

A DOUBLE BLIND PLACEBO CONTROLLED  
RANDOM CLINICAL TRIAL OF

# 'TONSILAT'

A HERBAL MEDICINE FOR TONSILLITIS  
(ACUTE & CHRONIC) & PHARYNGITIS

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## OBJECTIVE

The aim of the study was to see the efficacy of an Herbal medicine 'TONSILAT' in patients of Tonsillitis (acute & chronic) and Pharyngitis.

## ABSTRACT

A double blind placebo controlled trial was conducted in 112 patients (n=112) of acute tonsillitis, chronic tonsillitis and pharyngitis. Out of 112 patients, 40 patients had acute tonsillitis, 38 patients had chronic tonsillitis while 34 patients had pharyngitis. All the patients (n=112) were randomly allotted in Group A and Group B respectively. Patients of Group A received one tablet of Tonsilat three hourly for 10 days, while the patients for group B were given plain lactose tablet as Placebo in the same dose for the same duration. Specific signs and symptoms associated with acute & chronic tonsillitis as well as pharyngitis were recorded for all these patients in a proforma on 1st, 2nd, 5th, 7th and 10th day. Four patients out of 112 were excluded in the data as they did not come for follow up.

The specific signs and symptoms of tonsillitis (acute and chronic) and pharyngitis reduced significantly in patients receiving 'TONSILAT'. This was in clear contrast to non reduction and non-disappearance of symptoms and signs in patients receiving Placebo. Efficacy of treatment was greater among active drug in acute tonsillitis (75% against 42%,  $X^2 = 4.34$   $p < 0.02$ ), chronic tonsillitis (74% against 32%;  $X^2 = 9.13$ ,  $P < 0.001$ ) and pharyngitis, (81 % against 25%;  $X^2 = 7.61$ ,  $p < 0.005$ ). Thus this study clearly shows that 'TONSILAT' a Herbal medicine manufactured by SBL Ltd. is highly effective in tonsillitis (acute & chronic) and pharyngitis.

## INTRODUCTION

### [PATHOPHYSIOLOGY OF DISEASE PROCESS]

#### 1. TONSILLITIS

Tonsil is a large body of lymphoid tissue. The size of tonsil varies with age. In first few years of life rapid hypertrophy occurs. It reaches its maximum bulk at about the age of six, by which time the child is usually facing repeated infections in his environment.

##### (a) ACUTE TONSILLITIS

This is generalised inflammation of the mass of the tonsil and is usually accompanied by a degree of inflammation of the fauces and pharynx. The tonsils enlarge and project, and there is an excess of secretion of the pharynx due to exposure to cold or infection with virulent organisms may be the determining factor in tonsillitis. The first symptoms may be rawness at the back of throat. This can cause pain or feeling of pain on swallowing. The glands below jaw draining tonsillar area are frequently enlarged and tender. There are chills, malaise, rise of temperature and a general feeling of illness.

The tonsils are swollen, oedematous, thickened and bright red. Long standing cases show exudation of pus from surface which is characteristic of established tonsillitis.

(b) **CHRONIC TONSILLITIS**

Chronic tonsillitis may be caused by repeated attacks of acute tonsillitis. Resolution after acute tonsillitis may be incomplete and repeated slight inflammatory reactions may produce eventually marked chronic sepsis. The tonsils may be very small and they may be fibrosed. With a chronically infected tonsil, flushing of anterior pillar is often seen.

(c) **PHARYNGITIS**

Pharyngitis may be caused by cold, by irritation such as results from fumes, by certain fruits, severe digestive disturbances, climatic conditions, smoking or tonsillitis and sinusitis.

There is infection of the mucous membrane of the posterior pharyngeal wall and the lymphoid nodules stand out prominently enlarged and of a darker red than the surrounding membrane. The patient complains of irritation and rawness of the throat with possibly slight pain on swallowing. This pain is usually less when swallowing food than saliva. There is a constant desire to swallow which aggravates the symptoms.

TONSILAT is a product of SBL Ltd. and is a combination of drugs of herbal therapeutics which treats tonsillitis and pharyngitis.

**COMPOSITION**

|                           |     |
|---------------------------|-----|
| Mercurius biniodatus..... | 6x  |
| Belladonna .....          | 6x  |
| Kali muriaticum.....      | 6x  |
| Ferrum phosphoricum.....  | 6x  |
| Baryta carbonica .....    | 12x |

In equal proportions

Excipients q.s. To 1 tablet of 250 mg.

**MATERIAL AND METHOD**

Patients of different age groups and both sexes who reported to Phoolwati Jain Hospital SDA, New Delhi, Swami Vivekananda Hospital Mehrauli, Sunil Memorial Hospital Palam, Sivananda Hospital, Dakshinpuri and Sharma Medical Center, Sangam Vihar were included in present study. Patients were selected randomly for the drugs. Tonsilat & Placebo both the drugs were similar in respect of their appearance, consistency, flavour and taste. The age, sex, present and past history, symptoms and signs with relevant investigations were noted in predesigned proforma of their first visit. The patients were called for evaluation on 2nd, 5th, 7th, and 10th day. Each time patients were judged clinically for symptoms and signs like fever, pain discomfort in swallowing, irritable cough, redness of tonsils and mucosa and tiredness of voice supported with blood examination. Those patients on antibiotics and anti-inflammatory drugs were advised to stop their earlier medicines. All the cases were of acute type and no chronic inflammatory process was included in the study.

The trial was said to be completed when the data of all the patients was available. Drug 'A' was test drug 'Tonsilat' and 'B' was Placebo. The treatment allocation of active drug or Placebo was made on a randomised double blind basis.

**OBSERVATIONS**

Clinical data of drug trial is shown in table I -IV.

**DISCUSSION**

The patients who received drug Tonsilat and Placebo were homogeneous in all respects.

They were of same age group (8 to 65 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 alike.

### **ACUTE TONSILLITIS**

Out of forty patients of acute tonsillitis (20 vs 20), one patient of group B (Placebo) did not come for follow up.

Reduction of soreness and cough was faster in cases of tonsilat than Placebo. (100% to 15%; 95% to 15% against 100% to 58%; 100% to 37%) respectively. Fever, pain and feeling of foreign body sensation were associated features of tonsillitis. In patients receiving Tonsilat there is remarkable improvement of pain (90% to 10%), fever (80% to 10%) and feeling of foreign body sensation (85% to 15%) as compared to Placebo (100% to 37%), (85% to 32%), (89% to 37%) respectively.

Oedema & redness of tonsils is a constant feature of acute tonsillitis i.e. 100% in each groups which shows a marked reduction in patients receiving Tonsilat than Placebo (15% against 42%).

Tonsillar lymph node enlargement was markedly reduced with Tonsilat than with Placebo (60% to 15% against 53% to 33%).

### **CHRONIC TONSILLITIS**

It is the sequelae of repeated attacks of acute tonsillitis. Out of thirty eight patients (19 vs. 19) one patient of placebo group 'A' did come of follow up. There is a marked reduction in soreness (100% to 17%; against 100% to 53%) and fever (100% to 11% against 100% to 42%) with Tonsilat as compared to Placebo.

Redness of tonsils showed satisfactory improvement with Tonsilat (100% to 17%) while with Placebo only eight (47%) out of nineteen patients (100%) showed improvement.

Relief from pain & cough was more marked in Tonsilat as compared to Placebo. Two out of eight patients having tonsillar Lymphadenitis did not show any improvement with Tonsilat while with Placebo only three patients showed improvement out of six.

### **PHARYNGITIS**

It is a very common ailment. Out of 34 patients (17 vs 17), one patient each of group 'A' and 'B' was excluded from the study. Soreness, discomfort in swallowing, and irritable cough are major deterrent in assuming the normal activities, appeases to be significantly reduced with.

Tonsilat (100% to 12%, 100% to 6%, 100% to 18%), as opposed to Placebo (100% to 60%, 100% to 54%, 100% to 72%).

Tiredness in voice was almost relieved in 88% of patients with Tonsilat as compared to 46% in Placebo.

Redness of mucosa with Tonsilat was relieved in 88% as opposed to 40% with Placebo.

Pain was markedly alleviated in 88% of patients with Tonsilat as compared to Placebo in whom only 48% patients had pain alleviation.

Finally the number of patients who made favourable judgement on efficacy was greater among active drug which is as follows :

- (1) Acute Tonsillitis (75% against 42%;  $\chi^2 = 4.34$ ;  $P < 0.02$ ).
- (2) Chronic Tonsillitis (74% against 32%;  $\chi^2 = 9.13$ ;  $p < 0.001$ ).
- (3) Pharyngitis (81% against 25%;  $\chi^2 = 7.61$ ;  $p < 0.005$ ).

**TABLE - I**

**SYMPTOMS & SIGNS PROFILE (ACUTE TONSILLITIS) (n = 39)**

| <b>ACUTE TONSILLITIS</b>                    | <b>(n =20) Group A (TONSILAT)</b> |                |                |                |                    | <b>(n =19) Group B (PLACEBO)</b> |                |                |                |                     |
|---|-----------------------------------|----------------|----------------|----------------|--------------------|----------------------------------|----------------|----------------|----------------|---------------------|
|   | <b>1st day</b>                    | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>    | <b>1st day</b>                   | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>     |
| <b>1. SORENESS</b>                          | <b>20<br/>(100%)</b>              | <b>16</b>      | <b>10</b>      | <b>6</b>       | <b>3<br/>(15%)</b> | <b>29<br/>(100%)</b>             | <b>19</b>      | <b>17</b>      | <b>15</b>      | <b>11<br/>(58%)</b> |
| <b>2. DISCOMFORT SWALLOWING</b>             | <b>18<br/>(90%)</b>               | <b>15</b>      | <b>9</b>       | <b>5</b>       | <b>2<br/>(10%)</b> | <b>17<br/>(89%)</b>              | <b>17</b>      | <b>15</b>      | <b>13</b>      | <b>10<br/>(53%)</b> |
| <b>3. FEELING OF FOREIGN BODY SENSATION</b> | <b>17<br/>(85%)</b>               | <b>13</b>      | <b>7</b>       | <b>3</b>       | <b>1<br/>(5%)</b>  | <b>17<br/>(89%)</b>              | <b>17</b>      | <b>14</b>      | <b>12</b>      | <b>7<br/>(37%)</b>  |
| <b>4. FEVER</b>                             | <b>16<br/>(80%)</b>               | <b>12</b>      | <b>6</b>       | <b>2</b>       | <b>2<br/>(10%)</b> | <b>18<br/>(85%)</b>              | <b>18</b>      | <b>13</b>      | <b>11</b>      | <b>6<br/>(32%)</b>  |
| <b>5. PAIN</b>                              | <b>18<br/>(90%)</b>               | <b>15</b>      | <b>7</b>       | <b>3</b>       | <b>2<br/>(10%)</b> | <b>19<br/>(100%)</b>             | <b>19</b>      | <b>14</b>      | <b>12</b>      | <b>7<br/>(37%)</b>  |
| <b>6. OEDEMA &amp; REDNESS OF TONSILS</b>   | <b>20<br/>(100%)</b>              | <b>17</b>      | <b>10</b>      | <b>4</b>       | <b>3<br/>(15%)</b> | <b>20<br/>(100%)</b>             | <b>19</b>      | <b>14</b>      | <b>12</b>      | <b>8<br/>(42%)</b>  |
| <b>7. COUGH</b>                             | <b>19<br/>(95%)</b>               | <b>18</b>      | <b>12</b>      | <b>7</b>       | <b>5<br/>(25%)</b> | <b>19<br/>(100%)</b>             | <b>18</b>      | <b>15</b>      | <b>13</b>      | <b>7<br/>(37%)</b>  |
| <b>8. TONSILLAR LYMPHADENITIS</b>           | <b>12<br/>(60%)</b>               | <b>12</b>      | <b>9</b>       | <b>6</b>       | <b>3<br/>(15%)</b> | <b>10</b>                        | <b>10</b>      | <b>9</b>       | <b>8</b>       | <b>6<br/>(30%)</b>  |

**TABLE - II**  
**SYMPTOMS & SIGNS PROFILE (CHRONIC TONSILLITIS) (n = 38)**

| <b>CHRONIC TONSILLITIS</b>        | <b>(n =19) Group A (TONSILAT)</b> |                |                |                |                    | <b>(n =19) Group B (PLACEBO)</b> |                |                |                |                     |
|-----------------------------------|-----------------------------------|----------------|----------------|----------------|--------------------|----------------------------------|----------------|----------------|----------------|---------------------|
|                                   | <b>1st day</b>                    | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>    | <b>1st day</b>                   | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>     |
| <b>1. SORENESS</b>                | <b>18<br/>(100%)</b>              | <b>16</b>      | <b>13</b>      | <b>8</b>       | <b>3<br/>(17%)</b> | <b>19<br/>(100%)</b>             | <b>19</b>      | <b>17</b>      | <b>14</b>      | <b>10<br/>(53%)</b> |
| <b>2. FEVER</b>                   | <b>18<br/>(100%)</b>              | <b>17</b>      | <b>14</b>      | <b>9</b>       | <b>2<br/>(11%)</b> | <b>19<br/>(100%)</b>             | <b>18</b>      | <b>15</b>      | <b>10</b>      | <b>8<br/>(42%)</b>  |
| <b>3 PAIN</b>                     | <b>18<br/>(100%)</b>              | <b>16</b>      | <b>12</b>      | <b>8</b>       | <b>4<br/>(22%)</b> | <b>19<br/>(100%)</b>             | <b>17</b>      | <b>16</b>      | <b>9</b>       | <b>7<br/>(37%)</b>  |
| <b>4. REDNESS OF TONSILS</b>      | <b>18<br/>(100%)</b>              | <b>18</b>      | <b>11</b>      | <b>7</b>       | <b>3<br/>(17%)</b> | <b>19<br/>(100%)</b>             | <b>19</b>      | <b>15</b>      | <b>12</b>      | <b>10<br/>(53%)</b> |
| <b>5. COUGH</b>                   | <b>18<br/>(100%)</b>              | <b>18</b>      | <b>13</b>      | <b>10</b>      | <b>4<br/>(22%)</b> | <b>19<br/>(100%)</b>             | <b>19</b>      | <b>14</b>      | <b>13</b>      | <b>11<br/>(58%)</b> |
| <b>6. TONSILLAR LYMPHADENITIS</b> | <b>8<br/>(44%)</b>                | <b>8</b>       | <b>7</b>       | <b>5</b>       | <b>2<br/>(11%)</b> | <b>6<br/>(32%)</b>               | <b>6</b>       | <b>5</b>       | <b>4</b>       | <b>3<br/>(30%)</b>  |

**TABLE - III**  
**SYMPTOMS & SIGNS PROFILE (PHARYNGITIS) n = 32**

| <b>CHRONIC PHARYNGITIS</b>         | <b>(n =16) Group A (TONSILAT)</b> |                |                |                |                    | <b>(n =16) Group B (PLACEBO)</b> |                |                |                |                     |
|------------------------------------|-----------------------------------|----------------|----------------|----------------|--------------------|----------------------------------|----------------|----------------|----------------|---------------------|
|                                    | <b>1st day</b>                    | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>    | <b>1st day</b>                   | <b>2nd day</b> | <b>5th day</b> | <b>7th day</b> | <b>10th day</b>     |
| <b>1. SORENESS</b>                 | <b>16<br/>(100%)</b>              | <b>14</b>      | <b>12</b>      | <b>6</b>       | <b>2<br/>(12%)</b> | <b>16<br/>(100%)</b>             | <b>15</b>      | <b>15</b>      | <b>12</b>      | <b>10<br/>(60%)</b> |
| <b>2. DISCOMFORT IN SWALLOWING</b> | <b>16<br/>(100%)</b>              | <b>13</b>      | <b>10</b>      | <b>5</b>       | <b>1<br/>(6%)</b>  | <b>16<br/>(100%)</b>             | <b>16</b>      | <b>14</b>      | <b>11</b>      | <b>9<br/>(54%)</b>  |
| <b>3. FEVER</b>                    | <b>16<br/>(100%)</b>              | <b>12</b>      | <b>10</b>      | <b>4</b>       | <b>2<br/>(12%)</b> | <b>16<br/>(100%)</b>             | <b>14</b>      | <b>12</b>      | <b>10</b>      | <b>7<br/>(42%)</b>  |
| <b>4. PAIN</b>                     | <b>16<br/>(100%)</b>              | <b>15</b>      | <b>13</b>      | <b>4</b>       | <b>1<br/>(6%)</b>  | <b>16<br/>(100%)</b>             | <b>15</b>      | <b>14</b>      | <b>11</b>      | <b>7<br/>(42%)</b>  |
| <b>5. REDNESS OF MUCOSA</b>        | <b>16<br/>(100%)</b>              | <b>14</b>      | <b>11</b>      | <b>5</b>       | <b>2<br/>(12%)</b> | <b>16<br/>(100%)</b>             | <b>16</b>      | <b>15</b>      | <b>12</b>      | <b>10<br/>(60%)</b> |
| <b>6. IRRITABLE COUGH</b>          | <b>16<br/>(100%)</b>              | <b>12</b>      | <b>9</b>       | <b>6</b>       | <b>3<br/>(18%)</b> | <b>16<br/>(100%)</b>             | <b>16</b>      | <b>15</b>      | <b>13</b>      | <b>12<br/>(72%)</b> |
| <b>7. TIREDNESS IN VOICE</b>       | <b>16<br/>(100%)</b>              | <b>14</b>      | <b>11</b>      | <b>5</b>       | <b>2<br/>(12%)</b> | <b>16<br/>(100%)</b>             | <b>16</b>      | <b>15</b>      | <b>12</b>      | <b>9<br/>(54%)</b>  |

**Table- IV**

Age in years : 8-68 years

Total no. of patients (n) trial = 112  
(n = 112-4)\* = 108

**DISTRIBUTION OF PATIENTS ACCORDING TO DISEASE AND  
RELATIVE EFFICACY OF DRUG (TONSILAT & PLACEBO)**

| DISEASE                         | GROUP A TONSILAT            |           | GROUP B PLACEBO            |           | RELATIVE EFFICACY<br>&<br>P value |
|---------------------------------|-----------------------------|-----------|----------------------------|-----------|-----------------------------------|
|                                 | Cured                       | Not cured | Cured                      | Not cured |                                   |
| ACUTE TONSILLITIS<br>(n = 39)   | 15<br>(75%)<br><br>(n = 20) | 5         | 8<br>(42%)<br><br>(n = 19) | 11        | $X^2 P = 4.34 P < 0.02$           |
| CHRONIC TONSILLITIS<br>(n = 37) | 14<br>(74%)<br><br>(n = 18) | 4         | 6<br>(32%)<br><br>(n = 19) | 13        | $X^2 = 9.13 P < 0.001$            |
| PHARYNGITIS<br>n = 32)          | 13<br>(81%)<br><br>(n = 16) | 3         | 4<br>(25%)<br><br>(n = 16) | 12        | $X^2 = 7.61 P < 0.005$            |

\*Four patients did not come for follow up.

## **CONCLUSION**

Our study did not aim to evaluate the herbal approach as a whole, but to test a specific preparation 'Tonsilat'.

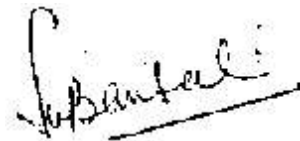
The constituents of the drug clearly proves the anti-inflammatory, antibacterial and antiallergic properties which enhance the body's resistance against infection in the tonsillar and pharyngeal mucosa but are different chemically from antibiotics and antihistamines. Patients not improving on conventional antibiotics showed improvement with this remedy.

Its use was devoid of any side effect. As tonsils play a significant role in maintaining the body's immune system, they scrutinize ingested material and react to those which pose threat to body. In addition tonsils produce antibodies which deal with infections locally.

It is worth trying for longer duration in chronic tonsillitis to avoid tonsillectomy. It is also worth where tonsillectomy is contraindicated like anaemia, haemorrhagic diseases, cleft palate, systemic diseases (diabetes, heart disease), intercurrent infections, advanced age. This study clearly indicates that 'TONSILAT' a HERBAL medicine manufactured by SBL Limited is highly effective in tonsillitis (acute and chronic) and pharyngitis.

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