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AN EFFECTIVE TRADITIONAL MEDICINE FOR BRONCHIAL ASTHMA : CLINICAL DEMONSTRATION AND PRELIMINARY TOXICOLOGICAL EVALUATION

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ABSTRACT: *This clinical paper reports the investigations conducted on a traditional African anti-asthmatic formulations and evaluates its toxicological and phyto-chemical effects.*

Introduction

The traditional therapeutic approach to asthma included vinegar of squills, cow-parship, mustard and round birthwort (Rosenblatt, 1976). Datura stramonium has been used for the relief of asthma and bronchitis (Watt and Breyer-Brandwijk, 1962; Lane and Storr, 1979). The prolonged relief in bronchial asthma by Tylophora asthmatica has also been observed clinically (Haranath and Shyamala Kumani, 1975).

Asthma is a disease characterized by an increase in airways resistance which is due to three main factors: (Rosenblat, 1976) contraction of the smooth muscle in the bronchioles; (Watt and Breyer-Brandwijk, 1962) oedema of the bronchiolar mucosa; and increased bronchiolar secretions (Bowman and Rand, 1980). Severe attacks of asthma are alarming and even if the thought of death itself is not necessarily threatening, inability to get enough air in and out of one's lungs is a horrible and frightening experience, which provokes considerable anxiety (Lane and Storr, 1979).

Drugs for therapy of asthma have multiplied over the past several years, but none is completely free of side effects (Poth, Haysman and Sieker, 1977 – 1978). Infact, these conventional medicines only offer brief relief to the patients and therefore investigation into the traditional medicine prepared by Mr. Obuya is fundamental to the destiny of the asthmatics.

We present here some of the preliminary findings of this traditional medicine.

Materials and Methods

Three traditional medicines were used in the study as shown in Table 1.

Drug A and Drug B were prepared by boiling two plants each in a mixture involving water Drug C was also prepared as an aqueous extract.

TABLE 1
Various drug regimen preparations

Preparation	Use
Drug A	For regular treatment
Drug B	For regular treatment
Drug C	For diagnosis

Clinical Study

In this pilot clinical study, we decided to observe a medicine man carrying out his treatment of asthma.

About eleven patients, both males and females with ages ranging from 17 years to 66 years were treated. The recruitment of these patients was based on the fact that they were confirmed asthmatics attending a chest clinic who had given informed consent to participate.

The initial treatment was started by the administration of the diagnostic medicine intranasally. This resulted in profuse nasal mucous secretion and conjuctival injection. The oral medicine was administered soon after the initial procedure and thereafter the regular oral treatment was continued.

Pulmonary function test was carried out on these patients prior to administration of the traditional medicine. The test was repeated one hour after the administration of the medicines, then daily for two days and thereafter, every month.

Toxicological Screening

Female mice weighing 20g to 30g were used. Various volumes of drug A and B were used.

A group of six mice were injected intraperitoneally with drug B at a volume of 0.4 ml. The effect of the preparation on the animals was observed immediately after injection and within 36 hours. The experiment was repeated with decreasing volumes of 0.2 ml and 0.05 ml.

Drug A was separated into fraction 1 and fraction 2.04 ml of fraction 1 was administered intraperitioneally to a group of mice and the effects observed immediately after injection and within 36 hours. The experiment was repeated using various volumes of fraction 2.

The control mice were injected intraperitoneally with normal saline at a volume of 0.4 ml and the effects observed as above.

Phytochemical Screening

The plant materials KOR 303, KOR 305 and KOR 379 were phyto-chemically screened.

Results

Clinical Study

The results of the clinical study are presented in Tables 2 to 9.

TABLE 2
Patient 1: (F) (26 Years)

Respiratory Function Index	FVC	FEV	FEV %
Baseline:			
% Fred PFT 1/8/86	94	91	-3
% Change 4/8/86	1.2	0	+ 1.2
% Change 5/8/86	- 4.1	+ 0.7	+ 4.9
% Change 6/8/86	- 4.9	- 7.8	- 11.6
% Change 11/8/86	- 16.7	+ 22.8	- 7.9
% Change 10/9/86	+ 10.2	+ 36.6	+ 12.9
% Change 9/10/86	- 3.5	- 7.3	- 3.8
% Change 5/11/86	+ 2.6	- 2.2	- 4.9

TABLE 3
Patient 2: (F) (51 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	17	20	+13
% Change 4/8/86	+ 323.5	+ 232.7	- 21.1
% Change 5/8/86	+ 16.2	+ 13.5	- 1.3
% Change 6/8/86	+ 6.8	+ 2.2	- 4.1
% Change 11/8/86	- 5.6	- 5.3	0
% Change 10/9/86	+ 4.0	+ 7.8	- 7.8
% Change 9/10/86	0	- 2.1	- 2.1
% Change 5/11/86	+ 0.8	- 0.5	- 0.5

TABLE 4
Patient 3: (M) (17 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	115	113	- 2
% Change 4/8/86	- 3.5	- 17.9	- 15.1
% Change 5/8/86	- 10.9	- 26.7	- 17.8
% Change 6/8/86	+ 8.5	- 60.4	+ 38.3
% Change 11/8/86	- 1.8	- 10.9	- 12.0
% Change 10/9/86	- 2.6	- 32.8	- 31.2
% Change 9/10/86	- 6.5	+ 36.2	+ 26.1
% Change 5/11/86	+ 8.0	- 2.8	- 9.7

TABLE 5
Patient 4: (M) (24 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	66	55	- 16
% Change 4/8/86	- 5.7	+ 4.8	+ 15.9
% Change 5/8/86	+ 29.7	+ 41.5	+ 9.1
% Change 6/8/86	+ 1.5	+ 6.2	+ 4.8
% Change 11/8/86	+ 0.5	+ 8.6	+ 8.0
% Change 10/9/86	+ 31.3	+ 58.3	+ 20.3
% Change 9/10/86	- 2.1	- 1.1	+ 1.2
% Change 5/11/86	+ 7.3	+ 12.8	+ 6

TABLE 6
Patient 5: (M) (47 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	74	50	- 25
% Change 4/8/86	- 59.5	- 28.7	+ 74.5
% Change 5/8/86	+ 162.9	+ 53.8	- 41.7
% Change 6/8/86	+ 125.8	+ 12.0	+ 3.6
% Change 11/8/86	+ 19	+ 46.8	+ 24.1
% Change 10/9/86	- 20.0	- 41.2	- 26.4
% Change 9/10/86	- 2.1	- 32.8	+ 0.4
% Change 5/11/86	+ 3.7	+ 5.2	+ 10.9

TABLE 7
Patient 6: (F) (43 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	78	63	- 16
% Change 4/8/86	72.2	- 21.4	- 10.3
% Change 5/8/86	0	- 0.9	0
% Change 6/8/86	+ 4.8	+ 10.6	+ 4.9
% Change 11/8/86	+ 2.6	- 0.8	- 3.1
% Change 10/9/86	- 7.5	+ 11.3	+ 19.4
% Change 9/10/86	- 6.5	- 16.7	- 10.8
% Change 5/11/86	- 9.2	- 10.4	- 1.5

TABLE 8
Patient 7: (F) (66 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	65	36	- 28
% Change 4/8/86	-36.0	- 36.4	+ 3.7
% Change 5/8/86	- 2.67	- 21.4	- 19.6
% Change 6/8/86	+ 9.6	+ 3.0	- 4.4
% Change 11/8/86	+ 57.5	+ 105.9	+ 30.2
% Change 10/9/86	- 23	- 37.1	- 17.9
% Change 9/10/86	+ 19.6	+ 43.2	+ 19.6
% Change 5/11/86	-	-	-

TABLE 9
Patient 8: (M) (43 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	63	39	- 31
% Change 4/8/86	- 6.0	- 37.9	- 16.3
% Change 5/8/86	+ 29.4	- 46.0	- 22.0
% Change 6/8/86	+ 12.8	+ 29.8	+ 12.5
% Change 11/8/86	+ 17.9	+ 77.0	+ 52.8
% Change 10/9/86	- 12.6	- 10.7	+ 2.0
% Change 9/10/86	- 28.9	- 47.2	- 24
% Change 5/11/86	- 18.1	- 7.6	+ 10.5

TABLE 10
Patient 9: (F) (57 Years)

Respiratory Function Index	FVC	FEV 1	FEV % 1
Baseline:			
% Fred PFT 1/8/86	43	29	- 27
% Change 4/8/86	- 10.7	+ 10.3	0
% Change 5/8/86	- 7.1	+ 24	- 18.5
% Change 6/8/86	- 20.3	- 1.8	22.7
% Change 11/8/86	+ 19.4	+ 10.7	- 7.4
% Change 10/9/86	-	-	-
% Change 9/10/86	-	-	-
% Change 5/11/86	-	-	-

TABLE 11

Patient	Self Evaluation	Clinician's Evaluation
1	+	-
2	+	-
3	-	-
4	+	+
5	+	+
6	+	±
7	+	+
8	+	+
9	Did not complete Treatment	±

Key: + Definite Improvement
± Some Degree of Improvement
- Inconclusive

A summary of qualitative evaluation based on both subjective and objective observation is shown in Table 11.

Toxicological Screening

Results of the toxicological screening in mice carried out on the two oral preparations are presented in Tables 12 and 13.

TABLE 12
Toxicological screening in mice drug A

S. No.	Experiment	Vol. Injected I.P. (ml)	Effects	Mortality after 36 hours
1	Fraction 1	0.4	- Flaccid behaviour - Mucoid excretion - Piloerection	0 - 9
2	Fraction 2	0.4	- Piloerection - Writhing reflex - Mucoid excretion - Gasping	9 - 9
3	Fraction 2	0.2	- Increased rate of breathing - Writhing reflex - Mucoid excretion - Gasping	6 - 6
4	Fraction 2	0.05	- Writhing reflex - Gasping - Mucoid excretion - Flaccid behaviour	0 - 6
5	Normal Saline	0.4	- No effect	0 - 6

TABLE 13
Toxicological screening in mice drug B

Experiment	Vol. Injected I.P. (ml)	Effects	Mortality after 36 hours
1	0.4	- Writhing reflex - Mucoid excretion - Gasping	6 - 6
2	0.2	- Increased rate of breathing - Writhing reflex - Mucoid excretion	3 - 6
3	0.05	- Writhing reflex - Hind leg paralysis - Mucoid excretion	0 - 6
4	0.4	- No effect	0 - 6

Phytochemical Screening

The compounds detected in the plant materials are presented in Table 14.

TABLE 14
Phytochemical screening results

Material	Alkaloids	Flavonoids	Triterpenes	Sterols	Cardiac Glycosides	Anthra Quinones
KOR 303	+	-	+	+	-	-
KOR 305	+	+	+	+	-	-
KOR 379	+	-	+	+	+	-

DISCUSSION

There are great advantages in the experimental asthma study of human subjects. Not only does this method avoid extrapolation of results in animals to man, but in the field of respiration human subjects are the most verstatile because they can perform voluntary breathing maneuvers to suit the purpose of the investigation (Bouhuys, 1976). The pulmonary function tests carried out in our study plus the interviews indicated that great improvements were obtained using the traditional medicines. We therefore feel that this traditional medicine has high potential and thus recommend further investigation.

The narrow thereapeutic range obtained with some of the preparations in the toxicological evaluation in mice does not necessarily indicate toxicity in man as has been seen in the clinical study. The species differences will therefore have to be considered.

The preliminary phytochemical screening of the plant materials indicated that the major compounds are steroids. Corticosteroids are frequently used as past of the treatment for patients with bronchial asthma and are probably the most effective agents (McPhillips and Wilson). There are several possible mechanisms which might account for the anti-asthmatic effects of corticosteroids. These include inhibition of histamine formation or storage and the direct effect on smooth muscle by steroids.

Corticosteroids under conventional use have vast side effects despite their greater potency and thus a safe and effective traditional medicine containing steroids would therefore be an ideal drug for the treatment of bronchial asthma.

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