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Clinical Evaluation of Septilin in Chronic Bronchitis

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ABSTRACT

Septilin was evaluated in 30 patients of chronic bronchitis at a dose of 2 tabs. t.i.d. for 4 weeks. Bronchodilators an antibiotics were given only where necessary.

Outstanding among its advantages were the findings that Septilin reduced the volume and purulence of the sputum, controlled episodes of superadded bacterial infections and facilitated expectoration. Serum IgG rose significantly after 2 months and this could have been responsible for the protection of the patients from recurrent bacterial infections.

None of the patients complained of any side-effects.

INTRODUCTION

Chronic bronchitis is amongst the most frequently encountered respiratory problems in our country and is responsible for a high degree of morbidity and disability. Inflammation of the bronchial mucosa, exudation from the mucosal glands and recurrent bacterial infections are salient pathological features of this condition. Most patients of chronic bronchitis expectorate viscid, tenacious sputum which is extremely exhausting to many of them.

COMPOSITION

Each Septilin tablet contains:

Balsamodendron mukul		0.612 g
Exts.	Maharasnadi quath	65 mg
	Phyllanthus emblica	16 mg
	Tinospora cordifolia	49 mg
	Rubia cordifolia	32 mg
	Moringa pterygosperma	16 mg
	Glycyrrhiza glabra	6 mg
Shankh bhasma		32 mg

Septilin (Himalaya) is a formulation of plant ingredients and has been reported to have anti-inflammatory, antiexudative and antibacterial properties which exactly counteract the pathological features of chronic bronchitis as mentioned above. Septilin has been reported to help build up resistance to infection in the mucosa and inhibit the growth of both gram-negative and gram-positive bacteria. It has been found effective in stubborn, chronic upper respiratory infections like sinusitis and pharyngitis. But since few reports are available regarding its effects in patients with chronic persisting infection/inflammation of the lower respiratory tract, the present study was undertaken to evaluate its efficacy in patients with chronic bronchitis.

MATERIAL AND METHODS

Thirty patients of chronic bronchitis with/without reversible/irreversible airway obstruction were included in the present study. The patients were aged between 19 and over 60 years. Twenty were males and 10 females. See Table 1 for details.

Table 1: Age and Sex Distribution			
Age in years	Males	Females	Total
18 - 30	1	0	1
31 - 40	5	3	8
41 - 50	4	2	6
51 - 60	8	4	12
Above 60	2	1	3
Total	20	10	30

Patients were considered to have chronic bronchitis when they presented with cough and expectoration on most of the days for three months in a year, for two consecutive years, in the absence of any other bronchopulmonary or cardiac disorder. After a detailed history of the illness, especially about the character and volume of sputum, frequency of respiratory infections and grade of dyspnoea, each patient was examined physically in detail. This was followed by further investigations as follows:

1. Total and differential leucocyte counts.
2. Urinalysis for sugar, albumin and microscopy.
3. X-ray of Ches (P.A. view).
4. Serum immunoglobulin estimations-- IgG, IgA, IgM.
5. Spirometry which included FEV_1, FVC, FEV_1/FEC% PEER FEF_{25-75}, MVV.
6. Twelve minutes walking distance (12 MD) to study exercise endurance.
7. Liver function tests which included serum bilirubin, alkaline phosphatase, SGOT and SGPT.

After explaining the purpose of the study and obtaining the written consent of the patients, they were given Septilin, 2 tablets 3 times a day for a period of 2 months. Bronchodilators and antibiotics were given as per the requirements of the patients. Pregnant women and children under 15 years were not included in this study.

FOLLOW-UP STUDIES

All the patients were asked to come for follow-up and for collection of Septilin every two weeks, and earlier if they so needed. At each visit they were thoroughly examined and asked about their symptoms, especially cough frequency, amount and character of the sputum, ease of expectoration, history of any acute respiratory infection during the period and grade of dyspnoea. They were asked to report early in case of suspicion of infection. Spirometry, serum immunoglobulins, 12-minute walking test, urinalysis and liver function tests were repeated after one and two months of starting Septilin.

RESULTS AND OBSERVATIONS

The control of symptoms and gradual improvement noticed after 2, 4 and 8 weeks of treatment with Septilin are depicted in Table 2.

Clinical spirometry is an ideal screening test to evaluate pulmonary function. The most reliable predictor is provided by expiratory flow parameters and the maximal breathing capacity (MBC) or maximal voluntary ventilation (MVV). The unique value of the MBC may lie in its dependence on the intangible variables of co-operation, motivation and stamina.[1,2]

The improvement in pulmonary function tests in out-patients is shown in Table 3. It is specially noteworthy that we observed an improvement of over 15% in MVV and 12 MD tests in 18 patients after Septilin administration.

Table 2: Effect of Septilin on the Symptomatology (Total No. of patient = 30)	
	Duration of treatment with Septilin

	2 weeks	4 weeks	8 weeks
Cough Bouts/Day			
No change	23	13	6
Increased	2	2	1
Decreased	5	15	23
Sputum Volume			
No change	22	11	5
Increased	0	1	1
Decreased	8	18	24
Purulence of Sputum			
No change	26	19	3
Decreased	4	11	27
Effort at Expectoration			
No change	26	18	7
Facilitated	4	12	22
Became more difficult	0	0	1
Dyspnoea Grade			
No change	26	17	10
Improved	3	13	19
Deteriorated	1	0	1
Frequency of Respiratory Infections			
No change	28	16	8
Decreased	2	14	22
Increased	0	0	0
Feeling of Well-being			
No change	25	14	6
Better	4	16	23
Worsened	1	0	1
Overall Impression			
No change	26	13	5
Septilin helped	4	17	24
Caused deterioration	0	0	1

Table 3: Improvements in Pulmonary Function Tests

Test	Before treatment	After 2 months of Septilin
FEV_1 (Litres)	1.7 ± 0.4	1.85 ± 0.5
FVC (Litres)	2.8 ± 0.65	2.85 ± 0.7
FEV_1/FVC (%)	66.5 ± 14.0	65.0 ± 12.6
MVV (Litres/Minute)	62.0 ± 17.5	72.0 ± 22.4
12 MD (Meters)	625.0 ± 72.0	850.0 ± 68.0

Table 4 shows the serum immunoglobulin status before and after Septilin administration. IgG immunoglobulins showed significant improvements after treatment with Septilin, thereby indicating that the protective action was enhanced with the use of Septilin. Recent investigation have shown that despite lower serum levels of IgA, IgA levels may be elevated in the local fluids bathing the infected surfaces (e.g. nasal mucosa and lung). It is the production of antibody (most prominently IgA) by locally deployed immunologically primed cells which may prove to be of great importance for the prevention of subsequent infection.[3]

Table 4: Improvement in Serum Immunoglobulin Status

Immunoglobulin	Before Septilin	After 2 months of Septilin
IgG mg %	1340 ± 205	1670 ± 220
IgA mg %	217 ± 86	230 ± 90
IgM mg %	256 ± 65	240 ± 78

In our series, IgA and IgM type immunoglobulins showed no consistent pattern of change improving in some, while decreasing in the others.

SIDE-EFFECTS

None of the 30 patients given Septilin complained of any untoward side-effects. Two patients reported mild dryness and one mild gastric discomfort, but these disappeared with continued treatment. All the patients completed the duration of 2 months of clinical trial. The overall acceptance of Septilin was excellent. No hypersensitivity reactions were recorded in any patient.

SUMMARY AND CONCLUSIONS

The clinical efficacy of Septilin, given orally at a dose of two tablets three times a day, has been evaluated in 30 patients of chronic bronchitis. The following conclusions were drawn:

1. The beneficial effects of Septilin became manifest mostly after 4 weeks of continuous treatment; by the eighth week the improvement in the clinical state was well established.
2. Septilin reduced the volume and purulence of the sputum, controlled infections and facilitated expectoration.
3. An increase in the level of serum IgG was noticed after 2 months and this may be responsible for the protection of the patients from recurrent bacterial infections.
4. Although there was no significant change in the air-flow limitation parameters like FEV_1, FVC and FEV_1/FVC%, the exercise endurance as assessed by MVV and 12 MD tests showed more than 15% improvement in 18 out of 30 patients.

For reasons mentioned earlier, in further trials it would be interesting to look into the IgA levels in the sputum before and after Septilin administration.

In conclusion Septilin, used orally, is a useful adjunct to other measures adopted for the management of patients with chronic bronchitis. It must, however, be remembered that the beneficial effects start after a latent period of a few weeks.

REFERENCES

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