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# **Aspergillus ruber and the Treatment of Hay Fever with an Isopathic/Homeopathic Preparation of Aspergillus ruber (RUBERKEHL)**

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## Description of the Fungus *Aspergillus ruber*

The Latin name of this fungus reflects what one can see under the microscope and the agar plate: *Aspergillus* = frond, *ruber* = red. The frond-shaped structure, which can be very beautifully seen through the electron microscope (Fig. 1), represents the so-called carriers of conidies, reproductive organs that release spores, and thus serve the asexual proliferation. The rust-red coloring of the fungal colony on seasoned agar occurs only at a certain stage of maturity. Then, special, red fruit bodies (kleistothecies) develop, containing the ascospores; they represent the sexual growth form of the fungus. In older, systematic literature, the diverse growth forms were given different names: *Aspergillus ruber* for the asexual growth form and *Eurotium herbariorum* for the sexual growth form.

In its growing characteristics, *Aspergillus ruber* is osmophilic (it requires more than 20% sugar content in its substrate), and xerophilic, in other words, it already grows in relatively damp air of < 70%. Through this property, it grows well in house dust, so that its spores are an important air allergen.

In agriculture, the fungus is a feared destroyer of seedlings by attacking and decomposing grain, rice, corn, peas, and others during damp summers. In the agricultural population, a syndrome called „Farmer’s lung“ is known, for instance, in England, Scotland, Manitoba and Wyoming among circa 10% of all farmers. The symptoms manifest a few hours after the inhalation of spores from damp hay, and characteristically consist of

coughing, dyspnoe, fever, and flu-type symptoms. Interestingly, antibodies for *Aspergillus ruber* have been proven in cases of „Farmer’s lung.“

## On the Disease Picture of Hay Fever

The disease picture of hay fever can be described as follows:

- The definition is „*Rhinitis allergica*“ = a chronic inflammatory

disease of the nasal mucous membranes, which is transferred by IgE and predominantly the result of aero-allergens; it usually occurs seasonally.

- It shows a distinct morbidity rate in the first 30 years of life, coinciding with allergic asthma.

- It is based on an allergic instant reaction due to contact with aller-



Fig. 1: Carrier of conidies of *Aspergillus ruber* (1500x magnified)

gens via the air, which induce the release of mediators, especially histamine, from the mast cells. The allergic late reaction follows 6-12 hours after contact with the allergen, and it conditions the heightened reactivity of the mucous membrane.

- The diagnosis is based on proof of the allergen by an allergy test, which, however, indicates only that a sensitization has taken place, that is to say, it can be false positive
- In laboratory tests, the specific IgE-antibodies are proven by a prick test, but these are present without allergic symptoms in up to 20% of cases. The *in vitro* proof of the specific IgE-antibodies occurs through the Radio-Allergo-Sorbent Test (RAST). The quantification of the increased reactivity of the nasal mucous membrane occurs through „anterior rhinomanometry“ for determination of the nasal flow resistance.

### **Allopathic Medical Therapy**

Avoidance of exposure to the allergens is recommended (observation of the pollen forecast, removal of damp areas and flower pots from the house). Pharmacological therapy, depending on the severity of the complaints, is practiced symptomatically with antihistamines and decongestant nose drops, with topically effective corticosteroids, up to the temporary intake of Cortisone. An allergenic prophylaxis occurs with DNCG (Dinatriumchronoglycinic acid) or Nedocromil. A specific hyposensitization with allergenic extracts is used only as a last,

individual measure when requested by the patient.

### **Homeopathic Therapy (According to Wiesenauer)**

The basic therapy is aimed at *Formica rufa* D12 and/or with autologous blond from C7 weekly for 4-6 weeks. Additional therapeutic drugs:

- *Galphimia glauca* from D4, also prophylactically with D12 for the Rhino-conjunctivitis
- *Sabadilla* from D6
- *Sinapis nigra* from D3
- *Cardiospermum* D3 for the eye and pose symptoms.

### **Therapy With Aspergillus ruber 5X (RUBERKEHL D5)**

A clinical study was performed with an Isopathic/Homeopathic preparation of the mold fungus *Aspergillus ruber* 5X (RUBERKEHL D5) based on the questions whether this product has an anti-allergenic action and whether symptomatically acting anti-allergenic drugs could be economized. This examination was designed as a non-comparative study by medical practitioners (general MD's/practical doctors). Forty-two patients under four testing doctors in four test centers gave their permission to participate.

### **Testing Substance and Dosage**

*Aspergillus ruber* 5X (RUBERKEHL D5) ampoule, manufactured according to HAB 1, was parenterally applied (single dosage: 1 ampoule per 1 ml each, i.m.). The frequency and time of applications was at each doctor's discretion. The suggested dosage to begin with was 2 to 3x weekly 1 ampoule of the test substance, applied i.m.

### **Criteria of Inclusion and Exclusion**

Patients of both sexes took part, who suffered from hay fever, i.e., the patients had acute, allergic symptoms involving eyes, nose, possibly the lungs, for no longer than the past seven days. If symptoms were so acute that other anti-allergic medication had been taken, the following period must have elapsed before being accepted into the study:

- Twenty-four hours after anti-histamine drugs, chromoglyzat or analogues, including the so-called biological remedies and the local application of steroids;
- One week after intake of systemic steroids;
- Eight weeks after application of depot steroids.

Patients, who had been treated with corticoid and/or other anti-allergenic drugs because of other diseases were excluded. Also, the patients were not allowed to apply locally-

**Course Report  
Aspergillus ruber 5X  
(RUBERKEHL D5) Study  
on Hay Fever**

**Degree of Intensity of Symptoms:**  
0 = no complaints  
1 = mild complaints  
2 = moderate complaints  
3 = serious complaints

**About the following Symptoms:**

- Itching of the eyes
- Reddening of the eyes
- Lagrimation
- Urge to sneeze
- Congested nasal breathing
- Runny nose
- Shortness of breath

Fig. 2

acting hay fever preparations to eyes or nose. As accompanying therapy, synthetic antihistamines with a systemic action were permitted, if needed (no eye or nose drops); their use had to be documented.

### Documentation of results

Once accepted to take part in the study, each participant's details of the initials, birth date, sex, and a brief anamnesis were entered onto a basic form. For the first and final exa-

minations, as well as for each interim examination (at the time of the injections), symptoms, other medications, as well as any side effects were ascertained and then documented on a standardized course report (Fig. 2). The symptomatic reports given by the patients were objectified by inspection and then entered into the report according to their degree of intensity, using a four step measuring scale: none, mild, moderate, serious complaints.

During the first and last examinations, additional laboratory tests were performed (Orpegen GmbH, Heidelberg). The blood sedimentation was determined in the labs of each trial physician. Each patient kept a standardized journal throughout the total period of observation, making ongoing entries about how they felt, about the weather and about any possibly needed additional medications.

The trial physician was urged to exactly document any undesirable effects on the report form. Side effects that occurred, or accompanying illnesses, were to be treated by established methods.

### Results of the Study

Forty-two patients were admitted to the study, of whom two prematurely broke from the test. There had been no side effects for these two patients; their entries were not taken into account.

The number of patients for evaluation comprised 26 women and 14 men of an average age of 36.6 years. The actual illness had begun 10.9 years ago on the average. Only 14 patients had an allergy test done

**Aspergillus ruber 5X (RUBERKEHL D5) - Hay Fever / Symptoms Beginning - End**

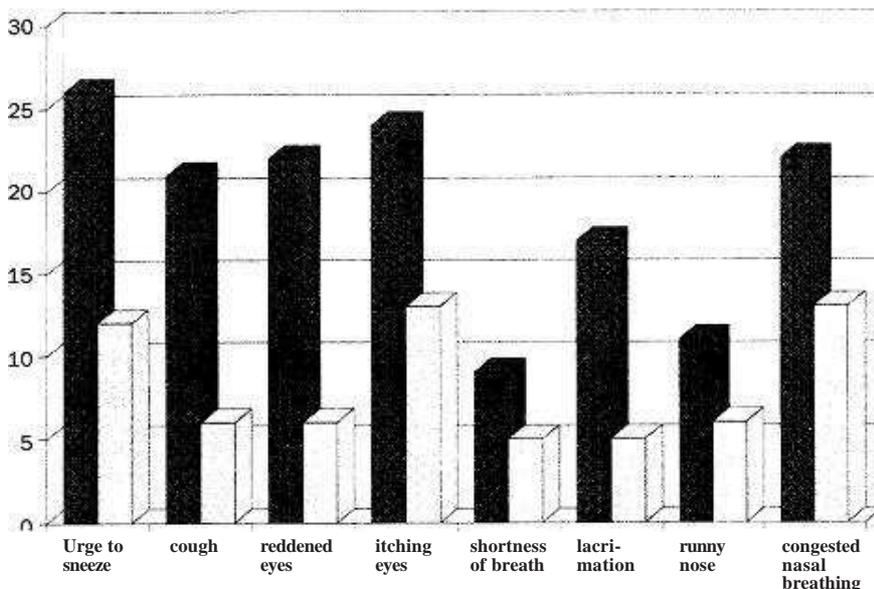


Fig. 3

**Aspergillus ruber 5X (RUBERKEHL D5) - Hay Fever / Significant Symptoms**

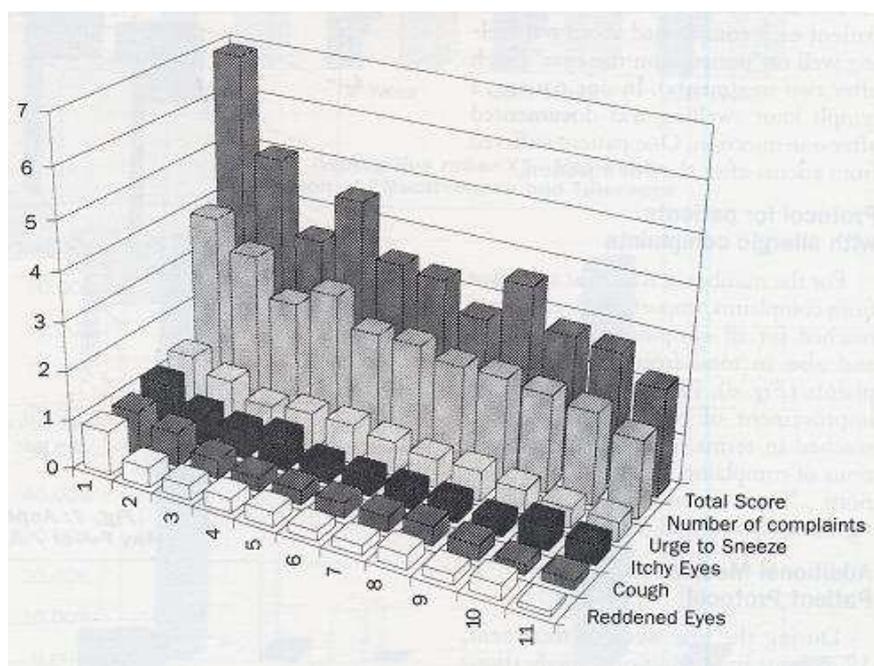


Fig. 4

**Aspergillus ruber 5X (RUBERKEHL D5) -  
Hay Fever / Patient Symptoms at First and Final Examination**

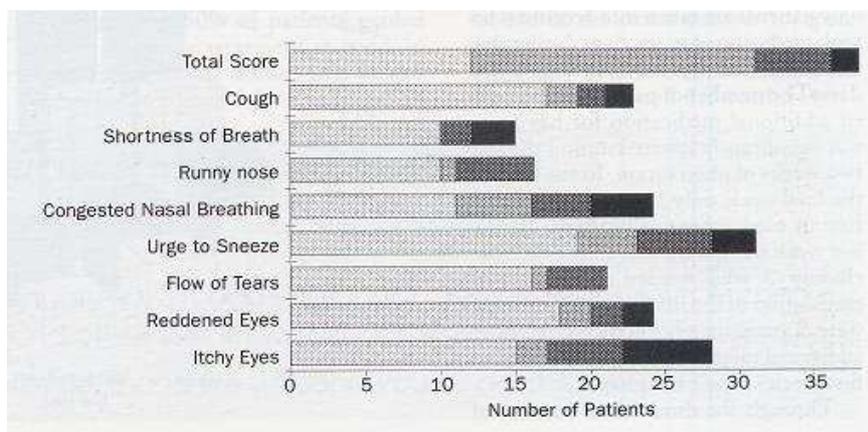


Fig. 5

**Aspergillus ruber 5X (RUBERKEHL D5) -  
Hay Fever / Number of Days per Week Without Complaints  
(Patient protocol)**

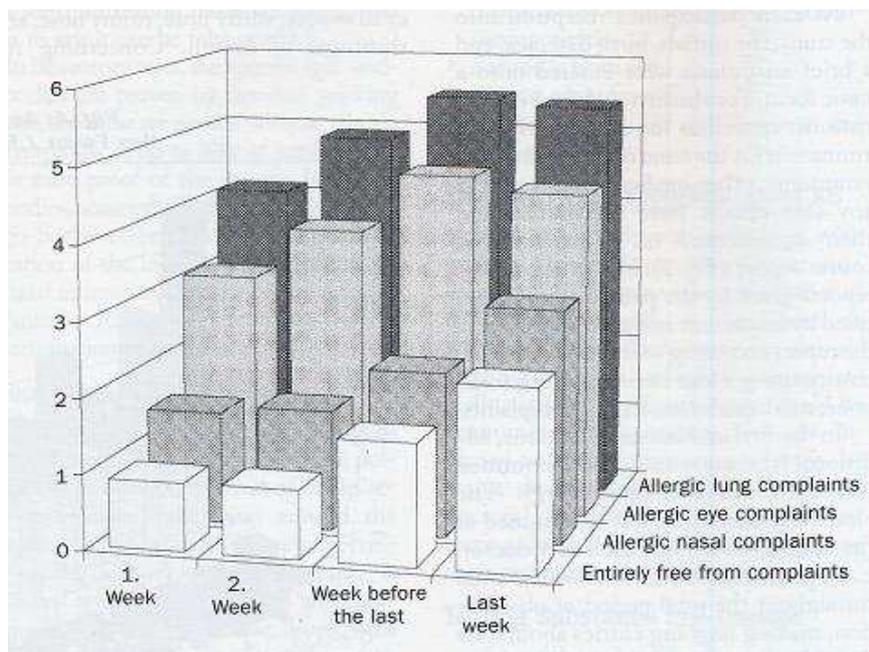


Fig. 6

previously. Five patients were under continuous medications for other illnesses; two patients used oral contraceptives during the testing period.

Thirty-eight patients had each received ten injections, two patients received only nine. The interval

between the single applications was, on the average, 2.8 days. The length of the treatment between the first and the last injection was, on the average, 26.4 days.

**Detailed Statements of the Study**

Comparing the values of the first

examination with those toward the end of the treatment or the final examination between all individuals, all symptoms show a significant improvement (Fig. 3). The number of patients suffering from any particular symptom was cut in half for such symptoms as itchy eyes, tendency to sneeze, stuffy nose, runny nose, and shortness of breath. Concerning red eyes, flow of tears and cough, the number of affected patients became even further reduced.

12 patients were fully free from complaints at their final examination. The number of complaints was reduced during the treatment from 3.9 to 1.6 and the total score from 6.9 to 2.2 on the average (Fig. 4). Out of 38 patients, 12 had no complaints at all on the day of the final examination, 19 scored an improvement, 2 showed no change and in 5 patients, the allergic complaints had become worse (Fig. 5).

Considering single symptoms - with the exception of the symptom „stuffy nose“ (46%) - more than 50% of the patients suffering from particular symptoms were healed, that is, the symptoms were absent on the day of the final examination. On the average, in two thirds of the cases the complaints disappeared, in an additional 10%, there was a gradual improvement of complaints. The best results were achieved for the symptoms of red eyes, tears and cough (healing to about 75%, improvement in more than 80% of cases). The poorest results were for itchy eyes (but still a 54% healing quote and 7% gradual improvement) and for stuffy nose (healing in 46%, gradual improvement in 21%).

Side effects were registered six times in two patients, skin reactions were recorded at each of the examinations. One patient each complained about not feeling well or „pressure on the eyes“ (each after two treatments). In one patient, a lymph knot swelling was documented after one injection. One patient suffered from edema after the 9th injection.

### Protocol for patients with allergic complaints

For the number of complaint-free days, important levels were reached for all symptomatic complexes as well as complete complaint freedom (Fig. 6). Likewise, a significant improvement of complaints was achieved in terms of the added evaluations of complaints in all recorded locations. The total score was significantly reduced (Fig. 7).

### Additional Medication/ Patient Protocol

During the first week of treatment, 19 patients used additional medications for the treatment of their hay fever (Fig. 8). The number of days, when additional medications were needed, was on average 2.3 days during the first week. If only patients are taken into account, who took medications at any time during this week, then the arithmetic average is 4.8 days. The number of patients who needed additional medication for hay fever was significantly lowered during the last two weeks of observation. In the next to the final week, only 11 patients reported that they used other medications. In the last week, there were still 13 persons, including 3 who needed no additional medication in the first week. Thus, there were 9 patients

who managed without additional medication, in contrast to the first week of their treatment.

Due to the diminished number of patients who took additional medications, the average number of days for additional medications was

**Aspergillus ruber 5X (RUBERKEHL D5) - Hay Fever / Allergic complaints**

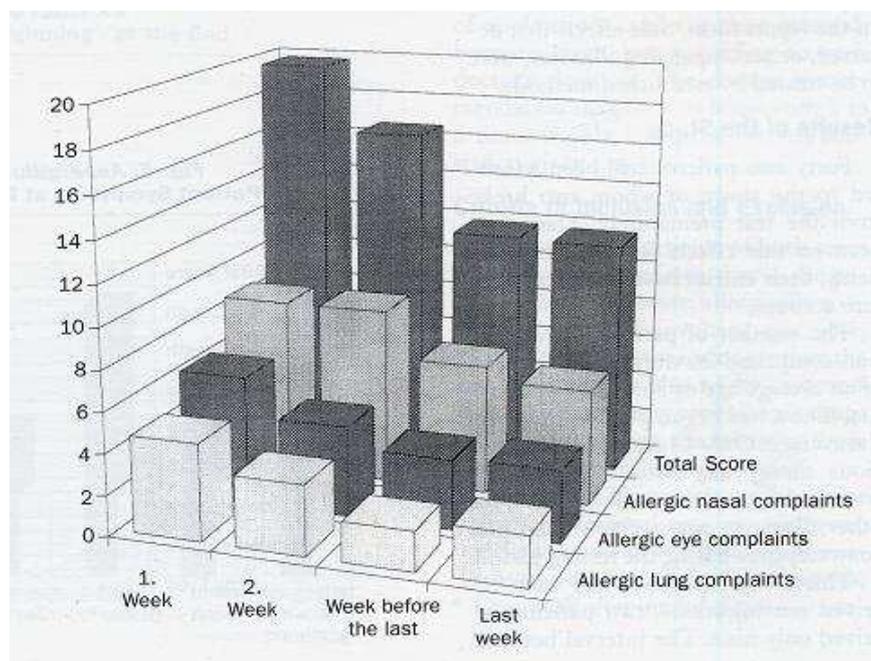


Fig. 7

**Aspergillus ruber 5X (RUBERKEHL D5) - Hay Fever / Supportive Medication (Patient Protocol)**

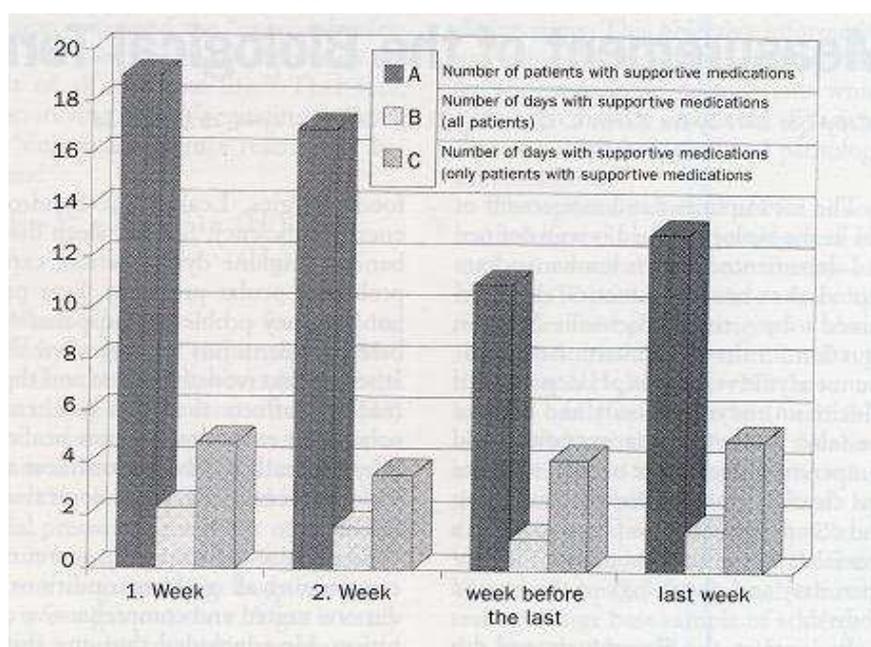


Fig. 8

somewhat, but not significantly, reduced. When only persons who consumed medications are considered, the value remains unchanged. This means that medications are economized by some patients not needing any all week, but not by „skipping“ an occasional day of medication.

### Evaluation of Effectiveness and Tolerance

The subjective evaluations of effectiveness by the patients or the doctor are in very good agreement (Fig. 9). In over 50% of the cases, the effect was rated very good both by the doctor and the patients; only six patients, or five times by a treating doctor, the treatment success was evaluated as poor. The tolerance factor was rated as moderate by only one patient, in agreement with his doctor. In all other cases, both the patient and the treating doctor

graded the tolerance as good. The subjective evaluation given by both patients and their doctors was independent of sex, age of the patient, duration of the illness, and from the treating doctor. This statement also applies for the course data and the entries into the patient protocol. The subjective evaluation correlates very well with the changing of symptoms in the course report, and respectively, with the entries concerning allergic complaints in the patient journal.

### Summarization

Significant improvement occurred for all symptoms in comparison of the first and the final examinations. The number of patients, who suffered from itchy eyes, urge to sneeze, stuffy nose, runny nose, or shortness of breath was cut in half, while the number of patients with red eyes, lacrimation, or cough

became even more reduced. Of the 38 patients who showed symptoms of hay fever on the day of their initial examination, 12 had no complaints at all at their final examination; at least a gradual improvement took place in 19 persons; 2 showed no improvement and for 5, a worsening of their allergic complaints was documented.

The individual comparison of the data concerning allergic complaints in the patient diary between the first and last week of the study also shows the success of the treatment: Both the number of days per week, experienced with discomfort, and the degree of complaints decreased. The number of patients, who took necessary additional medication, also decreased significantly.

More than 50% of patients graded the effect of the treatment as good, in agreement with the doctors who treated them; only 6% graded them as poor. The success of the treatment was independent from the sex and age of the patients, the duration of the illness, the doctor in charge, and the weather.

**Aspergillus ruber 5X (RUBERKEHL D5) - Hay Fever / Evaluation of Effectiveness and Tolerance**

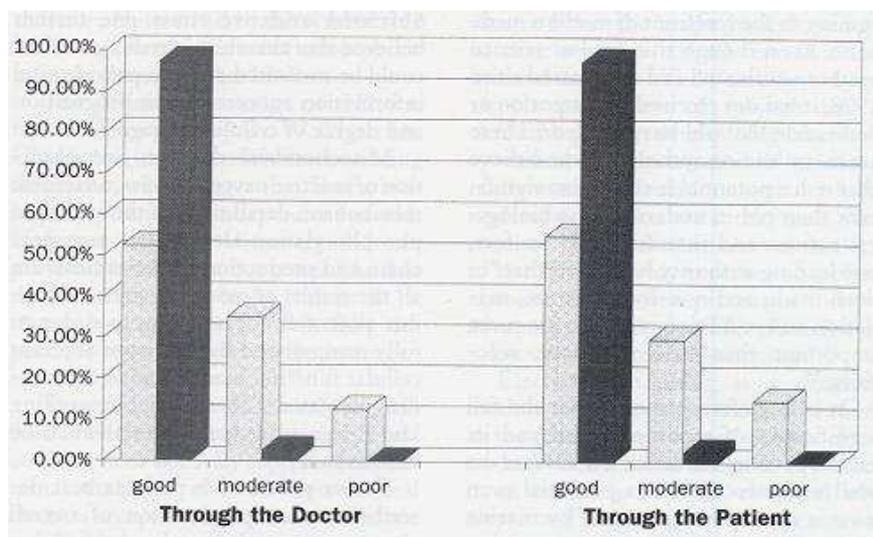


Fig. 9

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