern medicine confines its use as permanent remedy. According to contemporary science, its management shows many adverse effects like, tachycardia, tremors, headache, sedation, oral thrush, reflex coughing, etc.² On the other hand, in Ayurvedic system of medicine, treatment of respiratory disorders has advantages like safety, economy, effectiveness and easy availability. Kantakari, which is non-toxic and safe for human use, has been reported beneficial in treatment of asthma and chronic bronchitis⁹. The drug is indicated in Shvasa and Kasa in many Ayurvedic classics¹⁰⁻¹⁶. In present scenario inhalation therapy is the best way to effectively and safely manage the condition without any drug dependency. Unfortunately with the available source of information no clinical research has been done on wheezing children through nebulisation with Ayurvedic drugs. This study proposes to evaluate the bronchodilator effect of kantakari extract nebulisation in wheezing children.

Objectives

To evaluate the bronchodilator effect of Kantakari extracts nebulisation in wheezing children

MATERIALS AND METHODS**Source of Data**

Diagnosed cases of wheezing were included from Kaumarabhritya OPD and IPD of B. M. K. Ayurvedic Hospital Belgaum, India.

Inclusion criteria

- Patients of either sex.
- Patients between age group of 5-10 years.
- Patients having wheezing on chest auscultation.

Exclusion criteria

- Known case of tuberculosis or any other acute and grave infection.
- Patients with history of malignancy.
- Patients with congenital anatomical abnormalities of chest and respiratory system.
- Patients in life-threatening conditions viz, - respiratory acidosis, diabetic ketoacidosis, Respiratory Distress Syndrome, etc.

Diagnostic criteria

The diagnosis was made based on chest auscultation.

Research Design

It is a randomized comparative clinical trial. 40 patients were selected as per the inclusion criteria and randomly divided into two groups.

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Intervention

Trail group: - Patients were administered with Kantakari extract 1.5 ml for 5-7 years of age and 2 ml for 8-10 years of age as single administration.

Control group: - Patients were administered with Salbutamol 0.15 mg/kg/dose.

Assessment criteria

The assessment was done before and after treatment and the result was analyzed statistically as per the assessment chart.

Table 1: Subjective Criteria

Score	Respiratory rate	Wheezing present
0	18-20	No wheezing
1	21-30	End Expiratory Wheezing
2	31 – 40	Inspiratory and Expiratory Wheezing With Slightly Diminished Breath Sounds
3	> 40	Inspiratory and Expiratory Wheezing With Significantly, Diminished Breath Sounds or Chest Silent

Objective Criteria

- **Peak Flow Meter:** Forced peak expiratory volume (F.P.E.V) was noted before administration of drug and after nebulisation with the help of Peak Flow Meter to access improvement of lung functions.
- **Measurement of SPO₂**

Method of Preparation Kantakari Extract

The drug was made by continuous hot percolation process known as Soxhlet process in which small volume of hot menstrum was passed over the drug by the time, as again and again to dissolve out the active constituents until the drug was exhausted. 50 g of crude drug in coarse powdered form was taken in extraction chamber of soxhlet and moistened with water and alcohol in the ratio of 2:1 for few hours until the drug was totally moistened.

Thimble made of filter paper was then placed into the wider part of the extractor. Thimble is used to prevent chocking of the lower part of the extractor by drug particles. The vapors are allowed to pass through the side tube to the condenser where they are condensed and fall on to packed drug through which it percolates and extract out the active constituents. As the volume of mestrum in the extractor increase, the level of the liquid in the siphon also increase till it reaches the maximum point from where it is siphoned out into the flask. On further heating, the menstrum vaporizes while the dissolved active constituents remain behind in the flask. The alternate filling and emptying of the body of the extractor goes on continuously till the drug is exhausted. The extract carried out by this method was then dried to the solid mass. Out of 50 g of crude drug 6g solid extract was obtained.

RESULTS

Table 2: Results of effect of Trial drug (Kantakari extract) on different parameters

Parameter	Mean of BT	Mean of AT	Mean at 15 min	Mean at 30 min	Mean at 60 min	BT-AT	BT-15 min	BT-30 min	BT-60 min
FPEV	126.25	137.75	143.5	154	156	11.50 + 6.50 t = 7.901 p < 0.001	17.25 + 8.50 t = 9.073 p < 0.001	27.75 + 9.79 t = 12.67 p < 0.001	29.75 + 13.23 t = 10.06 p < 0.001
Wheezing	1.4	1.35	1.15	0.65	0.55	0.05 + 0.21 u = -1.0 p > 0.05	0.25 + 0.42 u = -15.0 p > 0.05	0.75 + 0.52 u = -105.0 p < 0.001	0.85 + 0.46 u = -136.0 p < 0.001
RR	1.1	1.05	1.05	0.85	0.95	0.05 + 0.2 u = -1.0 p > 0.05	0.05 + 0.2 u = -1.0 p > 0.05	0.25 + 0.4 u = -15.0 p > 0.05	0.15 + 0.3 u = -6.0 p > 0.05
Spo2	98.5	98.5	98.6	98.6	98.65	0 + 0.43 t = 0.0 p > 0.05	0.1 + 0.42 t = 1.0 p > 0.05	0.35 + 0.5 t = 1.45 p > 0.05	0.15 + 0.3 t = 1.83 p > 0.05

FPEV- forced peak expiratory flow, RR-respiratory rate, Spo2-Saturation of peripheral Oxygen, BT-Before Treatment, AT-After Treatment

Table 3: Results of effect of Standard drug (Salbutamol) on different parameters

Parameter	Mean of BT	Mean of AT	Mean at 15 min	Mean at 30 min	Mean at 60 min	BT-AT	BT-15 min	BT-30 min	BT-60 min
FPEV	113.5	133	143.75	151.2	156.2	19.50 + 8.870 t=9.831 p = 0.0001	30.25 + 13.42 t=9.831 p = 0.0001	31.90 + 29.02 t=9.831 p = 0.0001	42.75 + 19.02 t=9.831 p = 0.0001
Wheezing	1.35	1.2	0.75	0.3	0.15	0.15 + 0.3570 u=-6.000 p = 0.2500	0.6 + 0.6224 u=-78.00 p = 0.0005	1.05 + 0.3840 u=-190.0 p = 0.0001	1.2 + 0.509 u=-190.0 p = 0.0001
RR	1.2	1.05	0.9	0.7	0.75	0.15 + 0.357 u=-6.000 p = 0.2500	0.3 + 0.458 u=-21.00 p = 0.0313	0.5 + 0.5 u=-55.00 p = 0.0020	0.45 + 0.497 u=-45.00 p = 0.0039
Spo2	98.25	98.35	98.5	98.6	98.55	0.10 + 0.447 t=1.000 p = 0.3299	0.25 + 0.63 t=1.751 p = 0.0961	0.35 + 0.58 t=2.666 p = 0.0153	0.30 + 0.57 t=2.349 p = 0.0298

FPEV- forced peak expiratory flow, RR-respiratory rate, Spo2-Saturation of peripheral Oxygen, BT-Before Treatment, AT-After Treatment

Table 4: Results of comparative effect of therapy on different parameters

Parameter	Mean of standard Group BT	Mean of Trial Group AT	Mean of standard Group at 15 min	Mean of Trial Group at 15 min	Mean of standard Group at 30 min	Mean of Trial Group at 30 min	Mean of standard Group at 60 min	Mean of Trial Group at 60 min
FPEV	19.50	11.50	30.25	17.25	37.75	27.75	42.75	29.75
Wheezing	0.15	0.05	0.6	0.25	1.05	0.75	1.2	0.85
RR	0.15	0.05	0.3	0.05	0.5	0.25	0.45	0.15
Spo2	0.1000	0.0	0.250	0.10	0.35	0.10	0.30	0.15

FPEV- forced peak expiratory flow, RR-respiratory rate, Spo2-Saturation of peripheral Oxygen, BT-Before Treatment, AT-After Treatment

Table 5: Results of comparative effect of therapy on different parameters

Parameter	BT-AT	BT-15 min	BT-30 min	BT-60 min
FPEV	8.000 ± 0.528 t=3.252 p=0.0024	13.00 ± 1.101 t=3.659 p = 0.0008	10.00 ± 0.854 t=2.666 p = 0.0112	13.00 ± 1.296 t=2.510 p = 0.0165
Wheezing	0.1 + 0.031 u=0.6050	0.35 + 0.0126 u=0.0536	0.3 + 0.0341 u=0.0591	0.35 + 0.0074 u=0.0541
RR	0.1 + 0.0311 u=0.6050	0.25 + 0.0538 u=0.0915	0.25 + 0.015 u=0.1908	0.3 + 0.0314 u=0.0824
Spo2	-0.1000 ± 0.0026 t=0.4894	-0.1500 ± 0.0428 t=0.3950	-0.2500 ± 0.0624 t=0.0999	-0.150 ± 0.045 t=0.3292

FPEV- forced peak expiratory flow, RR-respiratory rate, Spo2-Saturation of peripheral Oxygen, BT-Before Treatment, AT-After Treatment

DISCUSSION

In the present study it was found that the trial drug and standard drug were statistically highly significant ($p < 0.001$) on the FPEV and Wheezing. Percentage of improvement in PEFV among standard group and trial group was 37.66 % and 23.56 % respectively. There was 88 % of reduction in wheezing observed in standard Group, whereas in trial Group 60.71 % reductions in wheezing was seen. For wheezes some part of the respiratory tree must be narrowed or partially obstructed, or airflow velocity within the respiratory tree must be

heightened. This phenomenon is due to the inflammation of the mucosal layer of tracheo bronchial tree producing obstruction airflow. This is common presentation in many diseases of respiratory tract including Shwasa (Asthma). The chemical constituents of kantakari like alkaloids and steroids might have anti inflammatory action on bronchial tree and Ushnavirya of drug that helps in srotoshodhana and may release the bronchospasm. It was found that standard drug shows significant result ($p < 0.05$) on respiratory rate but showed insignificant result on Spo2.

Figure 1: Kantakari fruits and leafs

Figure 2: Kantakari flowers

Figure 3: Soxhlet extraction

Figure 4: Katakari extract

Figure 5: Measurement of peak

Figure 6: Nebulization with katakari extract expiratory volume with peak flow meter

CONCLUSION

It can be concluded that Katakari extract has mild to moderate bronchodilator effect. Katakari extract shows marked improvement in FPEV and significant result in reduction in wheezing after 30 minutes, this can be concluded as effectiveness of Ayurvedic drug with new route of administration. The trial gives a direction for searching new route of herbal drug administration.

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