Role of Septilin in Chronic Tonsillitis

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ABSTRACT
A comparative study of fifty five cases of chronic tonsillitis was carried out using Septilin and co-trimoxazole. Twenty seven patients in Group A received Septilin, 2 tablets b.i.d. or t.i.d., depending on age. Twenty five patients in Group B received co-trimoxazole.

Fever was controlled faster in the Septilin group. Crypts and debris disappeared in some patients on Septilin but not in even a single patient in the co-trimoxazole group. In 75% of cases on Septilin, throat swab cultures returned to normal. But this was seen in only 50% of those who took co-trimoxazole.

Septilin did not cause anorexia or any other side-effects. In fact, there was better weight increase and a general feeling of well-being, with overall improvement in the general condition in 66.7% of cases receiving Septilin.

INTRODUCTION
To understand chronic tonsillitis, a knowledge of the structure of the tonsil is important. Forming part of the Waldeyer’s ring of lymphoid tissue situated at the junction of the mouth and nasal passages with the pharynx, the palatine tonsil is a sub-epithelial collection of lymphatic follicles with prominent germinal centres. Similar to a lymph node, it has no medulla or a sub-capsular lymph space and hence no afferent lymphatic vessels. The medial surface along with its penetrating branching crypts is lined by stratified squamous epithelium.

Neighbouring mucous glands commonly open into the depths of these crypts, possibly to flush them free of debris. Efferent lymphatic vessels drain to the jugulo-digastric lymph node and from there to the cervical chain (Last, 1978, Mawson, 1979).

After an episode of acute tonsillitis, the tonsil may not return to its previous healthy state and certain pathological changes ensue to ensure chronicity and the need for recurrent therapy. This chronicity can also be established by recurrent episodes of sub-clinical tonsil infections manifested only as a sore throat.

Chronic tonsillitis is diagnosed mainly by a history of recurrent sore throats or episodes of acute tonsillitis. In such cases a complaint of anorexia, loss of weight, palpitation or of joint pain may be present.

When such a history is accompanied by congestion of the anterior pillars of the fauces, widening of the mouths of the crypts of the tonsil with or without debris in them and chronic enlargement of the jugulo-digastric lymph node and nothing else in the upper respiratory tract accounts for the symptoms, then the diagnosis is reliably made of chronic tonsillitis.

Mawson (1979) states, ‘There is no medical treatment known that will eradicate chronic tonsillitis, as fibrosis within the tonsil barricades microscopic septic foci against effective concentration of an antibiotic. Acute exacerbations treated with antibiotics fail to sterilise the tonsil for the same reason.'
Long term administration of an antibiotic may be helpful in children who for some good reason are not suitable for surgery, but radical enucleation of the tonsils is the only certain cure for chronic tonsillitis and the only certain prophylaxis against acute tonsillitis.

The effectiveness of tonsillectomy in these conditions has been shown in controlled clinical trials and substantiated (Mckee, 1963, Roydhouse, 1969).

The treatment thus advocated for chronic tonsillitis is an absolute one, namely, tonsillectomy with its inherent morbidity and mortality due to the surgery and the anaesthetic risks. It was therefore felt that there was room to search for an alternative therapy or modality in the treatment of chronic tonsillitis.

This study was therefore carried out not only to evaluate the role of Septilin, an Ayurvedic preparation with antibacterial and anti-inflammatory properties (Mascarenhas, 1980) in averting tonsillectomy, but also to compare Septilin with a broad spectrum antibiotic, co-trimoxazole, in patients with established cases of chronic tonsillitis.

MATERIAL AND METHODS
Fifty five cases of chronic tonsillitis were selected at the Department of ENT, Safdarjang Hospital, New Delhi, for this study, which was carried out from August 1986 to July 1987. Out of these 55 cases, 3 were lost to follow-up and the remaining were divided into two groups. Group A received three months of Septilin therapy while Group B received co-trimoxazole therapy for seven days.

The patients selected for this study were those in whom chronic tonsillitis was established by a detailed history and through examination of the ear, nose and throat. Other causes of upper respiratory tract infection were excluded by radiography of the para-nasal sinuses and where necessary, by radiography of the soft tissue neck to visualise the nasopharynx. Chest PA views were also taken.

In all the cases swabs of the throat for culture were taken before and after the treatment. Routine blood and urine examinations were also done.

The patients were reviewed after one week of treatment and then every one month, for 6-9 months thereafter. Depending on the improvement in the symptoms and signs based on the following seven criteria, the results were classified as good, fair or poor:

1. Number of episodes of sore throat in one year
2. Fever during the attack of sore throat
3. Improvement in the general condition
4. Congestion in the anterior tonsillar pillars
5. Presence of debris in the crypts
6. Cervical lymphadenitis
7. Throat swabs for culture tests

(See Table I).

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Criteria</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Number of episodes of sore throat in one year</td>
<td>Marked to complete relief</td>
<td>Appreciable relief</td>
<td>No relief</td>
</tr>
<tr>
<td>2.</td>
<td>Fever during the attack of sore throat</td>
<td>No fever</td>
<td>Frequency appreciably reduced</td>
<td>Fever persists</td>
</tr>
</tbody>
</table>
3. General condition  
   - Improved markedly  
   - Appreciable improvement  
   - No improvement  

4. Congestion in the anterior tonsillar pillars  
   - Disappeared completely  
   - Decreased but not completely  
   - No change or increased congestion  

5. Presence of debris or pus in the crypts  
   - Disappeared completely  
   - Reduced appreciably  
   - No change  

6. Cervical lymphadenitis  
   - No palpable  
   - Palpable but reduced in size  
   - Palpable with no change  

7. Throat swabs for culture test  
   - Reverted to normal flora  
   - —  
   - Abnormal flora persist  

**COMPOSITION**

Each Septilin tablet contains:

- **Balsamodendron mukul** 0.162 g
- **Exts.** Maharasnadi quath 65 mg
  - Phyllanthus emblica 16 mg
  - Tinospora cordifolia 49 mg
  - Rubia cordifolia 32 mg
  - Moringa pterygosperma 16 mg
  - Pristimera indica 6 mg
- **Shankh bhasma** 32 mg

**Therapeutic action of the ingredients**

**Balsamodendron mukul (Guggul)** has been regarded as a sovereign remedy in ancient medicine. As described in standard Ayurvedic texts, Guggul is reputed to be an ancient broad spectrum drug with a wide therapeutic range. Its therapeutic action is similar to that of ACTH as it raises the general defence mechanism of the body and thus helps overcome infective and inflammatory processes.

**Phyllanthus emblica** is the richest natural source of ascorbic acid. The effects of Vitamin C on the adrenal cortex and in building up resistance to infection are well known.

**Moringa pterygosperma** the root bark of young trees contains a physiologically active, basic principle ‘spirochin’ and an antibiotic substance ‘pterygospermin’. Spirochin is effective in combating gram positive infections, specially staphylococcal and streptococcal. Pterygospermin exhibits pronounced antibacterial activity against both gram negative and gram positive organisms.

**Pristimera indica** contains the antibacterial principle ‘pristimerin’ which is active against a large number of gram positive cocci, particularly *Streptococcus viridans* and *Streptococcus pyogenes*.

**DOSES**

The dose of Septilin varied between 2 tablets b.i.d. to 2 tablets t.d. depending on the age of the patient. This course of Septilin lasted three months. co-trimoxazole was given either as suspension or tablets and the dose was calculated according to the body weight of the patient and administered over seven days.

**OBSERVATIONS AND RESULTS**

Of the 52 patients studied 27 were in Group A (Septilin) and 25 in Group B (Co-trimoxazole).

In Group A (Septilin), 16 (59.2%) were males and 11 (40.8%) females. The maximum number of patients, thirteen (48.1%) were in the age group of 21-30 years. The youngest patient was a 4½ - year-old female and the oldest, a 32-year-old male.
In Group B (Co-trimoxazole) there was more of an equal male: female ratio, viz. 12 (48%): 13 (52%). The maximum number of 110 (40%) patients randomly selected fell in the age group of 11-20 years. The youngest patient was a 6-year-old female and the oldest, a 26-year-old male (See Table II).

<table>
<thead>
<tr>
<th>Age group in years</th>
<th>Group A (Septilin)</th>
<th>Group B (Co-trimoxazole)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>0-10</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>11-20</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>21-30</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>31-40</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total No.</td>
<td>16</td>
<td>11</td>
</tr>
</tbody>
</table>

A comparative look at the results depicted in Table III reveals the following observations:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Signs and symptoms</th>
<th>Group A (Septilin) Before</th>
<th>Group B (Co-trimoxazole) Before</th>
<th>Group A (Septilin) After</th>
<th>Group B (Co-trimoxazole) After</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>No. of episodes of sore throat</td>
<td>10</td>
<td>11</td>
<td>3 (30%)</td>
<td>4 (36.3%)</td>
</tr>
<tr>
<td></td>
<td>a. &lt; 6</td>
<td>17</td>
<td>14</td>
<td>11 (64.7%)</td>
<td>8 (57.1%)</td>
</tr>
<tr>
<td></td>
<td>b. &gt; 6</td>
<td>12</td>
<td>12</td>
<td>2 (16.7%)</td>
<td>4 (33.3%)</td>
</tr>
<tr>
<td>2.</td>
<td>Fever during attack</td>
<td>21</td>
<td>19</td>
<td>3 (14.3%)</td>
<td>1 (5.4%)</td>
</tr>
<tr>
<td></td>
<td>3. Improvements in the general condition</td>
<td>18</td>
<td>16</td>
<td>1 (100%)</td>
<td>—</td>
</tr>
<tr>
<td>4.</td>
<td>Congestion of the anterior tonsillar pillars</td>
<td>13</td>
<td>5</td>
<td>1 (7.7%)</td>
<td>—</td>
</tr>
<tr>
<td>5.</td>
<td>Presence of debris in the crypts</td>
<td>12</td>
<td>15</td>
<td>1 (100%)</td>
<td>—</td>
</tr>
<tr>
<td>6.</td>
<td>Cervical lymphadenitis</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

The figures represent the number of patients treated

1. Although no patients reported symptom-free throat during the follow-up, the number of episodes decreased in 30% of cases who had less than six episodes and in 64.7% of those having more than six episodes sequel to Septilin treatment. In comparison, the decrease was noticed in 36.3% of cases with less than six episodes and 57.1% of those with more than six episodes following co-trimoxazole administration.

2. Fever persisted in only 58.3% of cases treated with Septilin, whereas 66.7% of patients had fever in spite of co-trimoxazole therapy. Fever was absent in 41.7% of cases on Septilin, while it was so only in 33.3% of cases on co-trimoxazole.

3. There was no incidence of anorexia and in fact, there was better weight increase and a general feeling of well-being, with overall improvement in the general condition, in 66.7% of cases receiving Septilin, as compared to only 52.7% in those receiving co-trimoxazole.

4. Crypts and debris in the mouth did not disappear in any case treated with co-trimoxazole. But in 15.4% of cases receiving Septilin, both debris and crypts disappeared.
All the patients underwent throat swab culture before and after their respective therapies and the results are recorded in Table IV.

<table>
<thead>
<tr>
<th></th>
<th>No. of cases with abnormal bacteriological flora before treatment</th>
<th>No. of cases with bacteriological flora after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>Group A (Septilin)</td>
<td>4</td>
<td>3 (75%)</td>
</tr>
<tr>
<td>Group B (Co-trimoxazole)</td>
<td>4</td>
<td>2 (50%)</td>
</tr>
</tbody>
</table>

Seventy-five percent of the cases after Septilin therapy and only 50% of the cases after co-trimoxazole, who initially had an abnormal bacteriological flora on throat swab culture, reverted to normal flora, that is *N. catarrhalis* and *Str. Viridans*.

Table V shows that the majority of the patients were advised tonsillectomy in both the groups as therapy failed to avert surgery.

<table>
<thead>
<tr>
<th></th>
<th>Total number of patients</th>
<th>Tonsillectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not advised</td>
<td>Advised</td>
</tr>
<tr>
<td>Group A (Septilin)</td>
<td>27</td>
<td>3 (11.22%)</td>
</tr>
<tr>
<td>Group B (Co-trimoxazole)</td>
<td>25</td>
<td>2 (8%)</td>
</tr>
</tbody>
</table>

**DISCUSSION AND CONCLUSION**

This study was carried out to evaluate the role of Septilin and compare it with co-trimoxazole in the treatment of chronic tonsillitis, which has been so overwhelmingly treated only by enucleation of the tonsils.

Both the therapies have more or less failed to avert surgery, viz. tonsillectomy, in almost all the cases. The ones in which tonsillectomy has not been advised are probably those in whom the diagnosis may not be totally accurate and in which a doubt can be entertained regarding it.

The reasons why drugs do not eradicate the chronicity of the disease are attributed to pathological changes such as formation of minute abscesses in the lymphoid follicles which may become walled off by the fibrous tissue and surrounded by a zone of inflammatory cells, entrapment of inflammatory debris in crypts by fibrous occlusion of the openings, and hyperplasia of germinal centres with thickening of fibrous septa (Mawson, 1979) — these, and the fact that at birth, the tonsils are without germinal centres and usually quite small in relation to the oropharyngeal inlet. With loss of maternal antibodies and later due to exposure of infection that occurs at entry into the nursery school and primary school at 3 and 5 years respectively, there occurs an enlargement of the tonsils and adenoids, which is taken to be probably an index of immunological activity. In the present state of knowledge it is generally agreed that certainly in the early years, the tonsils and adenoids should be conserved as probable immunological assets, unless by their size they are causing severe embarrassment to respiration, Eustachian tube function, speech or feeding, or unless they have become the seat of an infection, the best remedy for which is excision (Mawson, 1979).

From the above study we have come to the conclusion that tonsillectomy is the only answer in established cases of chronic tonsillitis. However, Septilin shows better results with regard to the symptomatology during the course of the therapy. We have also not observed any adverse effects due to prolonged use of Septilin.

**ACKNOWLEDGEMENT**

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REFERENCES