

Therapeutic Use of Lymphomyosot® - Results of a Multicentre Use Observation Study on 3,512 Patients

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The efficacy, tolerance and mode of use of the homeopathic preparation Lymphomyosot was investigated for both the drops and ampule drug forms in the context of a multicentre use observation study. 3,512 case histories were available for this study from a total of 264 doctors. The evaluation of therapeutic success, duration of treatment and co-medication was carried out separately for the central indications lymphoedema, inflammatory processes, and hyperplasia of lymphatic organs. Tolerance of the preparation was very good.

1.1. Introduction

Drugs for exerting a therapeutic influence on the lymphatic system are available on the market in relatively small numbers. This is already apparent from the fact that e.g. the "Rote Liste" (the German list of controlled drugs) (1) has no category for classifying these preparations and hence the few commercially available "lymphatics" have to be arranged more or less appropriately under the main headings "Umstimmungsmittel" (alterants) or "Antiphlogistika" (anti-inflammatories).

Yet there is quite clearly a need for such preparations: after all, lymphoedemas of the upper limbs, to name but one example, are still counted among the most common complications after surgical treatment of mastocarcinoma (2).

The therapy of lymphoedema normally implemented is based, apart from a few drug endeavours, mainly on mechanical procedures (3). Massage in the centripetal direction of the lymph current is used as a therapeutic method. Pneumatic compression with more or less complicated aids has been attempted up to the most recent times as a way of influencing lymphoedema. In most cases, however, the latter

measures hamper an active life and are rarely successful (3).

Chronic diseases of the lymphatic organs also frequently represent a problem in the doctor's practice. The first disorder to be mentioned in this context is chronic tonsillitis. One of the most feared complications of chronic tonsillitis is what is referred to as toxicosis due to foci. According to Boenninghaus (4), 70% of all head foci are suspected of being in the tonsils. Since the conservative therapeutic procedures usually employed, such as painting, gargling or oral antibiotics, have no effect on the focus in the tonsils, it is usually only tonsillectomy which is considered (4).

However, the therapeutic options listed in many medical textbooks for treating diseases of the lymphatic system usually disregard the fact that there are also drugs with phytotherapeutic and homeopathic constituents for this indication area. If these are used at the appropriate time and for a sufficiently long period, considerable therapeutic success can often be achieved. The preparation Lymphomyosot is just such a drug.

1.2. Drugs

Lymphomyosot is a homeopathic combination preparation which has already been commercially available for more than 30 years and which contains various individual constituents with a vegetable or mineral base. On the basis of the homeopathic drug picture of the individual constituents, the preparation has the following indications: lymphatism (overdevelopment of lymphatic organs), lymphoedema (post-operative and post-traumatic), lowered resistance, scrofula and other glandular swellings, tonsillar hypertrophy and chronic tonsillitis. Also for cleaning out the mesenchyma.

Several therapeutic successes have already been published for Lymphomyosot in specific individual indications. In 1982, Kirchhoff (5) published his therapeutic successes with Lymphomyosot in 80 female patients with post-operative arm lymphoedema after mastectomy and axillary scrape. An observational study with Lymphomyosot on 50 children with recurrent tonsillitis was published by Rinneberg in 1988 (6). The list of publications is further supplemented by several experiment reports. The aim of this study is to report treatment results relating to the entire indication spectrum of the preparation in an extensive patient population. On the basis of these results, points of emphasis can be found within the therapeutic options which can form the basis for determining the test indications in subsequent clinical trials.

1.3. Method

The study reported below relates to a multicentre use observation study. Data collection was effected with the aid of a uniform report form which was made available to the participating doctors. All relevant patient and therapy data were to be stated on this form using specific questions, e.g. age and sex, diagnosis, form of administration and dosage of Lymphomyosot, duration of treatment and success of therapy. In addition, the occurrence of any adverse drug effects was also asked for.

Specific inclusion and exclusion criteria were not given, since the study was intended to provide an accurate picture of the patients treated in the doctor's practice, the therapeutic measures effected and the success of treatment. Selection of the presentation of Lymphomyosot and the dosage and duration of treatment were left to the judgement of the individual doctor.

In principle, the administration of additional drugs and other supplementary measures were permitted. But it was necessary to note them on the record form.

The record forms extended back over a period of 1 1/2 years; all forms received at the company Biologische Heilmittel Heel GmbH between 1.1.1988 and 30.6.1989 were included in the evaluation.

1.4. Trial doctors

A total of 264 doctors with various specialisations participated in the study in all parts of the Federal Republic of Germany and West Berlin. Table 1 shows a breakdown of the doctors by specialization.

| | |
|---------------------------------|----|
| General practitioner | 80 |
| Doctor of general medicine | 45 |
| Specialist in internal medicine | 16 |
| Surgical specialist | 2 |
| ENT specialist | 22 |
| Pediatrician | 41 |
| Naturopath | 4 |
| Orthopedic specialist | 1 |
| Gynecologist | 1 |
| Dentist | 1 |
| Doctor without specialization | 51 |

Table 1: Classification of doctors by specialisation.

A total of 3,572 cases of treatment had been documented by the 264 participating doctors using the record forms. However, 60 of these (1.7%) had to be excluded from the evaluation due to omissions in the information provided. A statement of diagnosis and an evaluation of therapeutic success in particular were regarded as indispensable for a conclusive case history. Consequently, 3,512 record forms remained for the final statistical evaluation.

1.5. Patients

All data and figures given in the descriptive evaluation below relate to

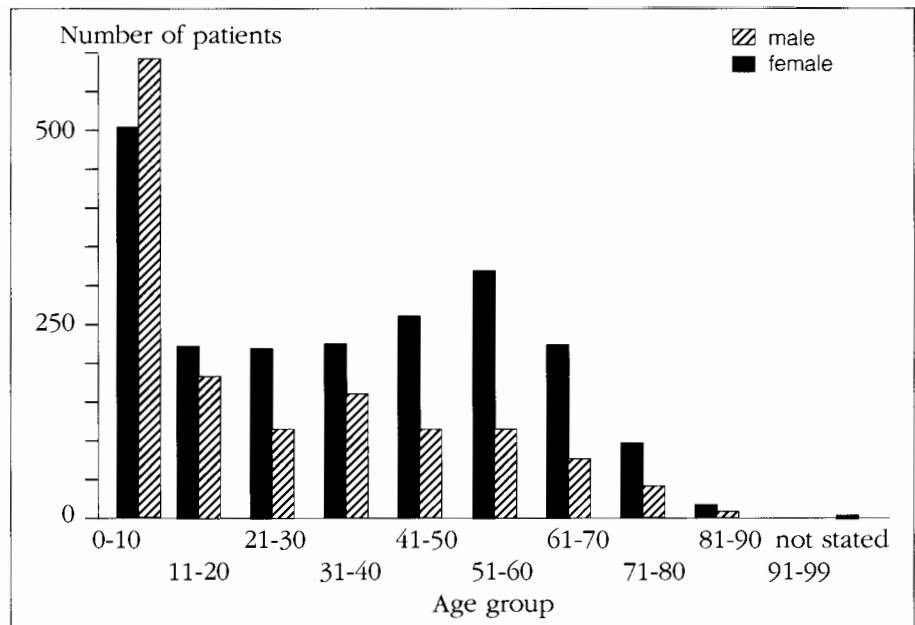


Figure 1: Age and sex distribution of the patients (n = 3,512).

the 3,512 patients whose treatment data had been documented sufficiently precisely for statistical evaluation. In addition, sub-groups of this patient sample, which show particular common features, will be investigated further in the course of this consideration. The age and sex distribution of the patients is shown in Figure 1.

Due to the high proportion of children, the mean age of the total patient population is calculated at 30.5 years. 2,094 (59.6%) patients were female, 1,418 (40.4%) male. The mean age of the female patients was noticeably

higher, at 34.7 years, than that of the males (24.4 years). Another unusual feature is the double peak in the age distribution. Both phenomena are explained by the fact that here, in essence, the age structures of two patient groups of differing basic disease are superimposed. Whereas the one group relates to patients with inflammations primarily in the ENT area with an age peak around 4 years of age, the second group consists overwhelmingly of female patients with lymphoedemas and an age peak around 55 years. This will be covered in more detail in the course of this consideration.

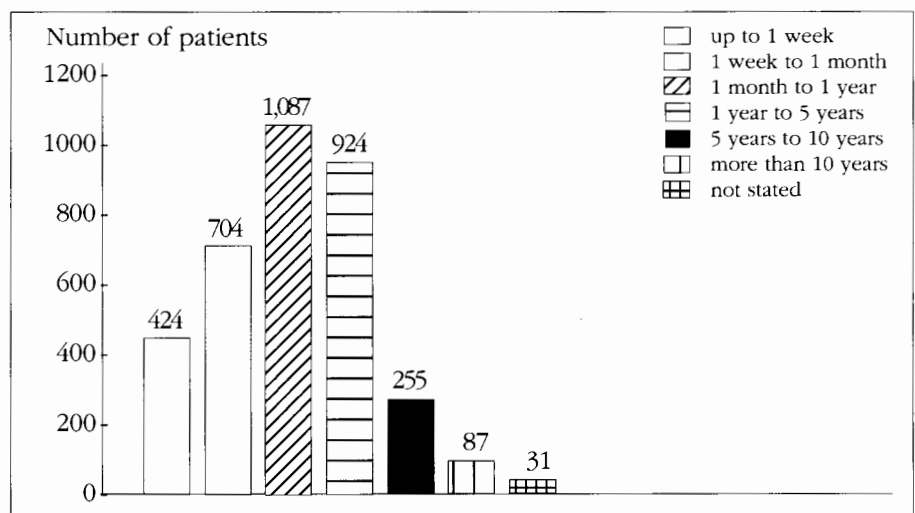


Figure 2: Duration of disease/disorders prior to commencement of Lymphomyosot therapy in patients treated (n = 3,512).

| Diagnosis | Number of cases |
|---|-----------------|
| Lymphatism (overdevelopment of lymphatic organs) | 144 |
| Lymphoedema | 684 |
| Lowered resistance (general susceptibility to infection) | 319 |
| Scrofula | 1 |
| Lymphadenitis | 391 |
| Other glandular swellings | 79 |
| Tonsillar hypertrophy | 177 |
| Tonsillitis | 594 |
| Other diagnosis | 1,123 |

Table 2. Classification of patients by diagnosis.

1.6. Disease duration and diagnoses

The diseases or complaints for which treatment with Lymphomyosot was instituted existed in the patients for widely differing periods of time. The shortest disease period up to the commencement of treatment was 1 day, the longest 60 years. Figure 2 shows a summary of disease duration.

A rough overview of the diagnoses will be given at this point and the detailed evaluation provided later. The first aspect to be investigated is whether the use of Lymphomyosot is restricted to the indications stated on the package insert or whether other areas of use over and above these are normal in doctor's practices.

Consequently, the diagnoses will firstly be broken down by a principle of classification which leans heavily on the wording of the package insert (Table 2). In the subsequent detailed evaluation, a slightly different principle of classification will be chosen for the purposes of systematic consideration.

As shown by Table 2, those prescribing the preparation did not limit themselves exclusively to the areas of use stated on the package insert. 68% of the patients included in the study were treated in accordance with the indications recommended by the

manufacturer. The remaining 32% received Lymphomyosot for therapy of various other disease states, which will be dealt with subsequently in the context of the detailed evaluation. Overall, this use observation study shows that the area of application of Lymphomyosot is considerably larger than expected.

However, before looking in detail at therapy results for the various indications, consideration will firstly be given to the question of whether perhaps other variables apart from the diagnosis, e.g. the choice of presentation, the method of administration or the nature of accompanying therapy,

play a decisive part in determining the success of treatment.

1.7. Presentations and methods of administration

Lymphomyosot is available in two different presentations, namely drops and ampules. The choice of presentation was left to the doctor giving treatment. Both drops and ampules could be given, and also both presentations in conjunction or one after the other. The evaluation showed that the majority of the study doctors preferred to prescribe drops only. The latter were used in 2,722 patients (77.5%). 491 patients (13.9%) received only Lymphomyosot ampules. The doctors decided in favor of combined use of drops and injection solution in 294 cases (8.4%). On 5 forms, the choice of presentation was not stated.

Figure 3 shows the percentage distribution of the individual presentations in graph form. According to the recommendations of the manufacturer, the injection solution of Lymphomyosot can be administered s.c., i.m., i.c. or i.v. The evaluation of this use observation study showed that in fact use is made of all these administration options in practice, albeit with differing frequency. An analysis will be given below of those cases where only one method of administration was used during the entire treatment. Whilst intramuscular injection led the field statistically with 438 cases, and exceeded all other

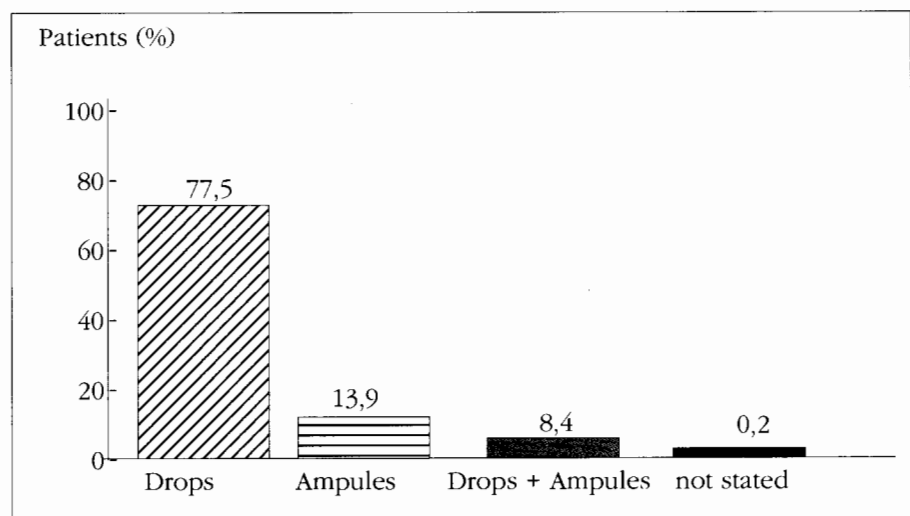


Figure 3. Percentage proportions of patients treated with the various presentations of Lymphomyosot (n = 3,512).

methods of administration together in frequency, intravenous and subcutaneous administration displayed approximately equal frequency (124 and 104 cases respectively). Intracutaneous injection came last with 5 cases.

Additionally, in 66 cases use was made of another administration option of the ampule solution, namely oral administration in the form of a drink ampule. Although this is not a drink ampule in the pharmaceutical sense, oral administration of the ampule contents is possible in principle. The contents of one ampule are usually diluted in a glass of water and swallowed, not sipped.

Whilst in the majority of patients the injection solution was always administered in the same way throughout the whole treatment period, the doctors decided in favour of combined use of more than one method of administration in 40 patients. A detailed analysis of all combinations would exceed the scope of this evaluation, however. In a further 8 cases, no information was given on the method of administration. The relative frequencies of the individual methods of administration are shown in Figure 4. It should be pointed out here that the analysis of administration methods also included those patients who simultaneously received drops.

1.8. Dosage

The dosage of Lymphomyosot drops is stated as follows in the user information: "Unless otherwise prescribed, take 15-

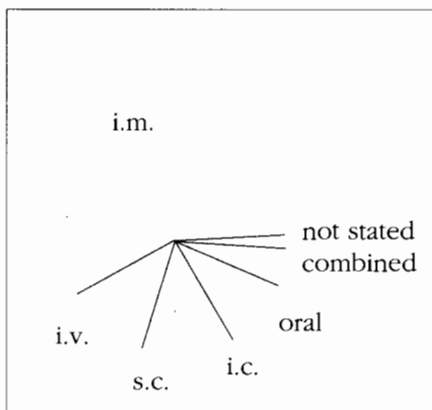


Figure 4: Relative frequency of the various methods of administration of Lymphomyosot ampules (n = 785).

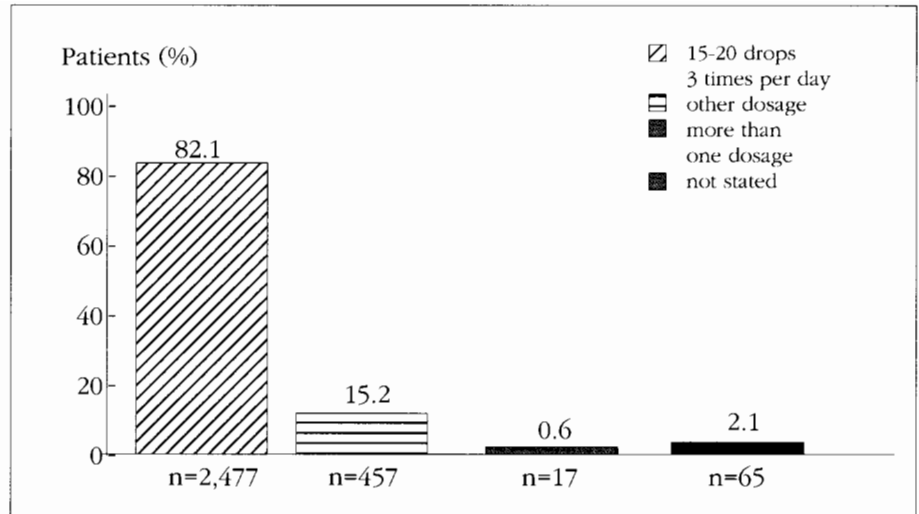


Figure 5: Percentage proportions of patients receiving various dosages of Lymphomyosot drops (n = 3,016).

20 drops 3 times per day". It was apparent that in the overwhelming majority of cases (82.1%), the study doctors observed the dosage stated on the package insert and only chose a different dosage in 15.2% of patients during the entire duration of therapy. In a negligibly small proportion of cases (0.6%), the stated guideline dose was given during one part of treatment and a different dose in another part. Information about the dosage of drops was absent from 2.1% of evaluated forms. Figure 5 shows an overview of the frequency of the various dosages of Lymphomyosot drops.

The dosage instructions for Lymphomyosot ampules in the user information state: "1 ampule s.c., i.m., i.c. or i.v. daily in acute conditions, otherwise 1-3 times per week." The

record forms contained the following options to be ticked: 1: 1 ampule per day; 2: 1 ampule per week; 3: 2 ampules per week; 4: other dosage. The statistical evaluation showed that in almost half of all cases (48.8%), the middle dosage was preferred by the study doctors. Injections were given daily in 25.3% of patients, whilst 18.2% only received an injection once a week. Only in 4.1% of cases was a different dosage of Lymphomyosot ampules given. 3.6% of the relevant patient forms gave no information about the dosage of injection solution. The frequency of the various dosages of Lymphomyosot ampules is shown in Figure 6.

In summary it can be said that a clear tendency to use a "middle" dosage is identifiable in most doctors both for

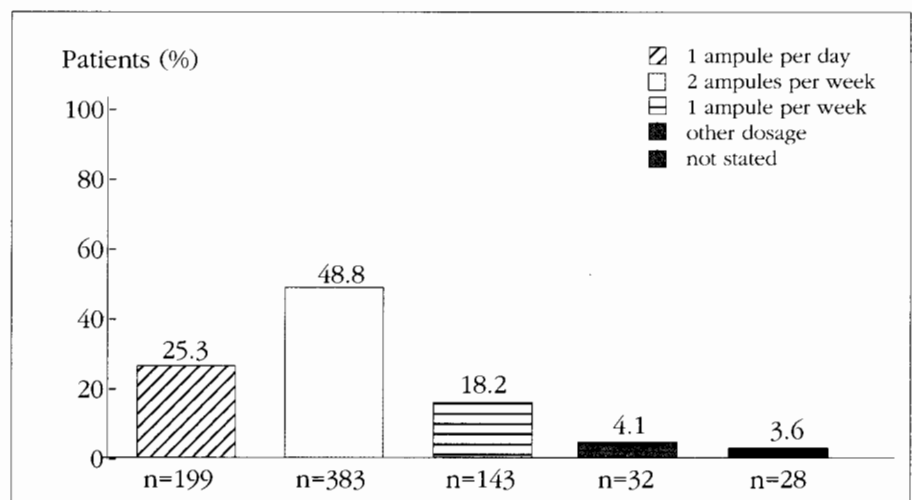


Figure 6: Percentage proportions of patients receiving various dosages of Lymphomyosot ampules (n = 785).

the drops and for the ampules of Lymphomyosot. In contrast, extreme dosages recede into the background in statistical terms.

1.9. Classification of therapy results by presentation

It has already been noted earlier in this study that in order to objectively evaluate the conclusiveness of the therapy results to be presented subsequently, some interfering variables should firstly be analyzed which could have diminished the conclusiveness of the therapy results. A possible interfering variable in this context is the fact that use of two different presentations of the test preparation was observed in this study, and that one of these presentations was administered in five different ways. Whether and to what extent the therapy successes described are attributable to particular forms of administration will be analyzed below.

Firstly, however, a few comments should be made concerning the collection of the therapy results.

In order not to make collection of the therapy results unnecessarily difficult and in order to give the most equal possible consideration to the numerous different disease pictures treated in this study with Lymphomyosot, a simple five-grade scale was used to assess treatment success. The grades were as follows: 1 = very good; 2 = good; 3 = satisfactory; 4 = unsuccessful (i.e. no change); 5 = worse. We were aware of the problems of such a crude classification, but nevertheless chose this after thorough consideration.

In addition to the possibility of quantifiable statements, this form of assessment scale offers the primary advantage that therapy results achieved in relatively different types of diseases can be compared directly with each other. This is particularly important because therapy results can be depicted in one and the same graph not only with reference to areas of use, but also with reference to other features such as individual presentations and methods of administration.

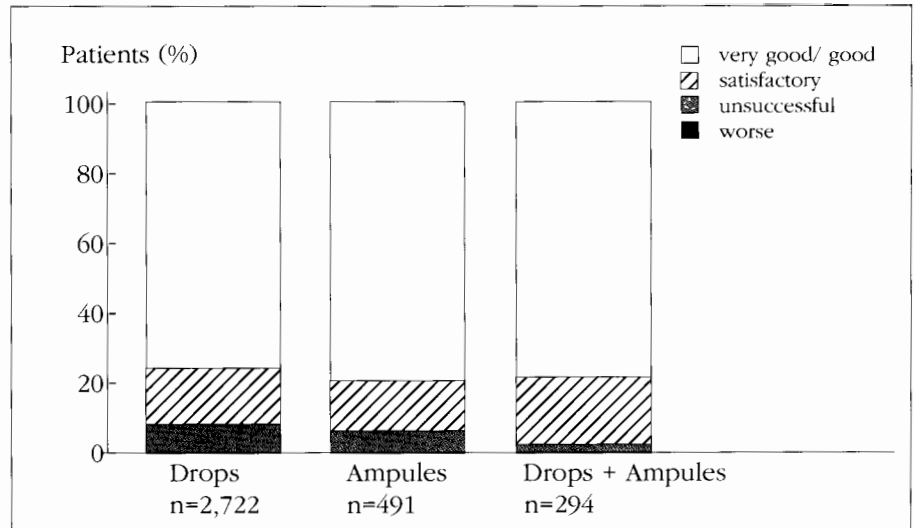


Figure 7: Therapy results with Lymphomyosot classified by presentation (n=3,507).

For the purposes of greater clarity, we have divided the therapy results into 4 groups in the following diagrams: very good/good; satisfactory; unsuccessful (i.e. no change); worse. Since the "worse" category makes up only a negligible proportion, most of the graphs show only 3 expressions of the aspect "therapy result". Moreover, in order to ensure the greatest possible comparability, absolute figures were not used in the following graphs but only percentage values. In this way, the therapy results are as comparable as possible, even if they were taken from patient groups of differing size.

The first two illustrations in this respect are intended to indicate to what extent

the different presentations and methods of administration of Lymphomyosot can be regarded as therapeutically equivalent. The therapy results for the administration of drops, ampules and a combination of both presentations are compared with each other in Figure 7.

It is apparent that with both presentations and also with a combination thereof, good and very good therapeutic success was achieved in the great majority of cases.

The second graph (Figure 8) is intended to clarify the question of to what extent the method of Lymphomyosot administration influences the results of

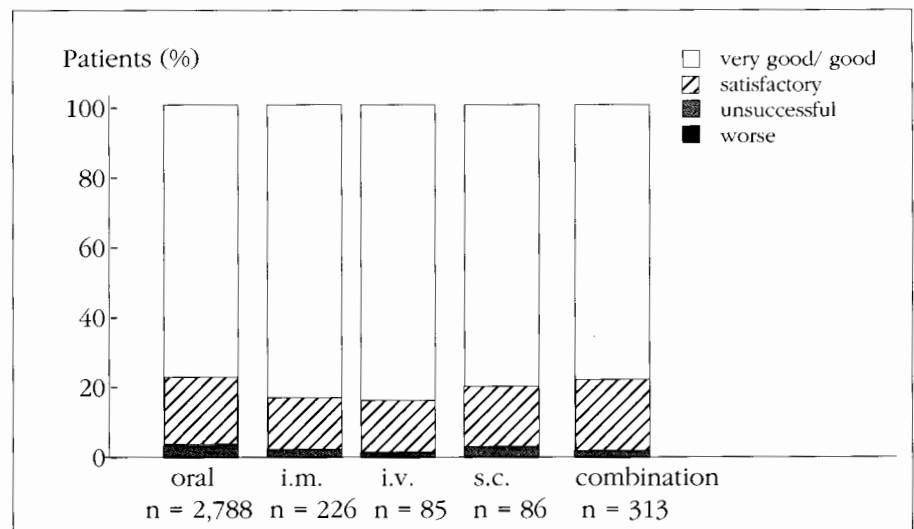


Figure 8: Therapy results with Lymphomyosot classified by method of administration (excl. i.c. administration; n = 3,498).

| Nature of drug administered | Number of cases |
|---|-----------------|
| Analgetics/Anti-rheumatics | 44 |
| Antibiotics | 83 |
| Antidiabetics | 5 |
| Antihypertensives | 8 |
| Anti-inflammatories | 14 |
| Antitussives/Expectorants | 131 |
| Beta-receptor blockers | 5 |
| Calcium antagonists | |
| Broncholytics/Anti-asthmatics | 27 |
| Diuretics | 17 |
| Circulation-stimulating agents | 9 |
| Influenza remedies | 42 |
| Cardiac agents | 8 |
| Coronary stimulants | 4 |
| Oropharyngeal agents | 28 |
| Rhinological agents | 27 |
| Sexual hormones and their inhibitors | 7 |
| Alterants/Immunostimulants | 107 |
| Preparations for the veins/Varicose vein remedies | 45 |
| Cytostatic agents/Metastasis inhibitors | 29 |
| Single homeopathic agents | 17 |
| Combination homeopathics | 560 |
| Other drugs | 400 |

Table 3: Accompanying drug therapy used in more than 1% of patients.

| Nature of therapy | Number of cases |
|--------------------------------|-----------------|
| Acupuncture | 27 |
| Balneotherapy | 11 |
| Movement therapy | 7 |
| Radiotherapy | 40 |
| Dietary measures | 20 |
| Autologous blood treatment | 52 |
| Haematogenic oxidation therapy | 7 |
| Hydrotherapy | 10 |
| Inhalation | 91 |
| Compression dressings | 7 |
| Lymphatic drainage | 255 |
| Massage | 6 |
| Neural therapy | 7 |
| Surgical measures | 4 |
| Physical therapy | 9 |
| Symbiosis guidance | 6 |
| Compresses/dressings | 39 |
| Other measures | 53 |

Table 4: Accompanying non-drug measures used in more than 1% of patients.

therapy. In order to obtain the most conclusive results possible, only those patients in whom only one specific method of administration was used during the entire treatment period were taken into account for the individual administration methods; consequently, intracutaneous administration had to

be excluded from the evaluation since only one single patient would have been available with an assessment of "satisfactory". Drops and "drink ampules" were counted together in oral administration.

It can be stated that the differences relating to the therapeutic success rates

are negligibly small and could also be determined or partly determined by statistical fluctuations, especially as patient groups of very different sizes were compared in some cases.

1.10. Accompanying therapy

As already stated elsewhere in this study, additional drugs and non-drug measures were in principle permitted without restriction in the Lymphomyosot use observation study if the doctor giving treatment regarded them as necessary in the individual case. However, in order to ensure that their possible influence on the therapy results could be estimated more effectively in retrospect, additional therapy of whatever kind had to be recorded in full on the record form.

Before the various accompanying therapies specific to the relevant disease pictures are dealt with more fully in the context of the subsequent detailed evaluation, all major additional therapies will firstly be listed in full and their influence on the therapy results represented in global terms.

Tables 3 and 4 list the major additional drug or non-drug measures employed in the patients under observation, broken down by nature and number of cases. Since accompanying therapy differs markedly among GPs from practice to practice and is very heterogeneous, we have restricted ourselves for reasons of space to those therapies employed in more than 1% of the total patient population. Due to the occurrence of multiple listing, the total number of cases in Tables 3 and 4 is greater than the number of patients in the relevant groups. The classification of the drugs administered additionally was carried out, insofar as allopathics or common phytotherapeutics were involved, in accordance with the main group list of the "rote Liste". Homeopathic agents were subdivided into single homeopathic agents and combination preparations and represented separately. Other drugs not listed in the "rote Liste" or which cannot be sensibly classified according to its classification scheme, are included in the category "Other drugs".

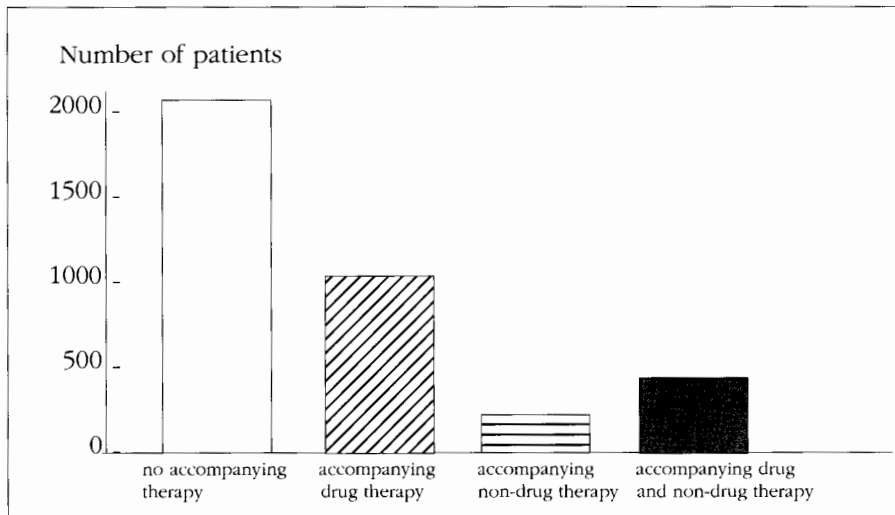


Figure 9: Number of patients receiving various forms of accompanying therapy in addition to administration of Lymphomyosot (n = 3,512).

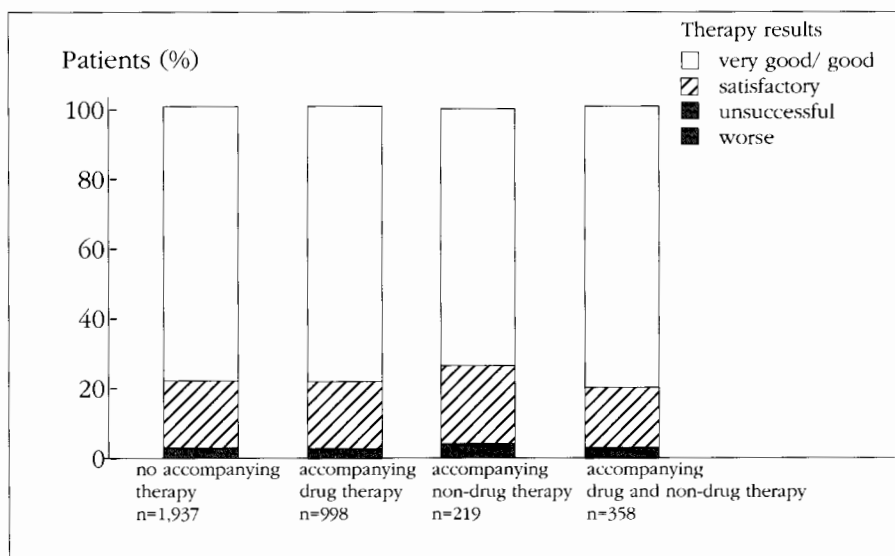


Figure 10: Therapy results with Lymphomyosot classified by accompanying therapy.

Figure 9 shows that despite the many additional therapies, the patients receiving only Lymphomyosot are clearly in the majority statistically and make up more than half (exactly 55.1%) of the total patient population. This fact is particularly important with regard to the following detailed evaluation of the therapy results in the individual indication areas. It can therefore be assumed that the treatment successes presented later originate largely from patients treated exclusively with Lymphomyosot.

Since nevertheless just over 45% of patients received additional therapeutic treatment, a brief clarification will now be given as to whether the treatment success in patients with additional

therapy differs fundamentally from the success rates of patients with Lymphomyosot therapy only. Figure 10

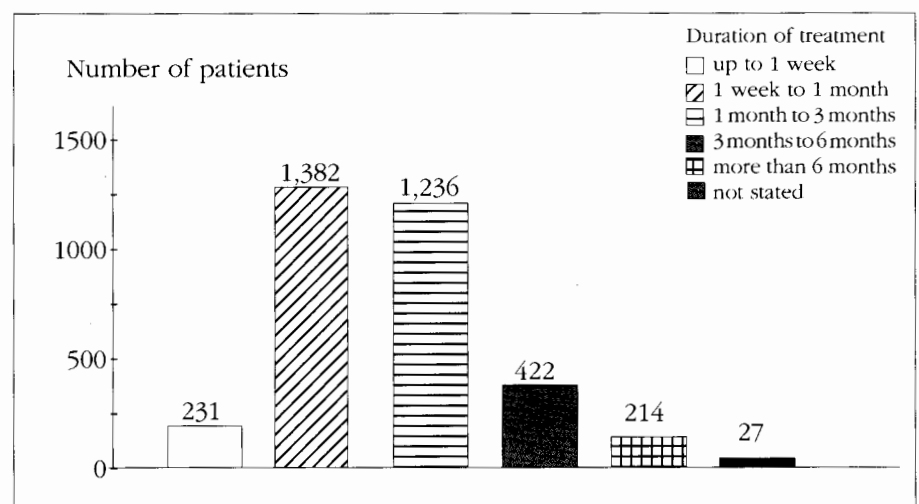


Figure 11: Duration of treatment with Lymphomyosot (n = 3,512).

therefore shows the therapy results in 4 groups: group 1 = Lymphomyosot therapy only; group 2 = further additional drugs; group 3 = additional non-drug measures; group 4 = additional drugs and non-drug measures combined.

As Figure 10 shows, the various configurations of accompanying therapy differ remarkably little in their therapeutic success rates. Accompanying non-drug therapy alone falls slightly out of the frame due to somewhat poorer therapeutic results. Detailed evaluation showed that this group contained a large proportion of patients with pronounced lymphoedema, in whom Lymphomyosot and simultaneous lymphatic drainage were used due to the severity of the symptoms, and where simply due to the severity of the basic disease less positive results were to be expected.

It must also be considered that the patients with additional non-drug measures represent, at 219 cases, the statistically smallest group and that with a group of this order of size statistical fluctuations weigh more heavily than with larger patient samples.

At any rate, it can be demonstrated on the basis of Figure 10 that the therapy results of the patients with Lymphomyosot therapy only do not differ markedly from those with combined therapy. However, this should not be taken to indicate that accompanying therapy is fun-

1.11. Duration of treatment

The most important preconditions to be met for optimum drug effect include not only correct dosage but also a sufficiently long duration of treatment. The period over which the preparation Lymphomyosot is normally used in the doctor's practice is therefore of great interest. The data forms contained 5 levels for recording the individual duration of treatment:

1. less than 1 week
2. 1 week to 1 month
3. 1 month to 3 months
4. 3 months to 6 months
5. more than 6 months.

Figure 11 shows how the study period statements on duration of treatment are distributed over the individual levels. A mean value for the duration of therapy cannot sensibly be calculated on the basis of this data (especially due to the open-ended category "more than 6 months"). However, an approximate value for the median can be given. This is of the order of 5 weeks. Thus approx. 50% of patients were treated with Lymphomyosot for less than 5 weeks and the other 50% for more than 5 weeks.

Another interesting aspect could be how the therapy results are influenced by the duration of treatment. Account must be taken here, however, of the fact that in this study, condition development was not documented and hence no interim results are available for assessing treatment success as a function of treatment duration. Therefore, only therapy results from completed cases of treatment can be compared with each other.

Since the duration of treatment was entirely a matter for the judgement of the individual doctor, it must be assumed that in general the more severe and more stubborn the underlying disease, the longer the patients were treated with Lymphomyosot. Evidence that this is the case can be seen from Figure 12 where the duration of treatment is plotted against the duration of the disorder. It can be clearly seen that

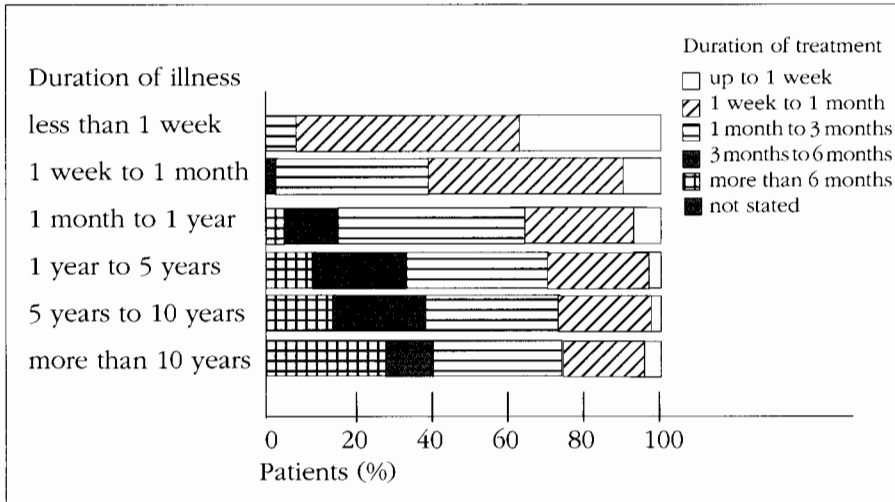


Figure 12: Duration of treatment with Lymphomyosot as a function of duration of disease or disorder prior to commencement of therapy (n = 3,481).

fundamentally superfluous or even unfavourable. The question of whether treatment additional to the administration of Lymphomyosot is necessary and worthwhile can only be decided by the doctor giving treatment in the individual case, taking account of all the disease symptoms and constitutional factors applying to his patient. Since it can be assumed that the group with additional therapy contained a higher proportion of patients with severe basic diseases than the group without additional therapy, it cannot necessarily be expected that

the contribution made by the additional therapeutic measures to achieving treatment success in this negative selection from the total patient population immediately makes itself felt in higher success rates.

Nevertheless, the comparison of therapy results for the various patient groups allows the conclusion to be drawn that the various forms of accompanying therapy employed do not in any way falsify the recorded treatment results as a whole.

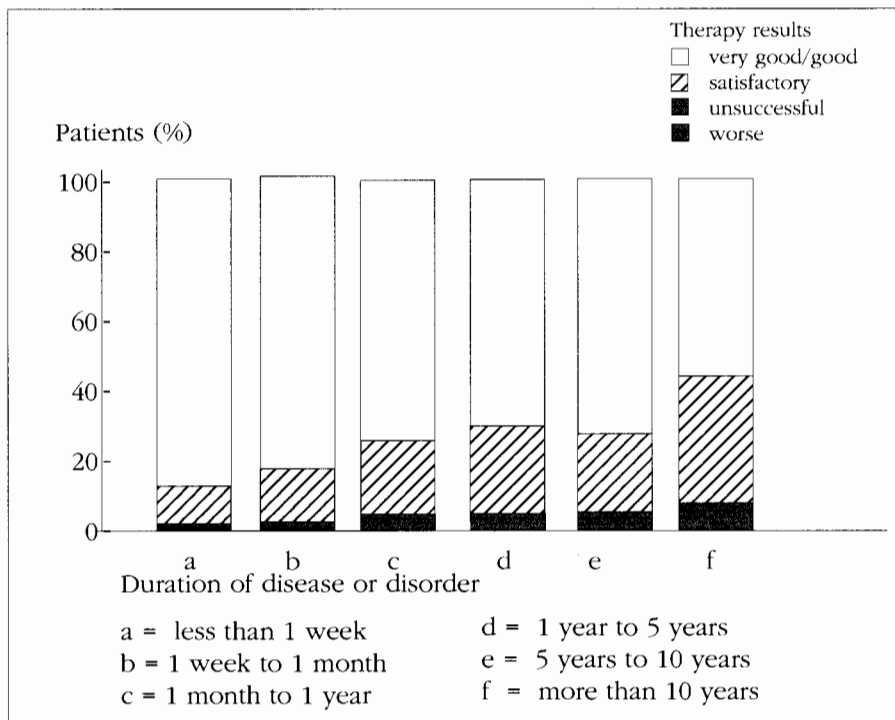


Figure 13: Therapy results with Lymphomyosot as a function of disease or disorder duration prior to commencement of treatment (n = 3,481).

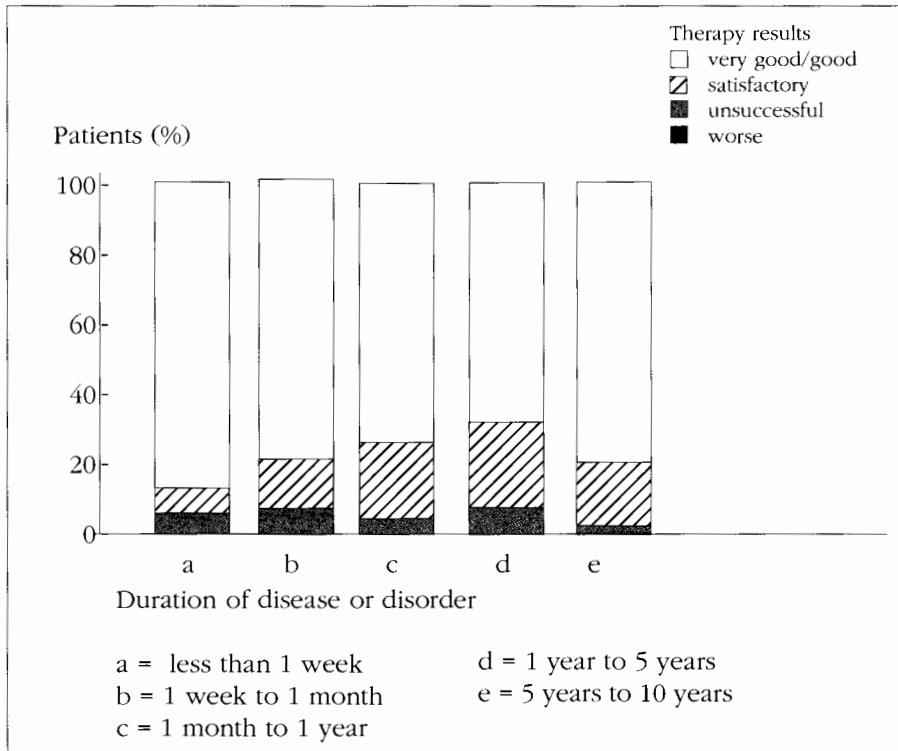


Figure 14: Therapy results with Lymphomyosot as a function of duration of treatment (n = 3,485).

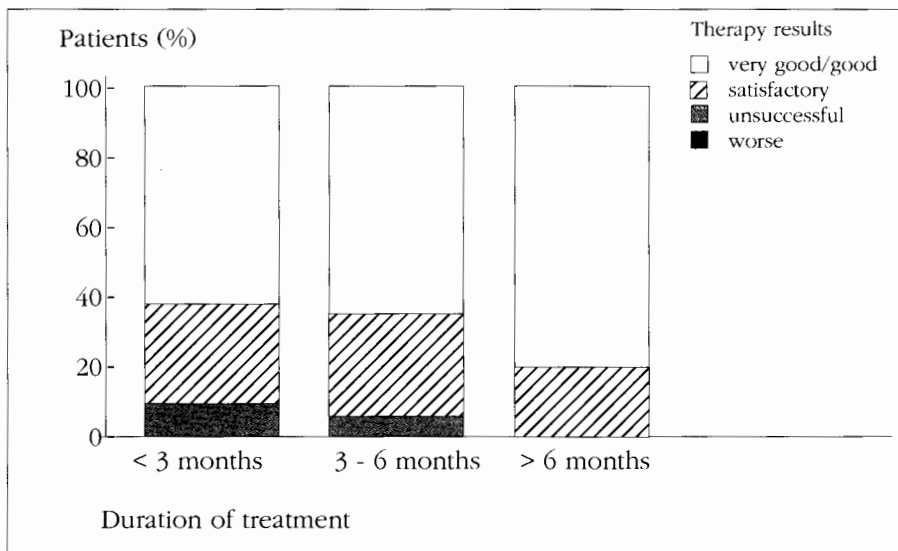


Figure 15: Therapy results as a function of duration of treatment in patients suffering from disease for between 5 and 10 years (n = 252).

with increasing duration of illness, longer and longer treatment times were given on the record forms.

If the therapy results from the various patient groups with differing duration of illness or disorder are compared (Figure 13), it is evident that the therapeutic success rates are lower for patients with longer lasting disease than for those with shorter duration of disease. This finding is not surprising, however, when it is considered that

chronic conditions are by nature very much more difficult to treat than acute disease conditions. So it is all the more remarkable that nevertheless very good or good therapeutic success was achieved in over 67% of patients in the group with more than 5 years' duration of illness and in over 56% of cases in the group with more than 10 years' duration of illness.

Against the background of Figures 12 and 13 which show that longer

disease periods are accompanied by longer treatment periods and at the same time by rather poorer success rates, it could be expected that the therapeutic success rates decrease continuously in parallel with increasing duration of treatment. This is not the case, however, as shown by Figure 14. Rather, the patient group with a treatment duration of more than 6 months is distinguished by decidedly good success rates and indeed by the smallest proportion overall of very good or good successes achieved in the five groups. This is all the more remarkable since the patients with long duration of treatment must be regarded as a distinctly negative selection. Consequently, this surprising result can in all probability be interpreted to the effect that it was only in the patient group with the longest treatment duration that the effect potential of the preparation Lymphomyosot was fully exploited and hence the poorer initial state was, as it were, overcompensated. Evidently there is therefore still a "therapeutic effect reserve" in the preparation even after a six-month treatment period, which certainly remained unused in some of the patients in whom satisfactory therapeutic success was not achieved in the context of a shorter treatment period.

In this connection, a particularly interesting question is how the therapy results for differing durations of treatment behave with respect to a patient group whose disease or disorder duration is not as widely scattered. To this end the patient group whose duration of disorder - represented on a logarithmic scale - would show the lowest breadth of scatter was investigated.

Figure 15 therefore shows the therapy results for the patients suffering from disease for between 5 and 10 years. Due to the considerably smaller number of patients (252 cases) compared to the total patient population, a classification into 3 sub-groups with different durations of treatment was selected. It is apparent that in this special patient selection, the therapy results were in fact rated by the study doctors as increasingly better with increasing duration of treatment.

In principle, therefore, it can be stated that precisely in chronic disease conditions and disorders, Lymphomyosot therapy should not be ended too early in order to achieve optimum treatment results.

1.12. Repeat treatment

It was also permitted in this use observation study to document cases in which repeat treatment with Lymphomyosot had already been carried out. It is therefore of fundamental interest whether the therapy results in repeat treatments are better than in initial treatments, i.e. whether there is still a therapeutic effect reserve in the preparation after completion of the first treatment too. Figure 16 shows that this is in fact the case. It is particularly noticeable that the percentage of patients treated unsuccessfully in repeat treatments makes up less than a third of that recorded for first treatments. It can therefore be stated that it is worthwhile in most cases to continue an initially apparently unsuccessful treatment over a longer period, or if appropriate, at a later date.

2. Therapeutic use of Lymphomyosot in lymphoedema and other oedemas

Having discussed in detail the methodology of the study and the different variables which may be important for the assessment of the therapy results, the individual indication groups will now be looked at in detail, taking particular account of the therapy results achieved.

2.1. Patients

Since lymphoedemas form the statistically largest single diagnosis group with 684 cases, and in practice represent a very important indication area for the preparation Lymphomyosot, these cases will be investigated first.

Lymphoedema is a protein-rich, pasty oedema due to a congenital defect (e.g. in lymph vessel aplasia) or an

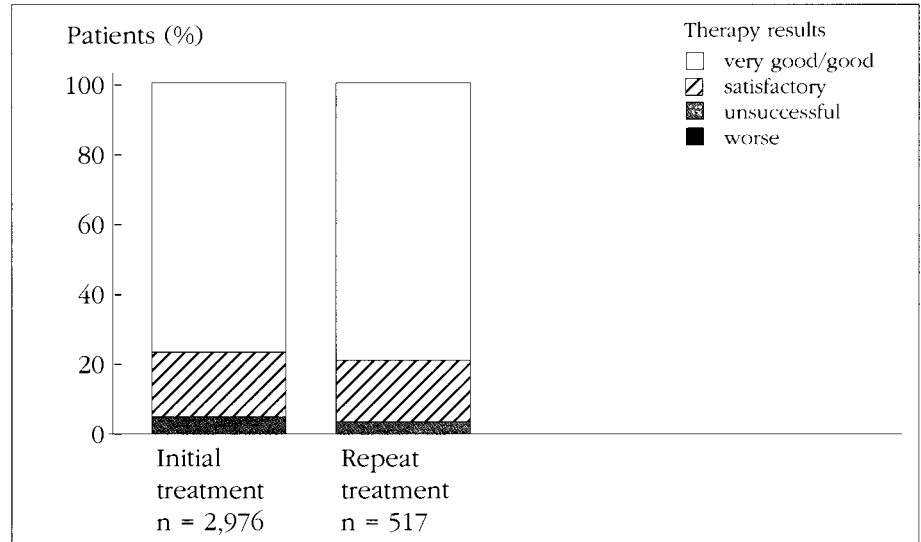


Figure 16: Comparison of therapy results in initial treatment and in repeat treatment (n = 3,493).

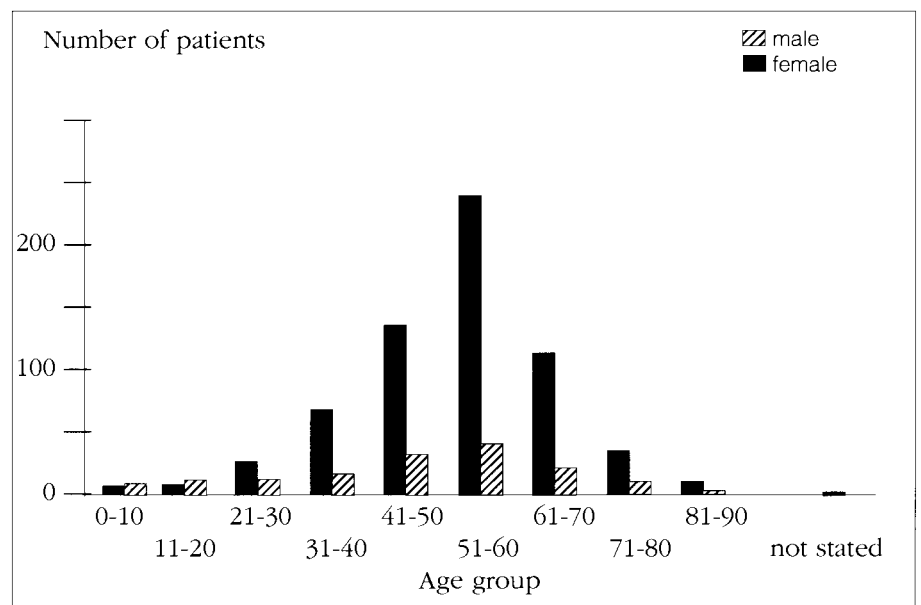


Figure 17: Age and sex distribution of all patients with oedemas (n = 751).

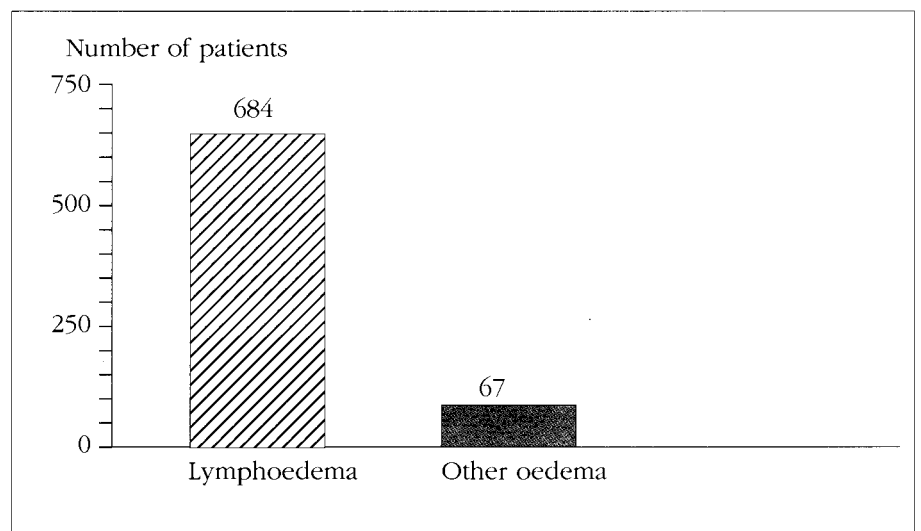


Figure 18: Number of patients with lymphoedemas and oedemas of other kinds (n = 751).

acquired occlusion of lymph tracts with chronic lymphostasis (7). Lymphomyosot exerts a channelling effect on the mesenchyma in these diseases (8).

However, it was not exclusively lymphoedemas which were treated in this Lymphomyosot study. In a further 67 cases, the preparation was used to treat oedemas of other kinds, primarily those due to cardiac or venous congestion. This means that a total of 751 patients were treated with Lymphomyosot due to oedemas.

As mentioned earlier in this report, the oedema patients are characterised by an age and sex distribution which differs considerably from that of the total patient population. Whilst the total patient population includes a high proportion of children under the age of 10 years (32%), the patients with oedemas display a practically symmetrical age distribution with a peak in the 6th decade and a proportion of only 1.5% of children under the age of 10. A further conspicuous feature is that female patients are statistically more in the majority with 80.7% than among the patients as a whole. The age and sex distribution of the oedema patients is shown in Figure 17. A mean age of just over 52 years was calculated for this patient group.

Figure 18 shows the statistical distribution of patients between lymphoedemas and oedemas of other kinds. A particularly interesting question in this context is whether equally good therapy results were obtained with all forms of oedema or whether Lymphomyosot shows superior effect particularly in lymphoedemas.

2.2. Results

As Figure 19 shows, markedly better results were achieved with the lymphoedemas themselves despite a high proportion (61.2%) of very good or good therapeutic successes in oedemas of other kinds. These results will therefore be looked at in detail below.

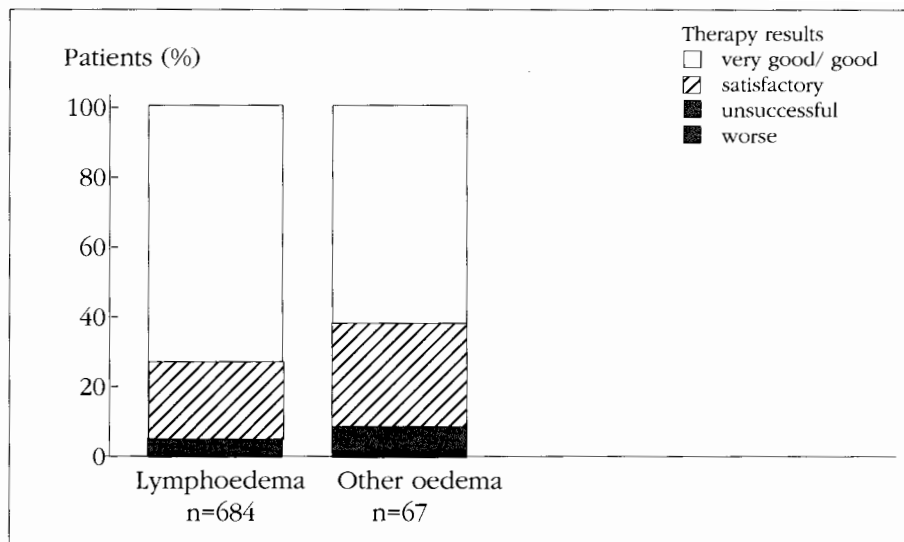


Figure 19: Therapy results with Lymphomyosot in lymphoedema and oedema of other kinds (n = 751).

In the following tables and graphs, the statements made by the study doctors about the nature of the lymphoedemas treated are classified according to various criteria. It must be pointed out firstly that the evaluated details concerning aetiology and localization were given spontaneously by the doctors and were not requested by us using standard questions. This explains the relatively high proportion of imprecise statements concerning the cause and localization of the lymphoedemas treated.

The most interesting feature for the use of Lymphomyosot in practice is certainly the classification by aetiology.

On the basis of the statements of the study doctors, the patients can be subdivided into a total of 5 groups:

1. Post-traumatic lymphoedema: All patients with the literal statement "post-traumatic lymphoedema" and also entries of lymphoedema following accident, contusion, sprain, fracture, compression, etc. were placed in this group.
2. Inflammatory lymphoedema: This group included patients with lymphoedema following lymphangitis, erysipelas, phlegmons, shingles, etc.

| Nature of cause | Number of cases | Mean age in years | Mean duration of disorder in months | Therapeutic success rate |
|---------------------------------------|-----------------|-------------------|-------------------------------------|--------------------------|
| Post-traumatic | 53 | 44 | 17.0 | 94.3 % |
| Inflammatory | 35 | 52 | 30.5 | 94.3 % |
| Post-operative | 247 | 55 | 31.0 | 93.9 % |
| Following therapeutic X-ray treatment | 9 | 52 | 15.5 | 100.0 % |
| Unknown cause | 340 | 51 | 21.5 | 96.2 % |

Table 5: Classification of treatment cases by lymphoedema causes.

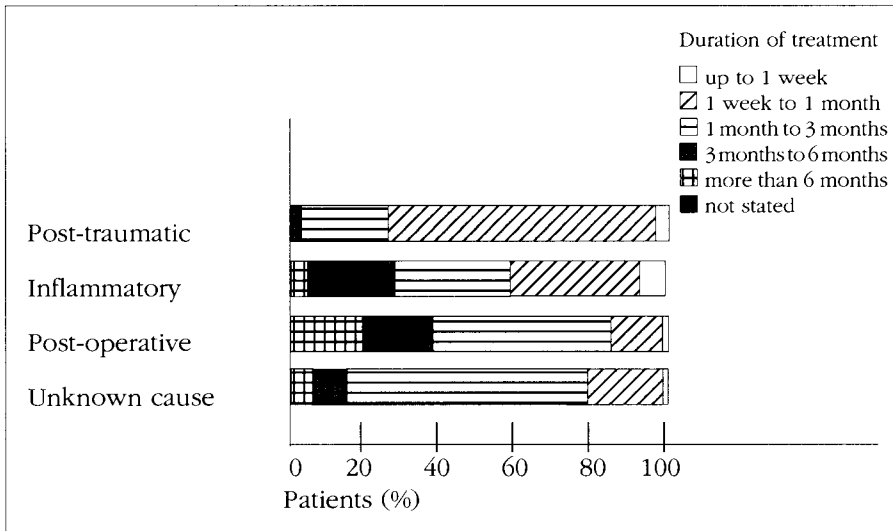


Figure 20: Duration of treatment with Lymphomyosot in lymphoedemas of various origin (n = 675).

breakdown of the data from patients with lymphoedema following radiation therapy was dispensed with in the following diagrams, since in this case the values cannot be regarded as representative for this indication area due to the small number of cases (9 patients).

Since the duration of treatment also constitutes a criterion which should always be taken into account in a critical evaluation of therapy results, the treatment periods of the 4 most important lymphoedema groups are compared in Figure 20. It is evident here that in general treatment was

3. Post-operative lymphoedema:

This group was mostly made up of patients with surgical lymph node removal due to neoplastic phenomena.

4. Lymphoedema following therapeutic X-ray treatment:

This related to secondary lymphoedemas following radiation therapy of malignant lymph node diseases or lymph node metastases.

5. Lymphoedema of unknown cause:

This last group included all lymphoedema patients where a triggering cause was not known to the doctor giving treatment or was not notified to us.

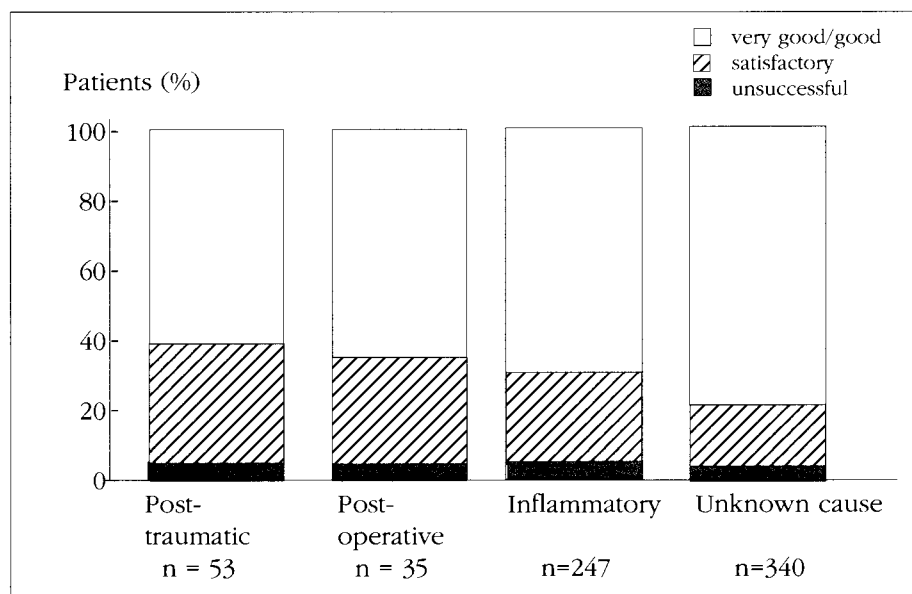


Figure 21: Therapy results with Lymphomyosot in lymphoedemas of various origin (n = 675).

Table 5 shows a detailed breakdown of the above 5 lymphoedema groups by number of cases, mean age, mean duration of disorder and therapeutic success rate. Here, as in the subsequent tables, a simplified representation was chosen for the therapy result for reasons of space, whereby all patients who were treated with at least satisfactory success were added together and related to the total number of cases in the relevant group in order to be expressed as a percentage. Where appropriate, the therapy results were also represented in detail in the form of graphs. Here, however, we have restricted ourselves to those indication groups where a sufficiently large number of cases were available for evaluation. For this reason, a detailed

| Localization | Number of cases | Mean age in years | Mean duration of disorder in months | Therapeutic success rate |
|-------------------------|-----------------|-------------------|-------------------------------------|--------------------------|
| Upper extremity | 203 | 56.5 | 32 | 96.1 % |
| Lower extremity | 299 | 51.5 | 22 | 95.3 % |
| Other localizations | 18 | 48.5 | 14 | 100.0 % |
| Localization not stated | 164 | 47.5 | 22 | 93.3 % |

Table 6: Breakdown of cases treated by localization of lymphoedema.

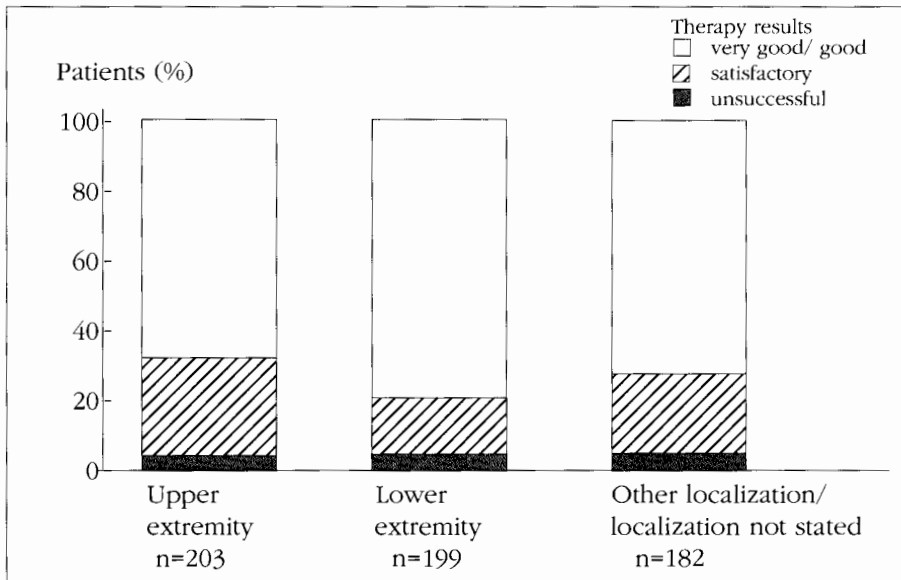


Figure 22: Therapy results with Lymphomyosot in lymphoedemas of various localization (n = 684).

| Non-drug measures \ Drug measures | Drug measures | | Total |
|-----------------------------------|---------------|--------|--------|
| | No | Yes | |
| None | | | |
| Number of patients | 344 | 89 | 433 |
| Patients successfully treated | 97.1 % | 92.1 % | 96.1 % |
| Lymphatic drainage | | | |
| Number of patients | 96 | 128 | 224 |
| Patients successfully treated | 95.8 % | 91.4 % | 93.3 % |
| Other measures | | | |
| Number of patients | 16 | 11 | 27 |
| Patients successfully treated | 93.7 % | 100 % | 96.3 % |
| Total | | | |
| Number of patients | 456 | 228 | 684 |
| Patients successfully treated | 96.7 % | 92.1 % | 95.2 % |

Table 7: Number of patients and therapeutic success rates in lymphoedema as a function of accompanying therapy.

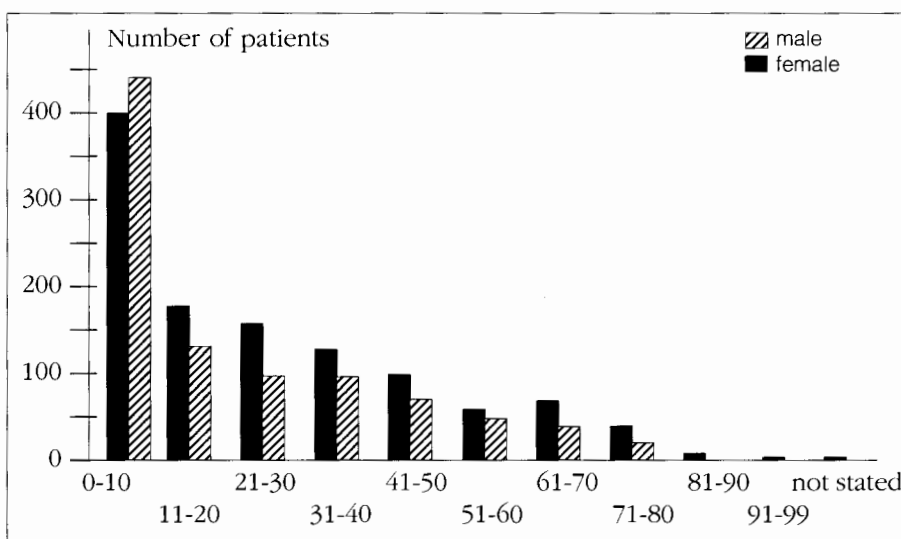


Fig. 23: Age and sex distribution of all patients with inflammatory conditions (n=2,135).

longest in post-operative lymphoedema and shortest on the other hand in post-traumatic oedema.

If the therapy results (Figure 21) are related to these treatment periods, it must be concluded that, precisely in the case of post-traumatic lymphoedema, even better therapy results would presumably have been achieved if a correspondingly longer duration of therapy had been observed. Another surprising aspect is the fact that evidently the patient group which responded best to Lymphomyosot was that in which a precise cause of the lymphoedema could not be stated. It can be seen from this and from the large number of patients in this group that Lymphomyosot seems to represent the therapeutic of choice precisely in diagnostically obscure cases of lymphoedema and can also be used here with good success.

Apart from a classification according to aetiology, a breakdown of the lymphoedemas treated by localization can also be made. As Table 6 shows, the localizations "upper extremity" and "lower extremity" are the most important statistically. The other lymphoedemas involve almost exclusively, where precise statements on localization were made, individual cases such as blepharoedema, facial oedema or oedema in the area of the nape of the neck. In Table 6 the 4 patient groups formed on the basis of the stated lymphoedema localizations are broken down by number of cases, mean age, mean duration of disorder and therapeutic success rate.

The therapy results achieved with these groups are shown in Figure 22, where due to the small number of cases in the "other localizations" group, these are collated with the group "localization not stated".

In order to be able to precisely assess the role of accompanying medication and the other accompanying therapies particularly in the treatment of lymphoedemas, the patients were subdivided into various groups according to the additional therapy carried out and these presented in a

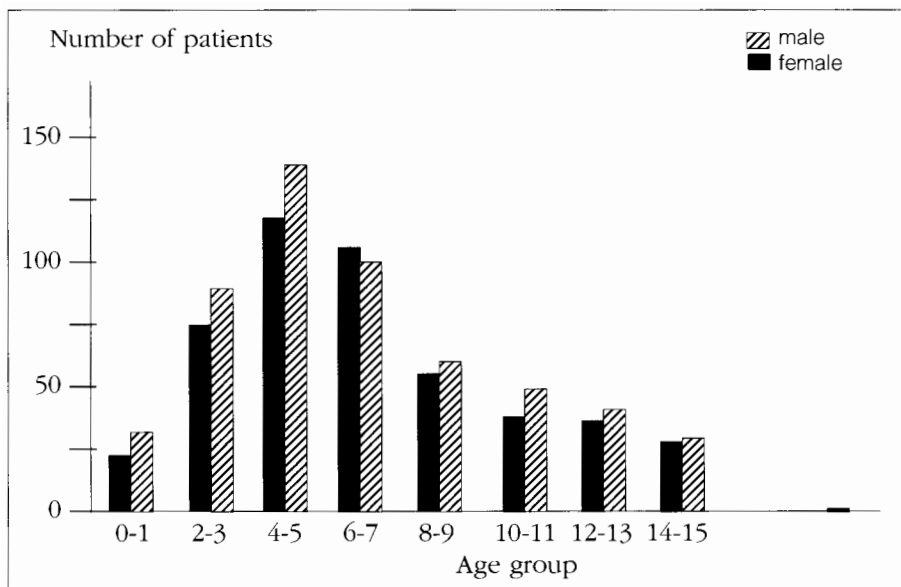


Fig. 24: Age and sex distribution of all children up to 15 years old treated for inflammatory conditions (n=1,006).

two-dimensional grid together with the relevant number of cases and the simplified therapeutic success rate (Table 7). Since lymphatic drainage naturally plays a special role as accompanying therapy for the indication area lymphoedema, this group was extracted from the other non-drug therapy procedures and presented separately.

It is apparent that irrespective of the relevant configuration of accompanying therapy, therapeutic successes were recorded in all groups, and in over 90% of cases in each individual group. It can be concluded from this that the accompanying therapy does not play a decisive role in treatment success even in the special indication area of lymphoedema. Lymphomyosot can therefore be described as a proven therapeutic for treatment of lymphoedema of various origin and localization, which is outstandingly suitable for use with and without accompanying therapy.

3. Possible uses of Lymphomyosot in inflammatory conditions

The second largest field of application for Lymphomyosot, which is not second in importance to the complex lymphoedema, is inflammatory conditions. In the data sheet the preparation is recommended for use in lowered

resistance (general susceptibility to infection) and in chronic tonsillitis. During the course of the present use observation study it was evident, however, that physicians sometimes use the preparation Lymphomyosot in practice for indications over and above those cited by the manufacturer.

3.1. Patients

A total of 2,135 cases classified under the generic term "inflammatory conditions", were documented by the investigators taking part in the use observation study. Fig. 23 shows the age and sex distribution of this group of patients.

It was evident that the age distribution of this patient group reached a peak in the first ten years of life and that the number of patients decreased almost continuously with increasing age. The average age of all patients with inflammatory conditions was 24.1 years. The number of children aged up to 10 was almost 40%, the number up to 15 was over 47%. To obtain a more accurate classification of the patients' age structure in childhood they were grouped in two-year spans and separated into male and female, as shown in the bar chart (Fig. 24).

It was clear that the peak was between the age of 4 and 5. It was also evident

that in childhood there were more male patients (53.6% of those aged up to 15 were boys, 46.4% girls) whereas in the whole patient group with inflammatory conditions the female patients were in the majority with 54%.

The patients treated with Lymphomyosot suffered from very different types of inflammatory or infectious conditions and the diagnoses tonsillitis, rhinitis, sinusitis, bronchitis, lymphadenitis and non-specific infections were those most quoted. In 1,556 cases there was only one diagnosis on the record sheet whereas in the other 579 patients there were mixed infections. Table 8 gives an overview of the diagnoses named by the investigators in so far as there was only one diagnosis. For reasons of space we had to forgo listing the combinations. However, these patients were of course also included in the further analysis.

888 of the 2,135 patients (41.6%) had previously already received different types of medical treatment. Tab. 9 gives the type of drugs administered together with the corresponding number of cases. They were mainly antibiotics, antitussives/expectorants and drugs to stimulate the immunological system. As drugs are given in the list which were also mentioned in the case of mixed diagnoses, the total number of cases in Tab. 9 is greater than the number of relevant patients. In the case of patients previously treated with other drugs it can be assumed that a large number were problem cases which did not respond adequately to the therapy previously carried out.

3.2. Results

The following tables and charts classify the treatment cases allocated to inflammatory conditions according to various criteria, e.g. form of the disease (acute, chronic, recurrent), site and type of concomitant therapy. Particular attention should be paid to the results of therapy in each case. As in the section "lymphoedema", for reasons of space, the therapy results were presented in a simplified form in the tables so that all the patients who

| Diagnoses | Number of cases |
|--|------------------------|
| Tonsillitis | 381 |
| Pharyngitis | 32 |
| Rhinitis | 82 |
| Sinusitis | 69 |
| Otitis | 27 |
| Parotitis | 25 |
| Sialadenitis | 1 |
| Stomatitis | 7 |
| Gingivitis | 3 |
| Laryngitis | 10 |
| Pseudocroup | 2 |
| Whooping cough | 3 |
| Bronchitis | 75 |
| Pneumonia | 3 |
| Pleurisy | 1 |
| Toxoplasmosis | 1 |
| Infectious mononucleosis | 2 |
| Rubella | 1 |
| Lymphadenitis | 298 |
| Lymphangitis | 12 |
| Mastitis | 4 |
| Dermatitis | 22 |
| Furunculosis | 6 |
| Hidradenitis | 1 |
| Pyoderma | 2 |
| Herpes simplex | 5 |
| Herpes zoster | 1 |
| Gastritis/gastroenteritis | 1 |
| Pancreatitis | 1 |
| Cholangitis | 8 |
| Crohn's disease | 2 |
| Colitis | 8 |
| Appendicitis | 4 |
| Inflammation of the mesenteric glands | 4 |
| Glomerulonephritis | 6 |
| Urinary tract infections | 13 |
| Prostatitis | 1 |
| Deferentitis | 1 |
| Adnexitis | 3 |
| Phlebitis | 6 |
| Osteomyelitis | 1 |
| Non-specific infections (incl. general susceptibility to infection) | 421 |

Tab. 8: Overview of the diagnoses reported by the investigators (single diagnoses) with the number of relevant cases.

| Type of drug administered | Number of cases |
|---|------------------------|
| Antibiotics | 502 |
| Antirheumatic/anti-inflammatory agents | 19 |
| Antitussives/expectorants | 125 |
| Broncholytics/anti-asthmatic agents | 11 |
| Corticoids | 4 |
| Remedies for skin diseases | 3 |
| Influenzal remedies | 49 |
| Oral- and pharyngeal therapeutic agents | 51 |
| Otological preparations | 2 |
| Rhinological preparations | 18 |
| Sulphonamides | 6 |
| Drugs to stimulate the immunological system | 95 |
| Urological preparations | 3 |
| Venous and varicose vein remedies | 5 |
| Vitamins | 1 |
| Single homeopathic remedies | 3 |
| Combination homeopathic remedies | 72 |
| Other drugs | 124 |

Table 9: Drugs used by the patients with inflammatory conditions prior to treatment with *Lymphomyosot*.

responded very well, well or satisfactorily to treatment, and related to the total number of cases in the relevant group, were summarized and expressed as a percentage.

Regarding the indication "inflammatory processes" *Lymphomyosot* is recommended mainly for chronic inflammations by the manufacturer, in the first instance for chronic tonsillitis. However, the present study has shown that the preparation is also used in acute forms and that it has a surprisingly good effect. 30.6% of the inflammations treated (654 cases) were termed acute by the investigators or were put in this category by ourselves because of the short duration of symptoms. 23.2% of inflammatory processes (495 cases) were of the chronic type. The largest group with 44.6% was made up of patients with recurrent inflammations (953 cases). This patient group also included the cases which the doctors designated as chronic-recurrent and those described as "generally susceptible to infection". In 33 cases the preparation was used as follow-up treatment only after the acute disease symptoms had regressed.

Tab. 10 gives a detailed classification of the different types of inflammatory processes according to the number of cases, average age, average duration of symptoms and percentage response to therapy.

The large difference in the duration of symptoms is remarkable, from 7.5 days for acute and 32 or 31 months for chronic or recurrent infections. The highest response rates were achieved for follow-up treatment and for acute inflammations. The results in chronic and recurrent processes were also evaluated as very successful, particularly in view of the long duration of symptoms which would indicate cases which were extremely resistant to therapy.

Fig. 25 gives a more informative presentation of the results of treatment for the different types of inflammatory diseases. Here it is evident that even in chronic processes a response to treatment was achieved in almost 70%

| Type | Number of cases | Average age in years | Average duration of symptoms | Therapeutic response rate |
|---------------------|-----------------|----------------------|------------------------------|---------------------------|
| Acute | 654 | 24.3 | 7.5 days | 96.9% |
| Chronic | 495 | 25.8 | 32 months | 92.9% |
| Recurrent | 953 | 22.8 | 31 months | 93.8% |
| Follow-up treatment | 33 | 27.5 | 8.5 months | 100.0% |

Tab. 10: Classification of treatment cases according to the type of inflammatory processes.

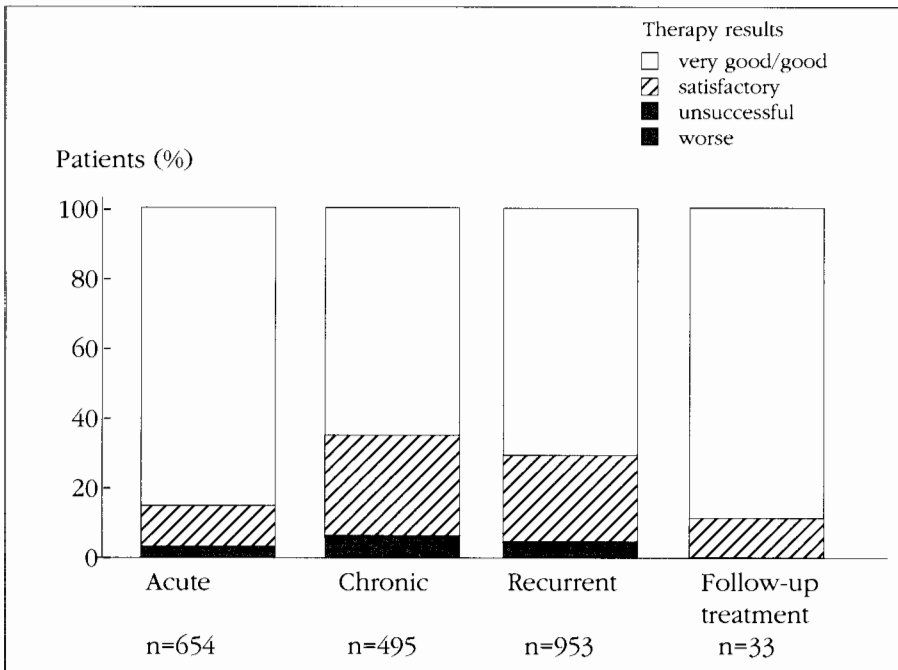


Figure 25: Results of therapy with Lymphomyosot in inflammatory conditions (n = 2,135).

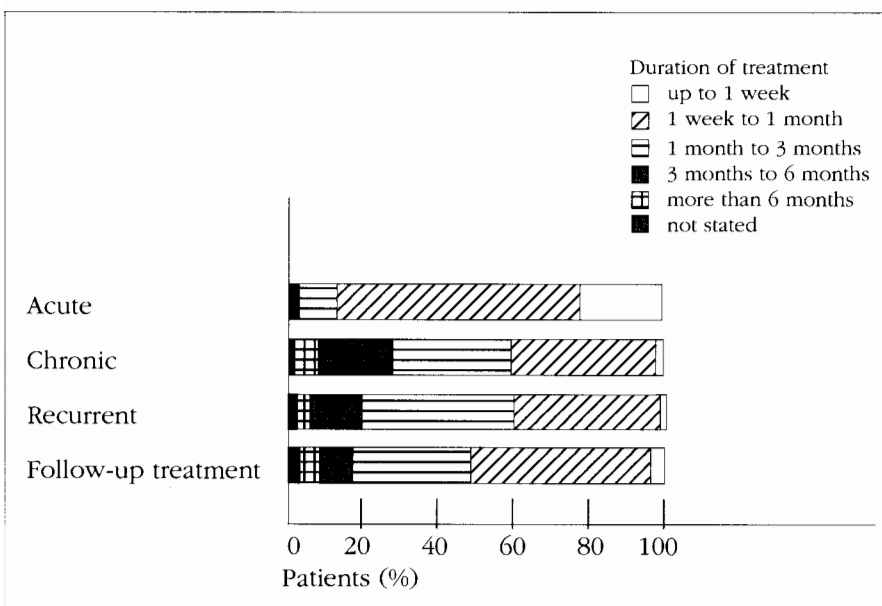


Fig. 26: Duration of treatment with Lymphomyosot in inflammatory conditions (n=2,135).

of all cases, and in recurrent forms in almost 75% of cases; this was assessed by the relevant doctor as very good or good.

Further to Fig. 25, Fig. 26 shows in detail the relevant treatment times necessary in the individual groups. It is evident that there was a good correlation between the duration of treatment and the duration of symptoms which would indicate that in patients with a short case history, a short duration of treatment was usually adequate whereas for persistent conditions treatment was correspondingly longer.

In addition to classification of the type of the disease, subdivision according to the site of the inflammatory processes is also of particular interest for practical use as it illustrates, for the different prescriber groups, the possible uses of Lymphomyosot relevant to their specific specialist areas. When allocating the patients to the different groups we also clearly allocated the cases where several inflammatory diagnoses were given on the record sheet. To avoid overlapping between the individual groups, the diagnosis which was the most likely indication for administration of Lymphomyosot was the one that determined the allocation.

Table 11 shows the patients, placed according to the site of inflammation reported by the investigators in 9 groups, together with the relevant number of cases, average age, average duration of symptoms and therapeutic response rate. It was evident that, without exception, the response rates (defined as at least a satisfactory response to treatment) were clearly above 90% in all groups. This, therefore, clearly illustrates the broad spectrum of activity of the preparation Lymphomyosot.

As other therapeutic measures, in addition to administration of Lymphomyosot, were taken in just under half of all patients we were also interested in the question of how specifically in this group of indications response to therapy was affected by the type of concomitant medication or non-me-

| Site | Number of cases | Average age in years | Average duration of symptoms in months | Therapeutic response rate |
|--------------------------|-----------------|----------------------|--|---------------------------|
| Tonsillitis | 594 | 22.3 | 27.0 | 93.6 % |
| Other ENT-area | 473 | 22.4 | 18.5 | 93.9 % |
| Bronchial system | 105 | 32.1 | 35.5 | 93.3 % |
| Gastro-intestinal tract | 24 | 41.1 | 42.5 | 100.0 % |
| Urogenital system | 28 | 42.4 | 31.0 | 100.0 % |
| Appendages of the skin | 38 | 38.5 | 61.5 | 94.7 % |
| Lymph nodes/lymph tracts | 391 | 21.6 | 11.5 | 94.8 % |
| Other sites | 61 | 26.0 | 11.0 | 96.7 % |
| Non-specific infections | 421 | 25.6 | 18.5 | 96.2% |

Table 11: Classification of treatment cases according to the site of the inflammatory process.

| Medical measures | Non-medical measures | No | Yes | Total |
|----------------------------------|----------------------|-------|-------|-------|
| | None | | | |
| Number of patients | | 1,151 | 80 | 1,231 |
| Those successfully treated | | 94.0% | 92.5% | 93.9% |
| Only homeopathic remedies | | | | |
| Number of patients | | 254 | 63 | 317 |
| Those successfully treated | | 98.0% | 98.4% | 98.1% |
| Antibiotics | | | | |
| Number of patients | | 65 | 11 | 76 |
| Those successfully treated | | 89.2% | 72.7% | 86.8% |
| Other drugs | | | | |
| Number of patients | | 414 | 97 | 511 |
| Those successfully treated | | 95.1% | 96.9% | 95.5% |
| Total | | | | |
| Number of patients | | 1,884 | 251 | 2,135 |
| Those successfully treated | | 94.6% | 94.8% | 94.7% |

Table 12: Number of patients and therapeutic response rates for inflammatory processes related to concomitant therapy.

| Diagnosis | Number of cases | Average age in years | Average duration of symptoms in months | Therapeutic response rate |
|-----------------------|-----------------|----------------------|--|---------------------------|
| Tonsillar hyperplasia | 115 | 13.6 | 25 | 89.5% |
| Adenoid vegetations | 64 | 7.8 | 18 | 87.5% |
| Lymphatism | 144 | 14.8 | 21 | 97.2% |

Tab. 13: Classification of the patients with hyperplasia of lymphatic organs according to primary diagnosis, tonsillar hypertrophy, adenoid vegetations and lymphatism.

dicinal concomitant therapy. For this purpose we separated the patients into different groups according to the additional therapy carried out and illustrated this as a two-dimensional table showing the relevant number of patients and the overall response rate (Tab. 12). The purely homeopathic and antibiotic concomitant medication (the latter because of its particular relevance in inflammatory processes) were shown separately. It was clear that there was a high percentage response to therapy in all the groups. However, the patients given concurrent antibiotic therapy did slightly worse than the treatment cases in the other groups. At first sight this could give the impression that a combination of Lymphomyosot plus antibiotic would not be beneficial. However, it should always be taken into account when comparing the different patient groups, that this was a non-randomized group of patients and that in each individual case the choice of therapy was left to the doctor treating the patient. It should, therefore, be assumed that the patients receiving concurrent antibiotic medication were, on the basis of the severity of their disease, a particularly negative selection so that a high percentage response to therapy, equivalent to those in the other groups, was not expected from the outset.

M. Fitzen (9) in a paper published in 1986 also discussed the question of efficacy of Lymphomyosot, with and without concurrent antibiotic therapy. In this study, which did however only include 10 patients, no marked difference was found in the response to therapy between patients who received only Lymphomyosot drops and those who were also given antibiotics or chemotherapy. Lymphomyosot can, therefore, also be recommended for administration together with antibiotics for therapy of inflammatory processes.

4. Therapeutic use of Lymphomyosot in hyperplasia of lymphatic organs

For many decades Lymphomyosot has been used successfully to treat hyperplasia of lymphoepithelial organs,

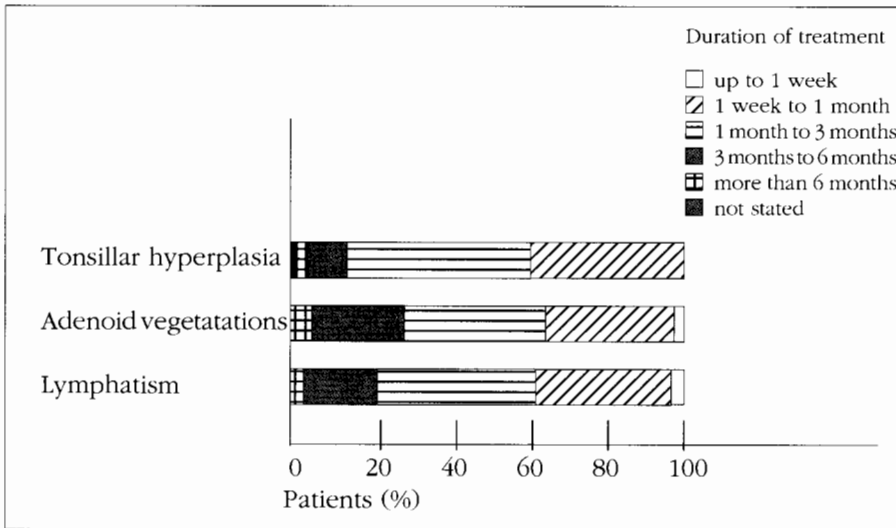


Figure 27: Duration of treatment with Lymphomyosot in patients with hyperplasia of lymphatic organs (n = 323).

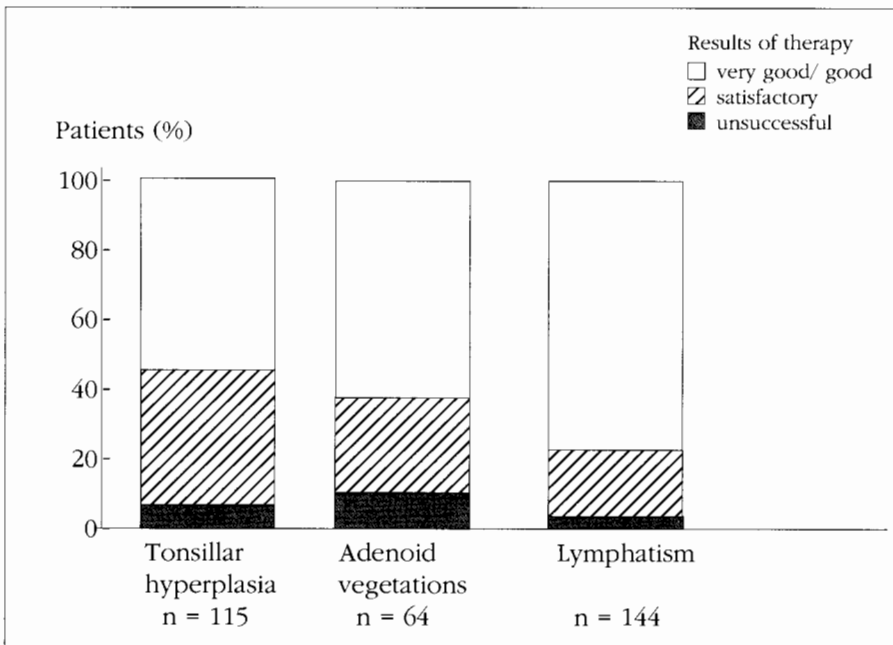


Figure 28: Results of therapy with Lymphomyosot in hyperplasia of lymphatic organs (n = 323).

in particular the pharyngeal and palatine tonsils. Hyperplasia of these organs is not in itself a disease but merely the morphological sequela of intense immunobiological activity (10). However, the increased size of the organs frequently causes a mechanical obstruction in the respiratory tract or oesophagus with very unfavourable sequelae for the whole body; these also include secondary inflammations of adjacent organs (10). For this reason we decided to show hyperplasias of lymphatic organs separately from the inflammatory processes.

4.1. Patients

There were a total of 320 documented treatment cases for this group of indications. In 115 patients the diagnosis of the investigators was "tonsillar hypertrophy" or "tonsillar hyperplasia". These terms are largely synonymous. Since, however, the expression "tonsillar hyperplasia" corresponds better to the pathological-anatomical basis and is more correct, we decided to use this term in the rest of the report. In 64 patients the diagnosis was "adenoid vegetations" which is

synonymous with hyperplasia of the pharyngeal tonsil. 144 cases diagnosed as „lymphatism“ were also allocated to this group. According to Roche (7) lymphatism is understood to be the tendency to hyperplasia of lymphatic organs.

Overlapping between these groups caused by mixed diagnoses occurred in only 3 cases. It should be taken into account that the expression "tonsillar hyperplasia" is the common generic term for hyperplasia of palatine and pharyngeal tonsils and, therefore, also includes the diagnosis "adenoid vegetations". It is, therefore, quite correct to summarize both diagnoses under the generic term "tonsillar hyperplasia" or "tonsillar hypertrophy" as is the case in Tab. 2. However, for the detailed analysis (Tab. 13, Fig. 27 and 28) we decided to show both diagnoses separately, as reported on the forms.

The average age of the whole patient group with hyperplasias of lymphatic organs was just under 13 years old. 155 patients were male, 165 female. The age and sex distribution was largely the same as that for patients with inflammatory diseases and did, therefore, not need to be shown separately.

4.2. Results

Tab. 13 gives an accurate classification of the 3 patient groups with hyperplasia of lymphatic organs according to the number of cases, average age, average duration of symptoms and therapeutic response rate. Fig. 27 also compares the duration of treatment for these groups. It was evident that duration of therapy was about the same in all 3 patient groups.

Fig. 28 also gives a detailed comparative overview of the results of therapy. It can be seen that even for these chronic changes in lymphatic organs the rates for very good or good responses were over 50% in each group.

In this connection it is remarkable that in over 78% of patients no therapeutic measures in addition to the administration of Lymphomyosot were carried out. Only 62 patients receiv-

ed concomitant medicinal therapy, in 14 additional non-medicinal measures were carried out. Tab. 14 shows a breakdown of concomitant therapy with the number of cases and the therapeutic response rate.

5. Efficacy of Lymphomyosot in various other clinical pictures

Over 91% of the patients monitored were included in the three large diagnosis groups (oedema, inflammatory diseases and hyperplasia) already discussed. The remaining treatment cases were distributed amongst a relatively large number of various other clinical pictures of which the most common will be detailed here and the response to therapy briefly illustrated.

| | Non-medical measures | No | Yes | Total |
|----------------------------------|----------------------|-------|-------|-------|
| Medical measures | | | | |
| None | | | | |
| Number of patients | | 250 | 8 | 258 |
| Those successfully treated | | 91.6% | 75.0% | 91.1% |
| Only homeopathic remedies | | | | |
| Number of patients | | 30 | 1 | 31 |
| Those successfully treated | | 100% | 100% | 100% |
| Other drugs | | | | |
| Number of patients | | 26 | 5 | 31 |
| Those successfully treated | | 96.1% | 100% | 96.7% |
| Total | | | | |
| Number of patients | | 306 | 141 | 320 |
| Those successfully treated | | 92.8% | 85.7% | 92.5% |

Fig. 28: Results of therapy with Lymphomyosot in hyperplasia of lymphatic organs (n=623).

| Diagnosis | Therapy result | Very good/good | Satisfactory | No response | Deteriorated | Total number of patients |
|-------------------------|----------------|----------------|--------------|-------------|--------------|--------------------------|
| Swollen lymph nodes | | 53 | 18 | 6 | 2 | 79 |
| Exudative diathesis | | 11 | 10 | 4 | - | 25 |
| Injuries and sequelae | | 32 | 7 | 2 | - | 41 |
| Bronchial asthma | | 16 | 2 | - | - | 18 |
| Cervical spine syndrome | | 12 | 3 | - | - | 15 |
| Hepatopathy | | 8 | 3 | - | - | 11 |
| Goiter | | 10 | - | 1 | - | 11 |
| Migraine | | 6 | 3 | 1 | - | 10 |

Table 15: Results of therapy in various other clinical pictures for which Lymphomyosot was used.

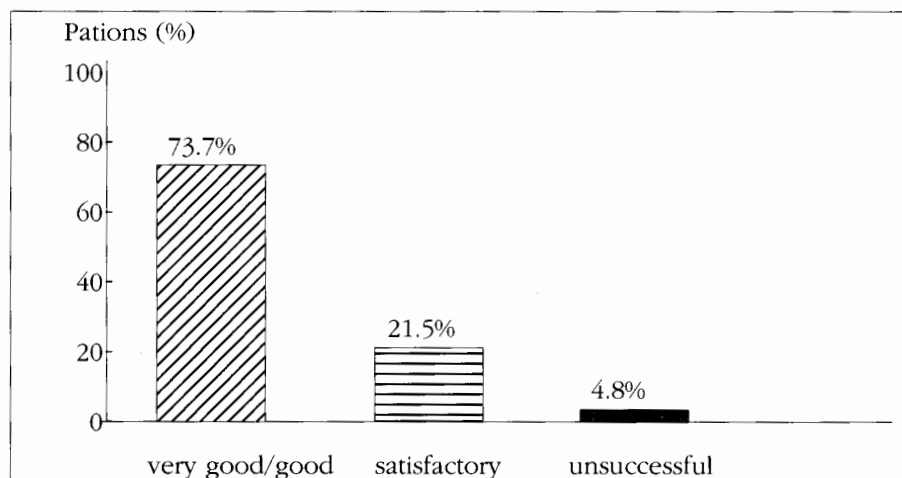


Fig. 29: Results of therapy with Lymphomyosot in lymphoedemas (n=684).

In 79 patients swelling of the lymph nodes, which could not definitely be attributed to lymphadenitis, was the reason for therapy; in the majority of cases swollen lymph nodes of undetermined origin were involved or swelling of the lymph nodes with no further details. The results of therapy in this group of patients are listed in Tab. 15.

In 25 patients the diagnosis was "exudative diathesis". This term which is not in common use today was defined by Roche (7) as "particular disposition to inflammatory reactions of the skin and mucosa" and could, therefore, also be allocated to the complex of "inflammatory diseases". The treatment results for these patients are also given in Tab. 15.

Furthermore, in the breakdown of therapy results we also took into account all the other clinical pictures for which at least 10 treatment cases had been documented (see Tab. 15).

These examples have demonstrated that the principle of dispersal and purification of the mesenchyme which forms the basis of Lymphomyosot therapy, produced a good response in very different diseases.

6. Tolerability of the preparation

Lymphomyosot is very well tolerated. Adverse reactions were reported in only one case after parenteral administration of the ampule solution (785 patients) and in 6 cases after oral administration of the drops (3,016 patients). In the 7 cases cited there was local redness at the site of the injection following subcutaneous administration; one 5-year-old boy complained of a painful neck/sore throat and abdominal pains and a 2-year-old vomited, a reaction which is very common in this age group. One 14-year-old boy reported unpleasant irritation which the doctor in charge did not consider serious. One 3-year-old male suffered from diarrhoea during the observation period. A 67-year-old male patient also complained of nausea. One 5-year-old girl reported restlessness at night.

Related to the number of individual ampule doses administered of at least 8,500 and drops, at least 325,000, the value calculated for the side effect rate after parenteral administration was lower than 0.0118% and after oral administration, lower than 0.00185%. The causal relationship between administration of the drug and the effects described was not proven in any case as not one single case was documented where the same symptoms occurred after withdrawal when rechallenged. In addition none of the effects was reported in more than one patient.

In 3,505 patients (over 99.8%) the preparation was tolerated without any problems over the duration of the treatment period.

7. Discussion

Use observation studies on drugs already on the market are intended to examine the use of these preparations in practice in a very large number of patients. Accurate records are kept of efficacy in individual indications and of tolerability.

The present study demonstrated that the preparation Lymphomyosot had

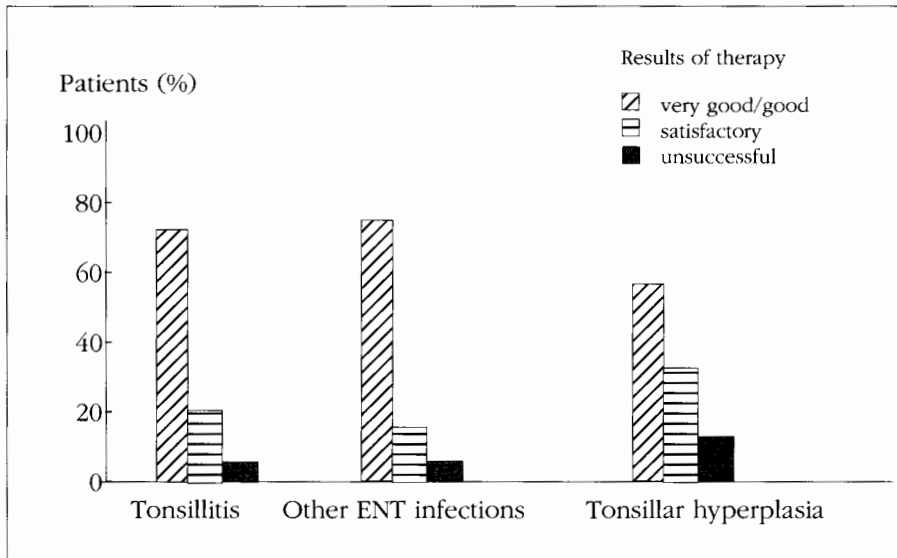


Figure 30: Results of therapy with Lymphomyosot in tonsillitis, other infections of the ENT area and tonsillar hyperplasia (n=1,244).

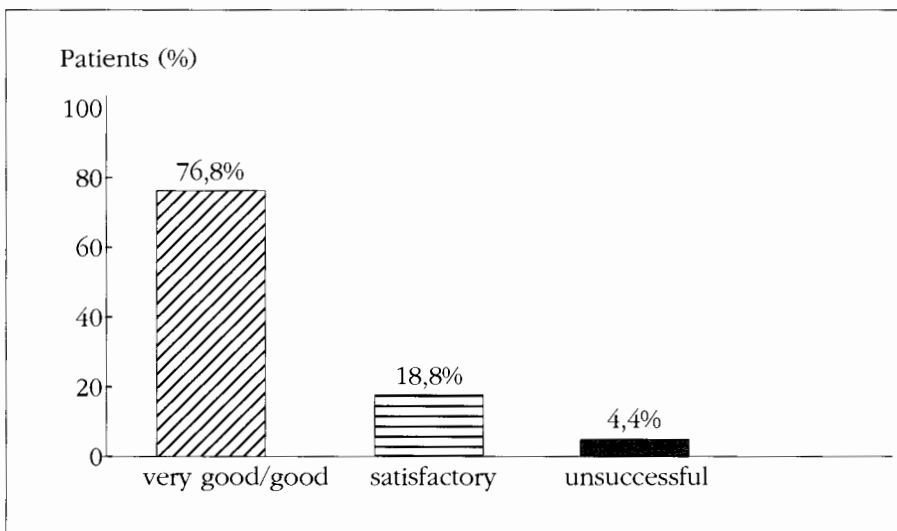


Figure 31: Results of therapy with Lymphomyosot in lowered resistance (general susceptibility to infection; n = 319).

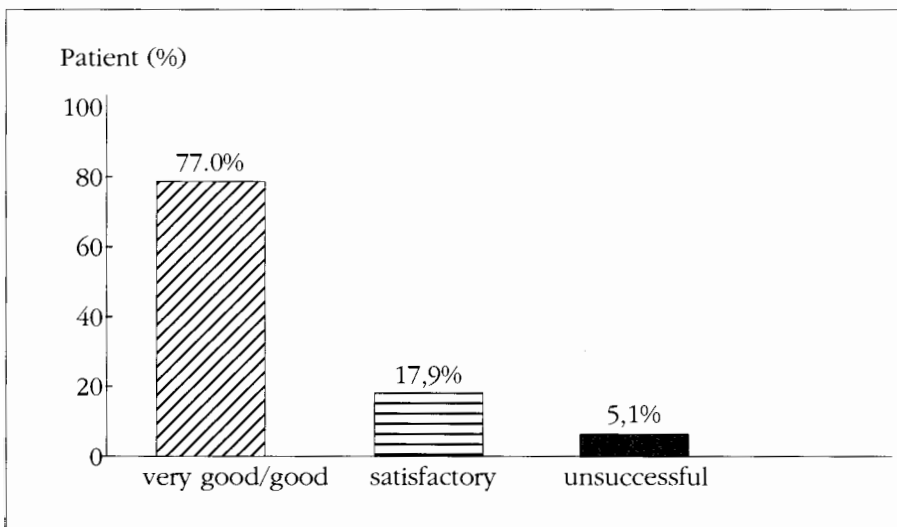


Figure 32: Results of therapy with Lymphomyosot in lymphadenitis (n=391).

some precisely defined applications which correlated well with the indications recommended by the manufacturer. In addition the homeopathic remedy produced a good response in a whole series of other clinical pictures.

There follows an overview of the main indications for the preparation as evidenced during the course of the use observation study:

1. Lymphoedema is the main indication for Lymphomyosot. The efficacy of the product in this indication, which has been known for a long time, was fully confirmed by the treatment results in 684 patients (Fig. 29).

2. The second largest area of use for the preparation is in inflammatory diseases of the upper respiratory tract. Here it should be taken into account that the doctor in practice when treating influenza, colds etc. often does not see tonsillitis or pharyngitis in isolation but that mixed forms made up of several different types of inflammation are the rule. Also, there is frequently overlapping between chronic tonsillitis and tonsillar hyperplasia. The spectrum of activity of Lymphomyosot takes account of this circumstance; as the treatment results in a total of 1,244 showed (of these 594 with tonsillitis, 473 with other inflammatory processes or infections of the ENT-area and 177 with tonsillar hyperplasia including adenoid vegetations), efficacy was good not only in tonsillar conditions but also in infections in other ENT-areas (Fig. 30).

3. The broad spectrum of activity of Lymphomyosot in inflammatory processes means that it is also possible to use this preparation for lowered resistance (general susceptibility to infection). The reliable effectiveness in this indication was documented in 319 cases (Fig. 31).

4. In view of its affinity with the lymph system and its efficacy in inflammatory processes it is also beneficial to use the preparation for inflammatory swelling of the lymph nodes (lymphadenitis). 391 treatment cases were evaluated. Here too the results of therapy were convincing (Fig. 32).

However, to achieve optimal therapy results therapy must be of adequate duration and adapted to the clinical condition concerned. In acute diseases the average duration of treatment in this study was approximately 1-3 weeks, in chronic conditions and recurrent forms 1-3 months. However, sometimes treatment was carried out for over 6 months whereby amazingly good results were achieved even for protracted disease processes. In view of the very good tolerability Lymphomyosot can be used for long periods usually without any particular problem.

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