

A study on clinical efficacy of *Abutilon indicum* in treatment of bronchial asthma

Archana N Paranjape and Anita A Mehta*

Department of Pharmacology, L.M. College of Pharmacy, Navrangpura, Ahmedabad - 380009, Gujarat, India

SUMMARY

The present investigation was carried out to determine the efficacy and safety of *Abutilon indicum* (*A. indicum*) (Eng: Country Mallow, Fam: Malvaceae) in patients of bronchial asthma. Dried aerial parts of *A. indicum* were finely powdered and given in the dose of 1 gm tid to 30 patients of either sex in the range of 15 - 80 years with mild to moderate bronchial asthma with or without any concurrent medication. The respiratory functions (FVC, FEV₁, FEF_{25-75%} and MVV) were assessed using a spirometer prior to and after 4 weeks of treatment. Efficacy of the drug in improving clinical symptoms and severity of asthmatic attacks was evaluated by interviewing the patient and by physical and hematological examination at the end of the treatment. 4 weeks treatment with the drug showed statistically significant improvement in various parameters of pulmonary functions in asthmatic subjects. Also significant improvement was observed in clinical symptoms and severity of asthmatic attacks. None of the patient showed any adverse effect with *A. indicum*. The results of the present study suggest the usefulness of *A. indicum* in patients with mild to moderate bronchial asthma.

Key words: Antiasthmatic activity; *Abutilon indicum*; Pulmonary function tests

INTRODUCTION

Abutilon indicum (*A. indicum*) (Fam: Malvaceae) is abundantly found as a weed throughout the tropical parts of India. It is used in both Ayurvedic and Unani systems as a febrifuge, anthelmintic and in urinary and uterine discharges, piles and lumbago. Leaves of this plant are demulcent, aphrodisiac, laxative and diuretic. Flowers are reported to be employed as an application to boils and ulcers. The root is a nervine tonic and antipyretic and is given in piles (Nadkarni, 1954).

Preliminary pharmacological screening of *A. indicum* has proven its analgesic and antimicrobial property (Sharma *et al.*, 1989; Mehta *et al.*, 1997). It is one of the ingredients of the Ayurvedic syrup used for prevention of upper respiratory tract infections (Sharma *et al.*, 1993). Seeds of this plant are expectorant and useful in coughs. The drug is reported to have anti-inflammatory action and is used internally for inflammation of the bladder (Nadkarni, 1954). *A. indicum* is reported to be used in treatment of asthma in several southern parts of India (Vishwanathan, 1995). However, no scientific studies are so far carried out to evaluate the antiasthmatic activity of *A. indicum*. Since bronchial asthma is considered as a chronic inflammatory disorder of the airways and the anti-inflammatory potential of *A. indicum* has been reported, the

*Correspondence: Anita A Mehta, Department of Pharmacology, L.M. College of Pharmacy, Navrangpura, Ahmedabad - 380009, Gujarat, India. Tel: +91-0265-5552159; Fax: +91-0265-2438317; E-mail: archana@edutechonline.com

present study was undertaken to evaluate the clinical efficacy of this drug in Indian asthmatic patients.

MATERIALS AND METHODS

Plant material

Aerial parts of plant of *A. indicum* were collected from Gujarat (India) in September and October at the end of flowering season. The plant was identified and authenticated by Dr. Daniel, Department of Botany, M.S. University, Vadodara, Gujarat, India and a voucher specimen was deposited in 'BARO' the herbarium of department of Botany, M.S. University, Vadodara. Aerial parts were collectively cleaned, dried under shade, powdered to a fine mesh and used for the study.

Clinical study

An open label, noncomparative clinical study was carried out on patients of either sex, having mild to moderate bronchial asthma and visiting Out Patient Department of Govt. Ayurvedic Hospital, Vadodara, India. The protocol for carrying out the clinical study was approved by Director, Department of Ayurveda and Homeopathic Medicine, Govt. of Gujarat, India and also by the institutional ethics committee for the clinical study. Informed Consent was obtained from all patients enrolled in the study.

All patients in age range of 15 - 80 years having mild to moderate bronchial asthma as diagnosed by their clinical history, commonly observed symptoms of bronchial asthma (Dyspnoea, wheezing, tightness in chest, cough etc.) and physical examination were enrolled in the study (Bethesda, 1995). Patients having breathlessness due to cardiovascular disorders were excluded. Patients having very severe bronchial asthma (PEFR < 20%, FEV₁ < 20% of predicted value) were not enrolled. Patients below age of 15 years and pregnant women were excluded. Patients with disorders such as pulmonary tuberculosis, cardiovascular

disorders etc. were also not enrolled in the study.

Of the patients satisfying the inclusion and exclusion criteria, baseline characteristics were measured and clinical and family history was recorded. Details of duration of bronchial asthma, other diseases present and concomitant medication taken were recorded. For patients taking concomitant medication for bronchial asthma, details of the drugs used and their dosages were collected before starting the treatment with *A. indicum* and at the end of the study. Patients were given finely powdered aerial parts of *A. indicum* in dose of 1 g tid for 4 weeks and were advised to take it with water.

General physical examinations which include temperature, heart rate, blood pressure and Respiratory rate were measured before start of the treatment and at every week after start of the treatment. Hematological examinations which include haemoglobin estimation, total leukocyte count, differential leukocyte count and erythrocyte sedimentation rate were carried out before start of the treatment and at the end of 4 weeks of treatment. Patients were given medication supply of 1 week and were asked to report every week. At every weekly visit, patients were asked for occurrence of any untoward effect if any and improvement in the symptoms observed. Symptom score was measured for all commonly observed symptoms of bronchial asthma i.e. dyspnoea, wheezing, cough and chest tightness before starting the treatment and at the end of 4 weeks of treatment. Score was graded as 3, 2, 1 and 0 for presence of severe, moderate, mild and absence of any symptom respectively (Anjuli, 2002). Grades were given by interviewing the patient and by physical examination.

Evaluation of lung functions was done with the help of computer aided spirometer. Spirometry was performed before starting the treatment with *A. indicum* and at the end of 4 weeks of treatment. The values were expressed as mean \pm S.E.M. Statistical significance of the differences in parameters

before and after treatment was calculated using student's paired *t*-test. $P < 0.05$ was considered to be significant.

RESULTS

Demographic profile

38 patients satisfying inclusion and exclusion criteria were enrolled in the study. However, 8 patients discontinued the study in between due to unknown reasons. 30 patients completed the total 4 weeks of study. Demographic profile of the patients enrolled is shown in Table 1. Patients enrolled were in the age range of 15 - 84 years with an average age of 51.92 ± 4.03 years. Out of total 30 patients enrolled, 87% patients were male and 13% were female. Average duration of asthma was found to be 5.52 ± 1.68 years with a range of 3 months to 40 years (Table 1). Types of asthmatic patients enrolled are shown in Table 2. 20% of patients were found to have extrinsic (allergic) asthma and 80% were found to have intrinsic (nonallergic) type of asthma.

Effect of *A. indicum* on physical parameters and hematological profile

General physical parameters like temperature,

Table 1. Demographic profile of patients enrolled in the study

Variables	Mean \pm S.E.M.	Range
Age (years)	51.92 ± 4.03	15 - 84
Male/Female	26/04	-
Height (cm)	159.71 ± 2.22	126 - 172
Weight (kg)	49.58 ± 2.89	20 - 74
Duration of Asthma (years)	5.52 ± 1.68	3 months - 40 years

Table 2. Types of asthmatic patients enrolled

Types of asthmatic patients	Number of patients
Patients with extrinsic asthma	06
Patients with intrinsic asthma	24

Table 3. Medication record of the patients

Medication	Number of patients
<i>A. indicum</i>	20
<i>A. indicum</i> + β_2 agonist	5
<i>A. indicum</i> + β_2 agonist + Xanthine derivatives	3
<i>A. indicum</i> + β_2 agonist + Corticosteroid	2

heart rate, respiratory rate, and blood pressure were recorded before, every week and at the end of 4 weeks of treatment with *A. indicum*. No significant change was observed in any of these parameters by treatment with *A. indicum*. Also hematological parameters were not changed markedly with *A. indicum* (Table 4).

Effect of *A. indicum* as an add on therapy to existing antiasthmatic drugs

Out of total 30 patients, 20 were exclusively on *A. indicum* treatment and in 10 patients, *A. indicum* was used as an add on therapy to existing treatment with allopathic medicine (Table 3). In all patients taking *A. indicum* as an add on therapy, there was decrease in requirement of concomitant allopathic medicine (Table 5).

Effect of *A. indicum* on commonly observed symptoms of bronchial asthma

In the present study, *A. indicum* was found to significantly improve the commonly observed symptoms of bronchial asthma. Symptom score of all symptoms was significantly reduced by *A. indicum* (Table 6).

Effect of *A. indicum* on lung function parameters

In the present study, *A. indicum* caused significant increase in Forced Vital Capacity (FVC) ($P < 0.05$) and highly significant increase in Forced Expiratory volume in 1 s (FEV_1) ($P < 0.05$) of the patients. Mean % increase found in FVC was $33.97 \pm 14.62\%$ and in FEV_1 was $16.69 \pm 5.26\%$ (Table 7). However, no significant change was observed in ratio of FVC

Table 4. Effect of *A. indicum* on general physical parameters and hematological profile

Parameters	Before treatment (mean \pm S.E.M)	After treatment (mean \pm S.E.M.)
Heart Rate (beats/min)	75 \pm 1.01	76.54 \pm 1.13
Systolic B.P (mm Hg)	132.83 \pm 3.14	131.42 \pm 2.65
Diastolic B.P (mm Hg)	82 \pm 1.06	82 \pm 0.79
Resp.rate (/min.)	21.96 \pm 0.68	18.71 \pm 0.60
Hb. (gm %)	13.04 \pm 0.27	12.95 \pm 0.19
TC (/cmm)	11 216.67 \pm 1 119.05	10 665 \pm 913.29
Neu. (%)	60.33 \pm 1.97	58.96 \pm 1.67
Lymp. (%)	31.37 \pm 2.01	30.79 \pm 1.96
Mono. (%)	0.54 \pm 0.16	0.66 \pm 0.19
Eosi. (%)	7.58 \pm 1.48	7.21 \pm 0.75
ESR(mm/hr)	35.87 \pm 5.50	31.08 \pm 4.38

*Significantly different from baseline values, $P < 0.05$, (Student's paired t test).

Table 5. Effect of *A. indicum* treatment on dosage of inhalational antiasthmatic drugs

Medications	Mean Frequency (Pumps/day) Before <i>A. indicum</i> treatment	Mean Frequency (Pumps/day) After <i>A. indicum</i> treatment
β_2 agonist	2 - 3	0 - 1
β_2 agonist + Xanthine derivatives	2 - 3	0 - 1
β_2 agonist + Corticosteroid	2 - 3	1

Table 6. Effect of *A. indicum* on symptom score

Symptoms	Score (Before treatment) mean \pm S.E.M.	Score (After treatment) mean \pm S.E.M.
Dyspnoea	2.83 \pm 0.08	0.95 \pm 0.13*
Wheezing	1.42 \pm 0.05	0.21 \pm 0.04*
Cough	1.16 \pm 0.03	0.17 \pm 0.01*
Chest Tightness	1.37 \pm 0.16	0.54 \pm 0.02*

*Significantly different from control, $P < 0.05$ (student's paired t test).

Table 7. Effect of *A. indicum* on lung volumes

Parameters	Before treatment (mean \pm S.E.M.)	After treatment (mean \pm S.E.M.)	% increase (mean \pm S.E.M.)
FVC (lit)	1.61 \pm 0.19	1.86 \pm 0.19*	33.97 \pm 14.62
FEV ₁ (lit)	1.30 \pm 0.12	1.48 \pm 0.14*	16.69 \pm 5.26
FEV ₁ /FVC (%)	80.18 \pm 3.18	82.74 \pm 2.88	6.43 \pm 5.58

*Significantly different from baseline values, $P < 0.05$, (Student's paired t test).

and FEV₁ (FVC/FEV₁%) by *A. indicum*.

In present study, *A. indicum* also significantly increased Peak Expiratory Flow Rate (PEFR) ($P < 0.05$) of the patients. Mean % increase found in PEFR was 24.75 \pm 6.85%. Forced Expiratory Flow

between 25 and 75% (FEF_{25-75%}), FEF_{25%}, FEF_{50%} and FEF_{75%} were not significantly increased by *A. indicum*. Mean % increases found in these parameters were 19.40 \pm 7.87%, 17.52 \pm 7.30%, 18.82 \pm 9.47% and 25.65 \pm 11.54% respectively. Maximum voluntary

Table 8. Effect of *A. indicum* on lung flow rates

Parameters	Before treatment (mean \pm S.E.M.)	After treatment (mean \pm S.E.M.)	% increase (mean \pm S.E.M.)
PEFR (lit/s)	2.97 \pm 0.38	3.54 \pm 0.39*	24.75 \pm 6.85
FEF _{25-75%} (lit/s)	1.66 \pm 0.28	1.84 \pm 0.26	19.40 \pm 7.87
FEF _{25%} (lit/s)	2.39 \pm 0.36	2.73 \pm 0.39	17.52 \pm 7.30
FEF _{50%} (lit/s)	1.75 \pm 0.27	1.96 \pm 0.28	18.82 \pm 9.47
FEF _{75%} (lit/s)	1.16 \pm 0.22	1.20 \pm 0.17	25.65 \pm 11.54
MVV (lit.)	46.91 \pm 4.28	51.84 \pm 4.68*	11.43 \pm 3.88

*Significantly different from baseline values, $P < 0.05$, (Student's paired t test).

ventilation (MVV) was also significantly increased by *A. indicum*. Mean % increase found in MVV was 11.43 \pm 3.88% (Table 8).

DISCUSSION

Asthma is best described as a chronic disease that involves inflammation of the pulmonary airways and bronchial hyperresponsiveness that results in the clinical expression of a lower airway obstruction that usually is reversible (Fireman, 2003). Varying airflow obstruction leads to recurrent episodes of wheezing, breathlessness, chest tightness and cough (Djukanovic *et al.*, 1992; Horwitz *et al.*, 1995; Bethesda, 1997). Various herbal drugs used in asthma have been reported to have anti-inflammatory activity e.g. *Picrorhiza kurroa*, *Boswellia serrata*, *Ginkgo biloba* etc (Harczy, 1986; Dorsch, 1991; Safayhi *et al.*, 1992). *A. indicum* is used as an anti-inflammatory drug for treating inflammation of bladder in ayurvedic system of medicine.

In present study *A. indicum* was found to significantly decrease the symptom score of all commonly observed symptoms of bronchial asthma suggesting the effectiveness of this drug in improving the symptoms associated with asthma.

Along with the symptoms, *A. indicum* was found to significantly increase FVC (Forced Vital Capacity) and FEV₁ (forced expired volume in one second) which are considered as the best measure of lung function for assessing airflow limitation or asthma severity (Rob *et al.*, 2002). *A. indicum* also signifi-

cantly increased peak expiratory flow rate (PEFR) which is reduced by more than 40% in asthmatic patients, where the resistance of the airways is increased owing to bronchial constriction. Response to asthma treatment is usually accompanied by an increase in PEFR and a decrease in its variability (Rob *et al.*, 2002). Statistically significant increase in lung function parameters by *A. indicum* suggests the effectiveness of this drug in the treatment of bronchial asthma. Decrease in requirement of antiasthmatic allopathic medicines by *A. indicum* in present study suggests that use of this drug can prevent the observed serious side effects of the modern medicine. No change in the general physical parameters and hematological parameters by treatment with *A. indicum* and absence of any untoward effect during the course of the study suggests the safety of this drug in the dose used. Thus the present study suggests the usefulness of *A. indicum* in treatment of bronchial asthma. However, the detailed experimental studies are required to investigate its mechanism of action.

ACKNOWLEDGEMENTS

Authors are thankful to Govt. Ayurvedic Hospital, Vadodara and Sanjiv Hospital, Vadodara for extending their help to perform the clinical studies.

REFERENCES

- Anjuli N, Robert L, Steven W, Patti S, Michael W. (2002) Efficacy and Safety of Beclomethasone

- Dipropionate Extrafine Aerosol in Childhood Asthma. A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study. *Chest* **122**, 1956-1965.
- Bethesda MD. (1995) Global strategy for asthma management and prevention. Global initiative for asthma. National Institutes of Health **95**, 3659.
- Bethesda MD. (1997) National Asthma Education and Prevention Program (National Heart, Lung, and Blood Institute) Second Expert Panel on the Management of Asthma. Expert panel report 2: guidelines for the diagnosis and management of asthma: National Institutes of Health **97**, 4051.
- Chopra RN, Nayar SL, Chopra LC. (1986) *Glossary of Indian Medicinal Plants (Including the Supplement)* pp. 152-153, Council of Scientific and Industrial Research, New Delhi.
- Djukanovic R, Wilson TW, Britten KM, Wilson SJ, Walls AF, Roche WR. (1992) Effect of an inhaled corticosteroid on airway inflammation and symptoms in asthma. *Am. Rev. Respir. Dis.* **145**, 669-674.
- Dorsch W, Stuppner H, Wagner H, Gropp M, Demolin S, Ring J. (1991) Antiasthmatic effects of Picorrhiza Kurroa: androsin prevents allergen and PAF induced bronchial obstruction in guinea pigs. *Int. Arch. Allergy Appl. Immunol.* **95**, 128-133.
- Fireman P. (2003) Understanding asthma pathophysiology. *Allergy Asthma Proc.* **24**, 79-83.
- Harczy M, Maclouf J, Pradelles P, Braquet P, Borgeat P, Sirois P. (1986) Inhibitory effects of a novel platelet activating factor (PAF) antagonist (BN 52021) on antigen-induced prostaglandin and thromboxane formation by the guinea pig lung. *Pharmacol. Res. Commun.* **18**, 111-117.
- Horwitz RJ, Busse WW. (1995) Inflammation and asthma. *Clin. Chest Med.* **16**, 583-620.
- Mehta BK, Neogi R, Kotra S, Mall OP. (1997) Antimicrobial activity of *Abutilon indicum*. *Fitoterapia* **68**, 273-274.
- Nadkarni KM. (1954) *The Indian Materia Medica* pp. 8-9, Dhootapapeshwar Prakashan Ltd., Panvel, India.
- Rob P, David P. (2002) The Measurement and Interpretation of Ventilatory Function in Clinical Practice. In: *Spirometry Handbook*, pp. 3.
- Safayhi H, Mack T, Sabieraj J, Anazodo MI, Subramanian LR, Ammon HP. (1992) Boswellic acids: novel, specific, nonredox inhibitors of 5-lipoxygenase. *J. Pharmacol. Exp. Ther.* **261**, 1143-1146.
- Sharma PV, Ahmed ZA, Sharma VV. (1989) Analgesic constituent of *Abutilon indicum*. *Indian drugs* **26**, 333.
- Sharma R, Kumar A, Tewari PV. (1993) Ayurvedic approach in prevention of upper respiratory tract infections in children. *J. Res. Educ. Indian Med.* **12**, 15-26.
- Vishwanathan MB. (1995) A note on some medicinal plants of the alagarkovil MPCA in Tamilnadu. *Industry Meet cum Seminar on Biodiversity and information on medicinal and aromatic plants*, New Delhi 60-61.