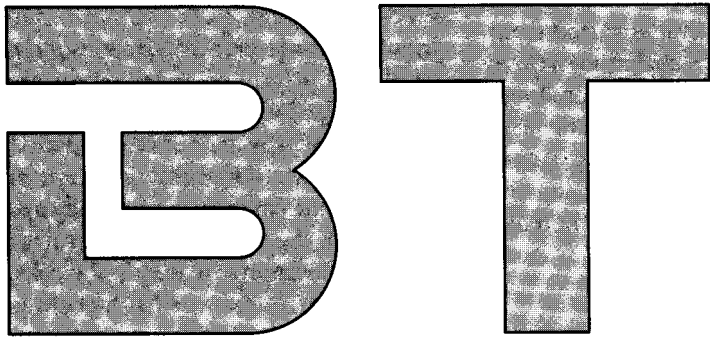


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A Biotherapeutic Approach to the Treatment of Inflammatory Disorders: A Drug Monitoring Trial

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In order to advance our understanding of the efficacy, tolerance, and safety of the homeopathic preparation Lymphomyosot, BHI and Heel monitored the use of this remedy in 104 consecutive patients. This drug monitoring was an uncontrolled trial, with subjective and objective information reported by the health care practitioners participating in the study.

Introduction

The lymphatic system is one of the key systems in the body for detoxification, yet there have been relatively few studies investigating the lymphatic system and its function. In homotoxicology and homeopathy, remedies are directed at stimulating the defense systems of the body and reinforcing the body's ability to heal itself. This mobilization and strengthening of the organism's own power of resistance involves stimulating the lymphatic system, one of the key physiological detoxification systems. It begins in the connective tissue, with one of its primary functions being to eliminate toxins from the body. Stimulation of the lymphatic system is not listed in the homeopathic repertories nor are there many preparations available on the market specifically designed to stimulate the function of the lymphatic sys-

tem. Nevertheless, there is clearly a need for preparations that can provide such stimulation. Chronic tonsillitis, edema, and upper extremity lymphedema following mastectomy are all examples of pathological conditions involving a blockage or dysfunction of the lymphatic system.

Lymphomyosot is a complex homeopathic preparation that has been on the market for over 30 years. It contains the following homeopathically prepared ingredients: Myosotis arvensis, Veronica, Teucrium scorodonia, Pinus silvestris, Gentiana lutea, Equisetum hiemale, Sarsaparilla, Scrophularia nodosa, Juglans, Calcium phosphoricum, Natrium sulfuricum, Fumaria officinalis, Thyroxin, Aranea diadema, Geranium robertianum, Nasturtium aquaticum, and Ferrum iodatum. Its main indication in the *Ordinatio* published by Heel is: "Lymphatism, exudative diathesis, scrofulosis and other glandular swelling; tonsillar hypertrophy and chronic angina tonsillaris; in mesenchymal purges." There have been numerous case reports on the successful primary or adjunctive use of Lymphomyosot for the treatment of a variety of illnesses published in the medical literature. In 1990

a drug monitoring study involving over 3,000 patients was initially published in *Biologische Medizin*. This drug monitoring study, although much smaller in scale, used much of the same methodology.

Methodology

Physicians ordering Lymphomyosot from Heel or BHI were recruited for this study and sent a uniform data collection form. Patient data and therapeutic information were collected in a uniform fashion. There were no exclusion criteria since this was an attempt to monitor the ongoing use of this remedy in the clinical setting. The data forms were received at BHI from February to December of 1991. Patient characteristics (age, sex, etc.) made up the first part of the data collection sheet. The next section was diagnostic information related to the condition for which the remedy was being given, concomitants, and the duration of the illness. Information on other therapies being administered at the same time was also gathered. This type of information was requested in order to attempt to clarify the degree to which Lymphomyosot could be integrated successfully with other therapies. The

next section involved information about the type of Lymphomyosot preparation being utilized by the practitioner, the dosage, and the duration of treatment. Lymphomyosot comes in ampules and drop form. The sterile ampules for injection can be administered IV, IM, SC, or even given orally. The final section contained information related to the success of the treatment, toleration of the medication, and information about any reactions to the medication.

Data

The age and sex distribution of the patient population is shown below in Figure one. Two characteristics stand out. First there is a much higher proportion of female patients than male patients in this drug-monitoring study. Secondly, there is a bimodal distribution, with one peak in children and again between the ages of 30-50. The pediatric peak is due to the use of this remedy for the treatment of acute and chronic tonsillitis. The later peak is multi-factorial.

Diagnosis and duration of disease

The patients suffered from a variety of conditions from tonsillitis to tuberculosis. There was even one case diagnosed with chronic *Trichosporon Beigelii* infection. The illnesses tended to cluster around certain diagnostic categories as listed in Table 1 below.

Table 1.

Diagnosis of Patients

- 35-Tonsillitis
- 9-Chronic Tonsillar Hypertrophy
- 15-Sinusitis
- 10-Rhinitis
- 7-Chronic Fatigue Syndrome
- 11-Lymphatic edema
- 12-Chronic infections, lowered resistance
- 5-Bronchitis
- 3-Otitis Media
- 3-Tuberculosis
- 5-Other Diagnosis

115-Total*

*Total number of diagnoses, exceeds total patients of 104 when 2 or more diagnoses were indicated.

Tonsillitis was by far the leading category of illness. The total number of diagnoses is greater than the total number of patients because some patients had more than one diagnosis.

Duration of Illness

The duration of illness varied from one day to over 10 years. Figure 2 gives a breakdown of the duration of illness in the patients in this study. The largest category was for acute illness; nevertheless, nearly one-half of the patients had been sick for more than one month.

Dosage and Route of Administration

Lymphomyosot is available in two different forms: sterile ampules for injection and as drops in an alcohol tincture. These two different preparations could be given separately or together and even in conjunction with other therapeutic interventions. The majority of practitioners preferred to prescribe drops alone, although a significant number of practitioners combined the drops with the ampules. Figure 3 shows the percentage distribution of the different preparations of Lymphomyosot that were prescribed.

Lymphomyosot in ampule form is available from the manufacturer as a sterile injectable solution and can be administered SC, IM, or IV. Of those practitioners using the ampule preparation the majority used the IV route of administration. It is likely that if the study sample size had been larger the IM route of administration for the ampules would have been the largest category. Figure 4 below gives a breakdown of ampule use according to the route of administration. In all cases where the ampules were administered as an injection, the dosage utilized was once per week. The generally recommended dosage is for one to three ampules per week.

The oral drop preparation was most commonly given in a dosage of 10 drops three times daily. The range was from 5 drops three times daily, primarily in children, up to 20 drops four times a day.

Duration of therapy

The duration of therapy ranged from a single dose in one patient to therapy that continued for over six months. The period of therapy was divided into five categories: less than one week, one week to one month, one month to three months, three months to six months, and more than six months. Although a precise mean duration of therapy cannot be calculated because of the variability inherent in the different categories, it would appear that the average duration of therapy was approximately 5-7 weeks. The duration of therapy has a positive correlation with the duration of the illness for illnesses that have been present for less than one week or from between one week and one month. In the last three categories for the duration of illness the duration of therapy was consistently greater than one month. If one makes the assumption that a long "duration of illness" involves a more chronic case which will be more difficult to treat, it is impressive to note that the majority of the patients with an illness for more than one year had a "very good" response to therapy. Figure 5 is a graph of the duration of treatment with Lymphomyosot as a function of the duration of the illness prior to the onset of therapy with Lymphomyosot. Figure 6 is a graph correlating the duration of therapy with the duration of the illness. Figures 7 and 8 then evaluate the therapy results as a function of the duration of the illness and the duration of therapy respectively.

Accompanying Therapy

As mentioned in the Methodology section, other drug therapy was permitted in this drug monitoring trial. The additional therapies that were utilized fell into five basic categories. The most frequently utilized accompanying therapies were other homeopathic remedies, herbs, acupuncture, and vitamins. The other major category was, as expected, traditional medications such as antibiotics, diuretics, anti-histamines, anti-tubercular therapy, etc. Other homeopathic remedies, herbs, or vitamins were used as adjunctive

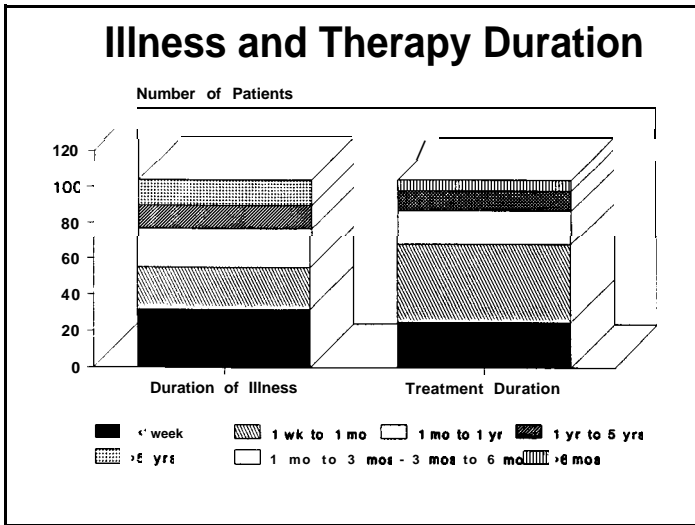


Fig. 5

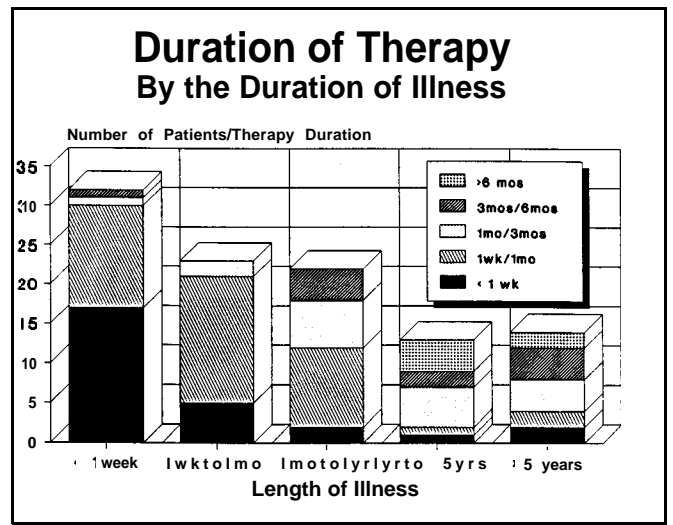


Fig. 6

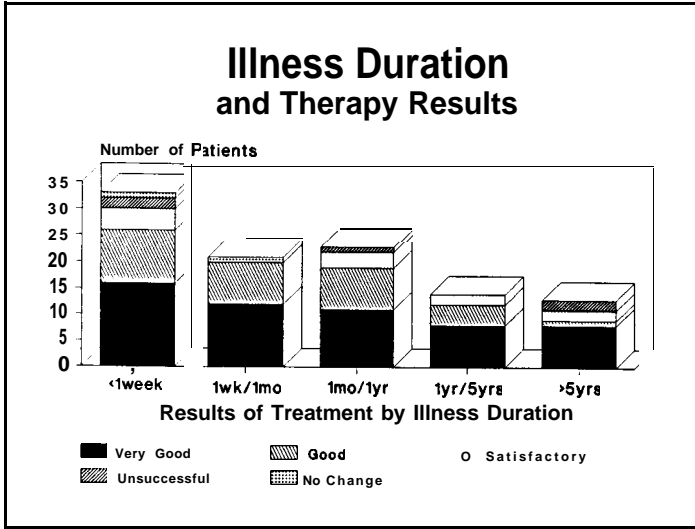


Fig. 7

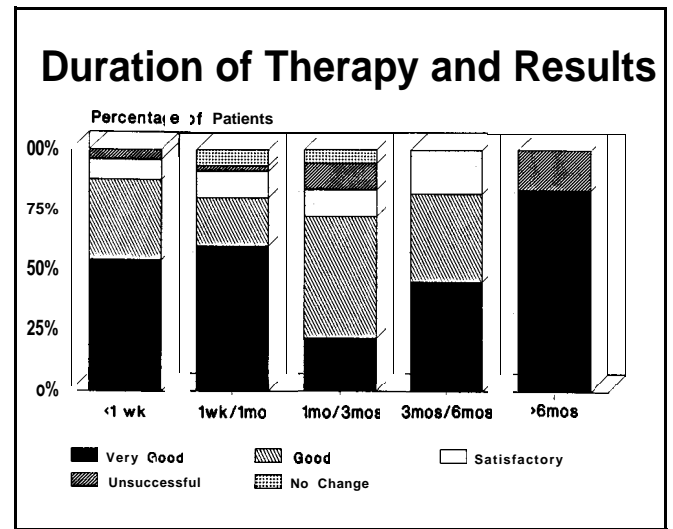


Fig. 8

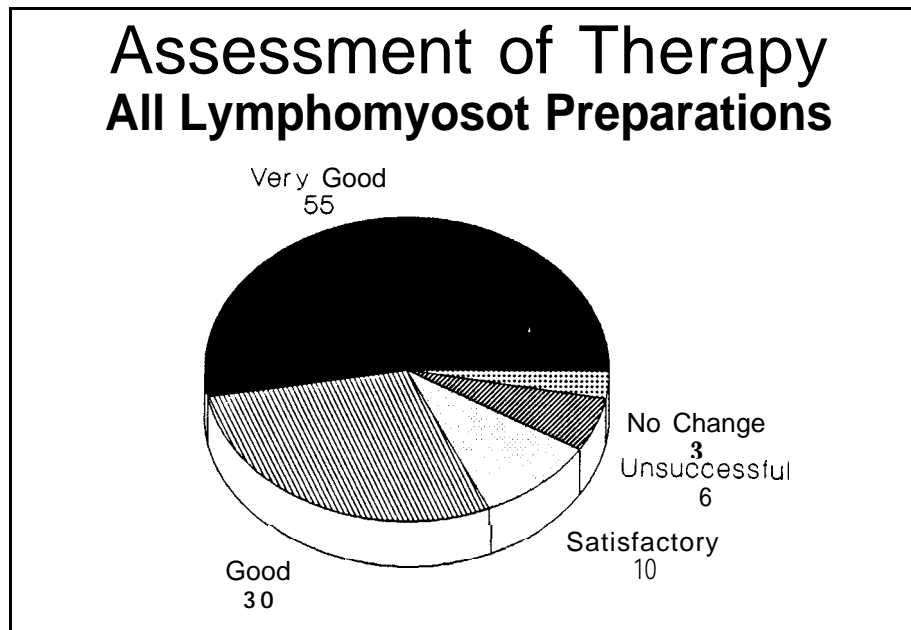


Fig. 9

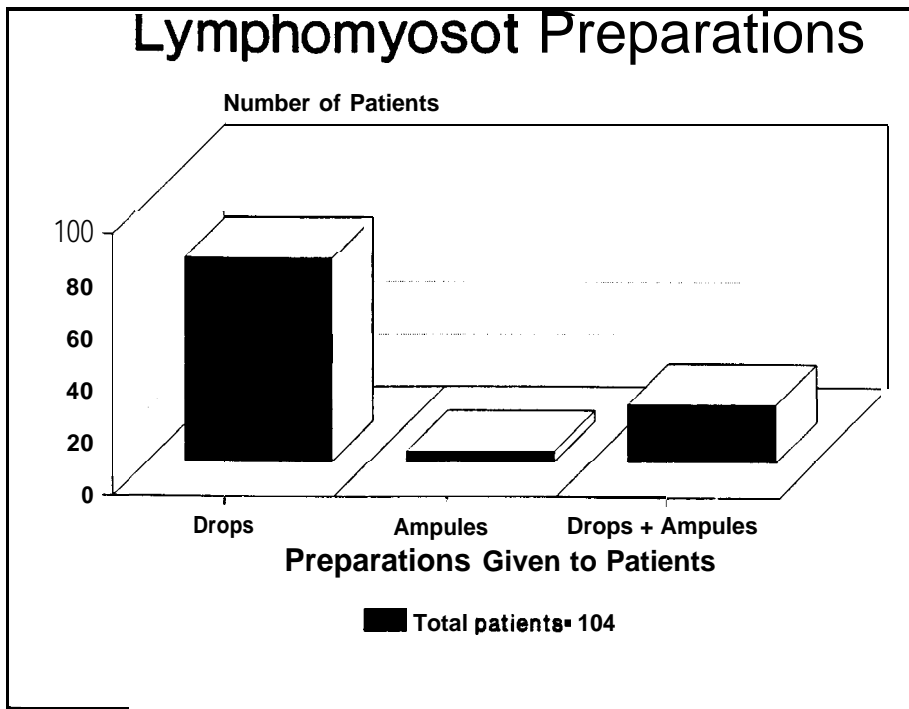


Fig. 3

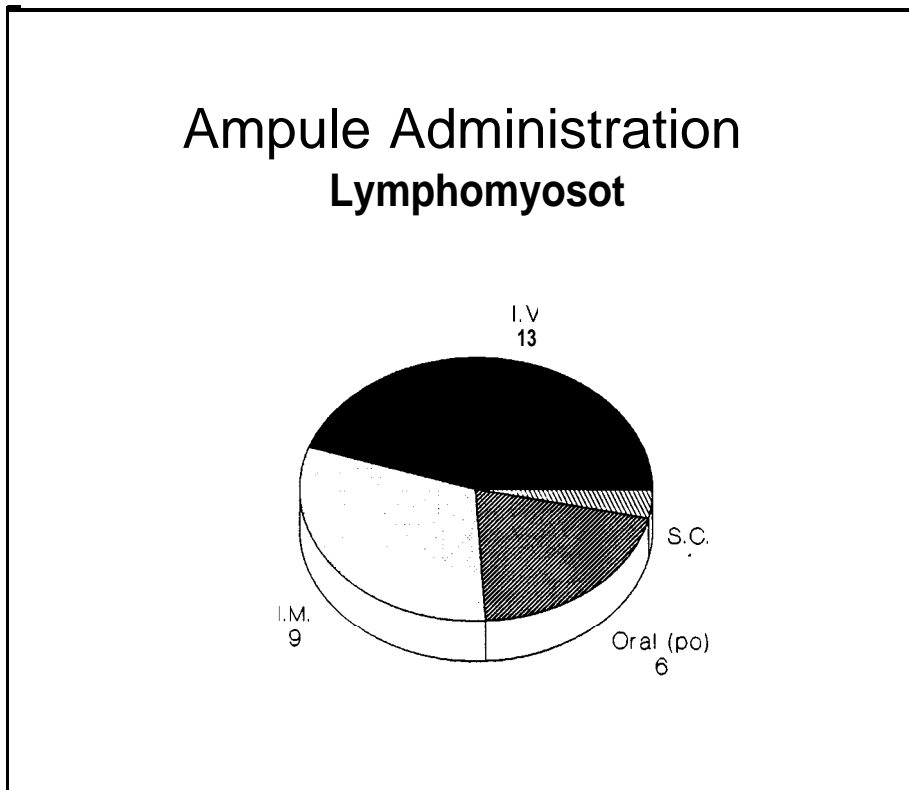


Fig. 4

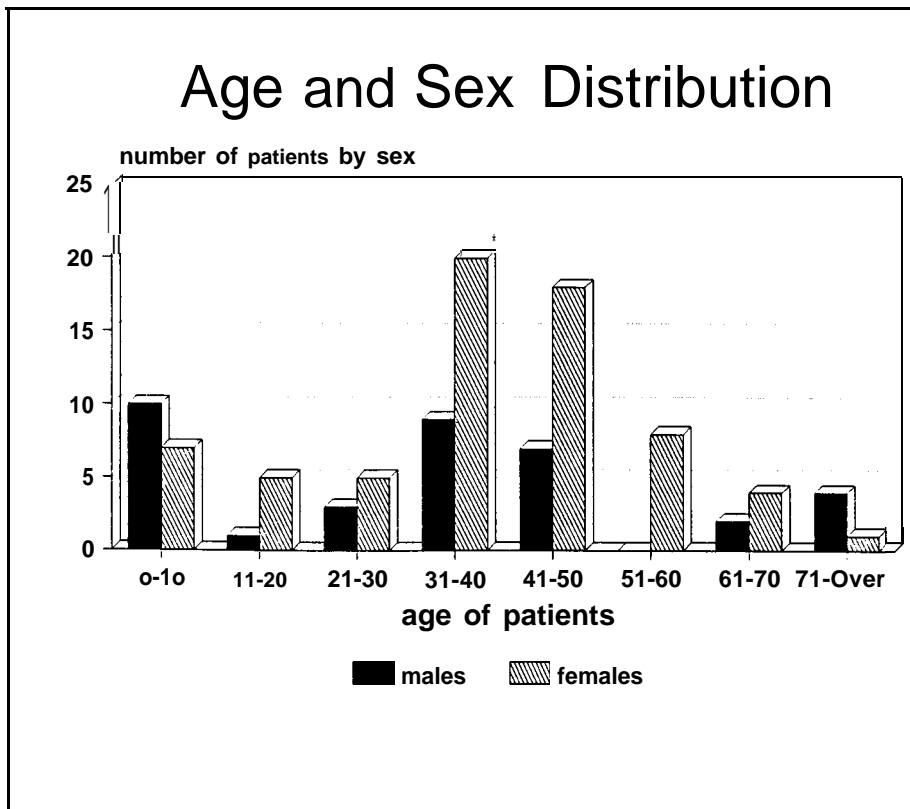


Fig. 1

therapy in over 60 per cent of all cases. The use of adjunctive therapy did not improve the results over Lymphomyosot alone. It is worthwhile to note that Lymphomyosot can be successfully integrated into a wide variety of other therapeutic modalities, including allopathic medicine. It is evident from this use of other therapeutic modalities, in particular the use of other homeopathic therapies, that Lymphomyosot is often used as a "terrain" remedy. Terrain remedies are often used for generalized homeopathic support and are given along with or in addition to other homeopathic treatment. The tables below outline both the drug and non-drug therapy that accompanied the treatment with Lymphomyosot,

Table 2
Accompanying Drug Therapy

- 6-NSAIDS anti-inflammatory
- 2-Diuretics
- 31-Homeopathic
- 8-Antibiotics
- 17-Herbal
- 7-Anti-histamines
- 20-Vitamin/Nutritional Supplements
- 8-Other

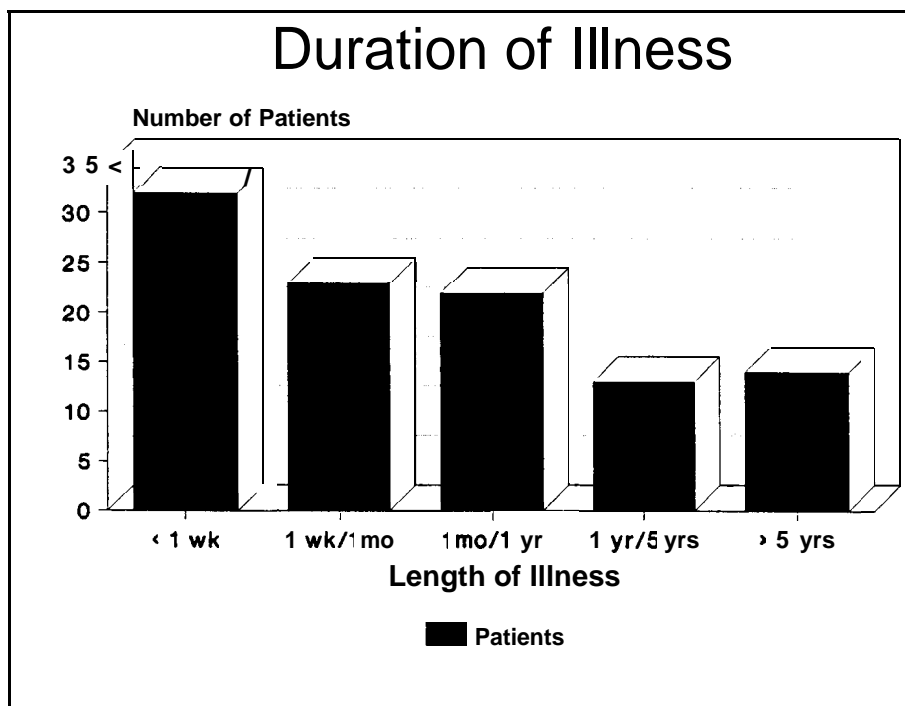


Fig. 2

Table 3
Accompanying Non-Drug Therapy

- 9-Acupuncture
- 4-Massage
- 9-Manipulation
- 6-Other

Assessment of therapy

The overall assessment of the efficacy of therapy with Lymphomyosot was strongly positive. Above, in Figure 9, is a graph with the assessment of therapy categories measured as a percentage of the total number of responses. If one refers back to Figures 7 and 8, the assessment of the therapy is evaluated against both the duration of the illness and the duration of therapy.

The assessment of the tolerance of the preparation Lymphomyosot was uniformly very good. The only negative comments were with regard to the alcohol content of the drops; some patients did not like the sensation of the alcohol drops in their mouth. This can be rectified by placing the prescribed number of drops in a glass of purified water and drinking the contents. As is customary with homeopathic medications there were no significant adverse effects. One patient noted a transient, 12 hour, difficulty in urinating.

Conclusion

It can be concluded that the preparation Lymphomyosot can be used to

effectively treat a wide variety of inflammatory conditions, such as sinusitis or tonsillitis. Approximately 80 percent of the conditions treated with Lymphomyosot in this drug monitoring study involved an inflammatory condition. One of the main indications for the use of Lymphomyosot is activation of the non-specific defense mechanism in the connective tissue, an area often overlooked in the treatment of disease. From a homeopathic and anti-homotoxic point of view this activation of the mesenchyme can be a critical part of the healing process.

Lymphomyosot can be effectively integrated with a wide variety of other therapeutic strategies. Lymphomyosot

is very well tolerated and effective whether given by oral drops or by an intravenous or intramuscular injection. In order to achieve optimum therapeutic results the therapy needs be of adequate duration, sometimes for as long as six months. Remedies that have the potential to stimulate the lymphatic system and the greater defense system of the mesenchyme can be of benefit, either when used alone or in conjunction with other therapeutic modalities.

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