EFFICACY AND SAFETY OF A HERBAL MEDICINE

AF-200

IN INFLUENZA : A DOUBLE BLINDED PLACEBO CONTROLLED CLINICAL STUDY

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OBJECTIVE

The aim of the study was to see the efficacy and safety of an herbal antiflu tablet AF-200 in patients of influenza.

ABSTRACT

One hundred patients of influenza (age ranging 16 to 78 years) were divided into two groups which were similar in age, sex ratio, duration of illness, symptoms and signs. Each group consisted of 50 patients. Patients of one group received 4 tablets ofAF-200, 4 times a day for 7 days, while the patients of the other group were given plain lactose tablets in the same dosage for the same duration. Specific signs and symptoms associated with influenza were recorded for all these patients in a predesigned proforma from 1st to 7th day. The specific signs and symptoms of influenza e.g. malaise, pain in back and limbs, fever, anorexia, suffused conunctivae, flushing of face, hyperaemic fauces etc. were remarkably attenuated on the 2nd day in patients receiving AF-200. This was in clear contrast to the non-alleviation of these specific signs and symptoms even upto 5th day in patients receiving the placebo tablets. These observations therefore cearly suggest that the herbal medicine AF-200 manufactured by SBL Ltd. in collaboration with Boiron, France is remarkably effective in the quick reduction of signs and symptoms of influenza. Furthermore, while 40% of patients in placebo group showed some degree of depression after the attack was over, none of the patient receiving AF-200 manifested with such post-influenzal depression.

INTRODUCTION

Influenza is an Italian word that means "influence".[1] The Italians believed that the epidemics were due to 'influence' of the stars. However, it is now known the this acute respiratory illness is due to a group of myxoviruses. [23] It ocurs in epidemics and occasionally pandemics, often explosive in nature. The illness starts suddenly with malaise, headache, pain in back and limbs, anorexia and sometimes nausea and vomiting. Pyrexia to 39^0C remits for 2 to 3 days, with chills and shivering but seldom rigors. The pulse is rapid. In many cases, no further symptoms develop and recovery ensues within 3 to 5 days. The disease may be complicated by tracheitis, bronchitis and bronchopneumonia. Toxic Cardiomyopathy may

cause sudden death especially when there is pre-existing air-ways obstruction, post-influenzal depression is not uncommon that may last for a week or two[4]

SBL Limited in collaboration with Boiron France, introduced AF-200 which is effective in combating the aforementioned signs and symptoms of influenza as follows:

AF-200 (Anti Flu Tablets)

Composition and Action

1. **Arsenicum album :**

   Thin watery, excoriating nasal discharge, blocked nose, sneezing and fever.

2. **Gelsemium sempervirens :**

   Dullness, drowsiness and chilliness heaviness of head, muscular soreness and great prostration.

3. **Eupatorium perfoliatum :**

   Influenza, acute bronchitis, naso-pharyngeal catarrh and congestion of the respiratory mucosa (British Herbal Pharmacopoeia, 1983) relieves pain in limbs and muscles that accompanies influenzas, occipital pain after lying down with sense of weight.

4. **Bellis perennis :**

   Acts upon the muscular fibers of the blood vessels, great muscular and joint sorenes. headache with bruised feeling.

5. **Byronia alba :**

   Acts as expectorant, bronchitis, rheumatic pains and lumbago (BHP, 1983) bursting, splitting headache, lips parched, dry, cracked, dryness of mouth, tongue and throat with excessive thrist.

MATERIALS AND METHODS

One hundred patients attending the OPD at Centre for Visceral Mechanisms, V.P. Chest Institute University of Delhi were included in the study. The patients met the following criteria (1) Diagnosis of influenza based of clinical criteria as given in Tablel. 1 (2) No systemic or other cardiorespiratory diseases.

The patients were divided into two groups, with about 50 patients in each group. One of the group received the Drug 'A' and 'B' were similar in respect to their appearance, consistency, flavour and taste. The indentification, symptoms, signs and findings on physical examination were recorded on their first visit in the predesigned proforma. Routine blood and urine examination was done on their first visit and on 5th day. The clinical evaluation was done daily from 1st to 7th day. The findings were noted in the predesigned proforma. The study was completed when the data of all the patients was available in the Predesigned proforma. The study was completed when the data of all the patients was available in the redesigned porforma. The study was completed when the data of all the patients was

available in both the groups. Drug 'A' was the test drug (AF-200) and Drug B was the placebo Drug (Lactose).

RESULTS

- Total number of patients (n) in the trial-100 i.e.(n=100).
- 50 patients received Drug 'A'

  Male n=27

  Female n=23
- 50 patients received Drug 'B'

  Male n=28

  Female n=22
- Range of ages - 16 to 78 years.
- The Drug was given for one week in the dosage of 4 tablets 4 times a day.
- The results have been shown through Table 1 and 2.

n= Number of patients

Table - 1

	Symptoms	DRUG 'A' AF-200 (N=50)							B PLACEBO (N=50)						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1.	Malaise	50 100%	23 46%	8 16%	3 6%	0	0	0	50 100%	46 92%	37 74%	22 44%	9 18%	2 4%	2 4%
2.	Headache	26 52%	12 24%	7 14%	0	0	0	0	23 46%	20 40%	10 20%	8 16%	1 2%	0	0
3.	Pain in the back and limbs	47 94%	24 48%	5 10%	1 2%	0	0	0	50 100%	47 94%	39 78%	22 44%	12 24%	3 6%	0
4.	Fever	50 100%	18 36%	7 14%	0	0	0	0	50 100%	42 84%	32 64%	26 52%	18 36%	1 2%	0
5.	Chills, Shivering or Rigor	18 36%	3 6%	0	0	0	0	0	22 44%	10 20%	6 12%	6 12%	0	0	0
6.	Anorexia, Nausea or Vomiting	50 100%	32 64%	18 36%	7 14%	0	1	0	50 100%	43 86%	31 62%	18 36%	3 6%	0	0
7.	Sneezing with no nasaldischarge or mild, moderate or profuse discharge	26 52%	18 10%	0	0	0	0	0	20 40%	18 36%	11 22%	9 18%	2 4%	0	0
8.	Dry and sore throat	24 48%	18 36%	7 14%	2 4%	0	0	0	22 44%	20 40%	14 28%	13 26%	3 6%	0	0
9.	The head feels stuffed	18 36%	6 12%	1	0	0	0	0	10 20%	8 16%	8 16%	8 16%	2 4%	0	0
10	Cough	24 48%	19 38%	2 4%	0	0	0	0	21 42%	19 38%	13 26%	10 20%	3 6%	0	0
	Signs														
11.	Flushing face	34 66%	22 44%	9 18%	0	0	0	0	30 60%	22 44%	20 40%	12 24%	4 8%	0	0
12.	Suffused conjunctiva	18 36%	10 20%	3 6%	0	0	0	0	16 32%	13 26%	11 22%	9 18%	2 4%	1 2%	1 2%
13.	Hyperaemic fauces	28 56%	13 26%	2 4%	0	0	0	0	23 46%	23 46%	20 40%	16 32%	6 12%	0	0
14.	Lymphoid follicles	7 14%	7 14%	5 10%	0	0	0	0	5 10%	5 10%	5 10%	2 4%	0	0	0
15.	Tenderness over the sinuses	18 36%	6 12%	3 6%	0	0	0	0	20 40%	18 36%	18 36%	16 32%	11 22%	3 6%	3 6%
16.	Rashes over the skin	7 14%	2 4%	0	0	0	0	0	5 10%	4 8%	4 8%	3 6%	0	0	0

TABLE 2

	Drug - 'A' / AF-200 n-50	Drug 'B' Placebo n=50
Number of patients (n) assumes normal activities on	Day 3 n = 86%	Day 3 n = 36%
	Day 4 n = 100%	Day 4 n = 48%
	Day 5 n = 100%	Day 5 n = 64%

DISCUSSION

The patients of influenza who received Drug 'A' were quite similar to those who were given Drug 'B'. The basis of their similarity is as follows.

Number of patients in both groups were same (50 vs. 50), they were of the same age group (16 years to 78 years), almost similar male/female ratio with exactly the same signs and symptoms. These parameters reflect the fact that patients of both the groups were similar.

Malaise was remarkably alleviated (in 54% of patients) within only one day of treatment with the medicine AF-200 as compared to placebo group in whom only 8% patients had malaise alleviated. (Table 1). The most significant appears to be 3rd day i.e. 2 days following the treatment of AF-200 ensued, where fever was subsided in 90% of patients but with placebo 22% patients had their fever subsided. This is significant as the 86% patient resumed to their office and other duties on the 3rd day as compared to only 36% patient (taking placebo) assuming their duties by 3rd day (Table 2). After fever subsided in AF-200 group but 48% of patients were still reeling under fever in placebo group (Table-1)

Fever in influenza as always variable [3,4] depending upon the type of myxoviruses, patients immunity etc. In this epidemic at Delhi, fever appears to take an average of 5 days to subside as reflected by placedo group (Table 1)

Pain in back and limbs, a major deterrent in assuming the normal activities, appears to be significantly reduced following 2 days of treatment with AF-200. 90% Patients recovered from this symptom on 3rd day. This is in clear contrast to placebo group in whom only 22% patients got rid from pain back and limbs by 3rd day (Table 1)

Sneezing with nasal discharges on 3rd day was almost relieved in 64% of patients with AF-200 (Tablel 1). In placebo group, on the other hand, only 38% patients had their sneezing relieved by 3rd day. This remarkable benefit of AF-200 on reducing the sneeezing must have been due to its a Arsenicum Album content.

Anorexia in Drug 'A' group was relieved in 64% patients as opposed to placebo group in whom only 38% patients had their anorexia relieved by 3rd day (Table 1). This may have been due to 'Eupatorium perfoliatum' which is one of the content of AF-200.

Cough was not a marked feature in the present series. Only 48% patients in Drug'A' group and 42% patients in Drug -'B' group presented with Cough (Table 1). This seems interesting as on clinical examination 56% patients in Drug 'A' group and 46% in Drug -'B' group was found to have hyperaemic fauses (Table 1). It appears all these patients did not have their hyperaemia marked enough to react to the classical cough receptor sites[5]. However, the impact ofAF-200 was quite interesting to observe. By 3rd day only 4% patients had cough in Drug -A' group while 26% patients continued with cough in Drug - 'B' group. This beneficial effect ofAF-200 must have been due to both the Bryonia Alba and Eupatorium Perfoliatum The former compound while acting as an expectorant, the latter must have been effective due to its property of reducing the congestion of respiratory mucosa and naso pharyngeal catarrh. The hypothesis was guided in part due to the fact that reduction in cough due to AF-200 almost paralleled the reduction of hyperaemic fauces.

Similar mechanisms appear to govern the reduction of tenderness over the sinuses that almost paralleled the reduction of stuffy head in AF-200 group (Table 1). All the patients in Drug -A' group got rid form the complaints of the head feels stuffed with the clinical finding of redsuction of tenderness over the sinuses.

Side effects :

No side effects of whatsoever nature could be seen in any patient,

Thus, in view of the quick and significant attenuation of sign and symptoms of influenza by AF-200 as compared to the patients who received placebo, it is concluded that AF-200 manufactured by SBL Limited is highly effective in the common cold or influenza.

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