Are there evidence-based studies on the efficacy of the bioresonance method?

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Health insurance companies, public bodies and courts have adopted the view that only randomised double-blind studies are scientific proof of the efficacy of a medical procedure. The supposed 'placebo effect' is also used as a way of discrediting as ineffective in principle any methods which do not involve conventional medicine. This is a step too far for one of the most prominent lawyers in the pharmacology industry. He writes in the German medical journal *Ärzteblatt*:

> *"A doctor's opinion is no longer worth anything ... The authorities are increasingly turning to policy recommendations ... Medicine has been reduced to natural science ... The randomised double-blind study is being used in an increasingly restrictive manner."*

The focus on randomised double-blind studies is an inappropriate attempt to apply the laws of inanimate nature to biological systems. Major pharmacological scandals go to prove the dubious reliability of randomised double-blind studies. Such experiments by their very nature necessitate an extreme reductionist approach which completely ignores the idiosyncrasies of biological systems.

From an ethical point of view it is also a very questionable way of proceeding.

Yet our aim here is not to condemn randomised double-blind studies in general. Rather, the process of only accepting this method as scientific evidence is a very arbitrary and restrictive way of establishing proof which goes against scientific principles.

From the 260th edition of Pschyrembel onwards the term 'evidence' was included and explained in detail. The term "evidence" (of a scientific nature) is at present predominantly used in the English-speaking world. In the literature evidence is graduated in a number of ways.

We commissioned Dr. Volker W. Rahlfs, C. Stat. (RSS), Head of the Institute for Data Analysis & Study Planning, founded in 1966, to carry out an expert analysis of the studies available on BICOM bioresonance therapy. Dr. Rahlfs has 40 years' experience as a biometrician/biostatistician in the area of clinical research and has given expert advice and opinion to 140 pharmaceutical companies and university institutes and led more than 400 scientific studies in Germany and overseas.
He has written more than 60 specialist publications. He is holder of the "Biometry in Medicine" certificate, is a certified statistician at the Royal Statistical Society, UK (1993), member of the *Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie (GMDS)* [German Medical Informatics, Biometry and Epidemiology Society], the International Biometric Industry Association (IBIA), the American Statistical Society (ASA), the Royal Statistical Society (RSS), the New York Academy of Sciences, the International Society for Clinical Biostatistics (ISCB), the Society for Clinical Trials (SCT), the Drug Information Association (DIA), the *Gesellschaft klinische für Pharmakologie und Therapie e.V. (GKPharm)* [German Clinical Pharmacology and Therapy Society], the *Fachgesellschaft der Ärzte in der pharmazeutischen Industrie* [German Society of Physicians in Pharmaceutical Industry], the International Association for Statistical Computing (IASC) and other professional societies and working groups.
In his report he initially defined eight levels[1] for the classification of studies in accordance with the guidelines for cardiopulmonary resuscitation (CPR). According to Dr. Rahlfs, levels 1 and 2 are

[1] Levels of evidence used in scientific reports

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of greatest significance. They are customary in major mortality and morbidity studies but are not required in all cases. For patient case series a level 4 or 5 is sufficient in terms of evidence.

The assessors were given the studies on the application of BICOM bioresonance therapy to appraise. In the following I would like to give you a detailed illustration of the studies with their results and classification within the 8-level scheme of evidence (i. e. evidence of a scientific nature).

The levels of evidence used in scientific reports

Classification of the levels of evidence according to the American Heart Association (AHA).
Modified according to W. F. Dick: Evidence based emergency medicine; (abridged).

Level 1: Statistically significant, randomised, controlled trials (double-blind studies) or meta-analyses
Level 2: Statistically insignificant, randomised, controlled trials (double-blind studies) or meta-analyses
Level 3: Prospective, controlled, but not randomised cohort studies
Level 4: Historic, nonrandomised cohort or case-control studies
Level 5: Human case series
Level 6: Animal or mechanical model studies
Level 7: Reasonable extrapolations from existing data
Level 8: Rationale conjecture

ASSESSMENT SUMMARY

The assessor makes the following concluding remarks about the studies:

> "All previous studies and research work indicate that the BICOM procedure does not only show statistically significant (and in the sense of random statistics, demonstrable) effects. These are to be interpreted in a clinical context as demonstrating efficacy. Undesirable side effects, particularly those that are serious, are not found in any study.
>
> The work discussed and assessed here corresponds in principle to the quality standard of university research. Evidence level 1 with controlled double-blind studies is not the norm in that area. This quality standard is currently only required in the area of pharmacological research. The documents presented correspond to the requirements of the clinical assessment of medical products. (cf: R. Prestel, *Anforderungen an die klinische Bewertung von „bekannten" Medizinprodukten aus der Sicht einer benannten Stelle* [Clinical assessment requirements of "known" medical products from the point of view of a Notified Body], Medizintechnik 121 (2001) 9-13.)"

The assessor goes on to sum up his assessment as follows:

> "It is standard practice worldwide to publish your own results, even those with a low level of evidence and, as demonstrated in the present report, to derive the level of evidence from the reproducibility. In practical terms this means that even studies with a lower level of evidence are considered as providing proof if other researchers – who are also carrying out studies with a lower level of evidence – come to the same conclusions.
>
> This generally recognised technique of external validation can be seen in the studies appraised here, carried out by Huang S. et al. (2005), Yang J. Zhang (2004) and Zhang X. et al. (2005) in which the named authors each compare their findings with the results of other authors in their publications."

Summary: The studies carried out using the BICOM method were appraised by experts Dr. Volker W. Rahlfs, C. Stat. (RSS) and Dr. med. Andreas Rozehnal from the **idv** Institute for Data Analysis & Study Planning as follows.

4	studies were awarded a level of evidence	1
1	study was awarded a level of evidence	1-2
1	study was awarded a level of evidence	2
1	studies were awarded a level of evidence	3
4	studies were awarded a level of evidence	4-5
4	studies were awarded a level of evidence	5

All clinical studies were carried out without our knowledge, i. e. the studies were not commissioned, which further increases the evidentiary power of the studies presented.

Is it now possible to claim that the efficacy of BICOM bioresonance therapy is scientifically proven? Clearly YES. Anyone suggesting otherwise is ignoring these studies and the levels of evidence they provide.

BRIEF PRESENTATION OF THE STUDIES, THEIR RESULTS AND ASSESSMENTS

Study 1:

Single group cohort study[2] with 204 cases of allergy patients with different strains.

Author: Schumacher, P.

The results of this study should be well known within our circles. Nevertheless I would like to reproduce the results in a pie chart.

The biometric/medical assessment: "For this indication spontaneous healing is extremely rare. There is no known evidence of healing using therapeutic measures. Therefore an 83 % recovery rate is an extremely convincing statistic (15 % recovery rate would be deemed of clinical significance). **Level of evidence: 4/5".**

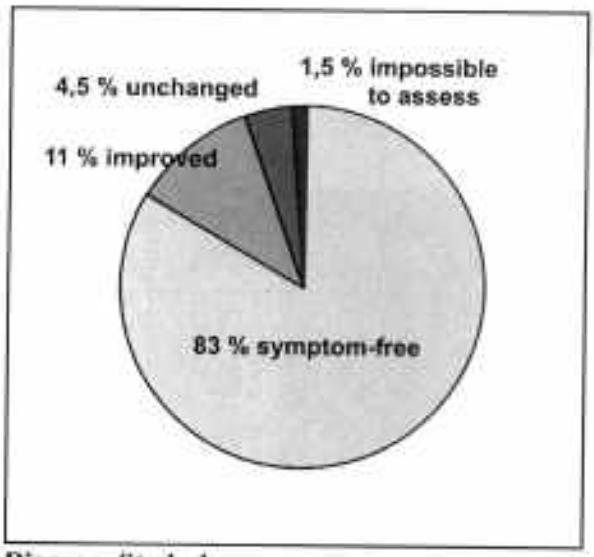

Diagram Study 1

Study 2:

Prospective, controlled but not randomised study with 2 groups: 213 patients treated with BICOM, 87 patients with corticoids and anti-allergy medication. Study of patients with asthma.

Study carried out by: Yang Jinzh and Zhang Li, Research Centre of the Jian Paediatric Clinic for the Prevention and Treatment of Asthma.

The results of the treatment were classified after 6 months as:

1. Visible effect (symptom-free)
2. Improvement
3. Effectiveness (slight reduction)
4. Ineffectiveness

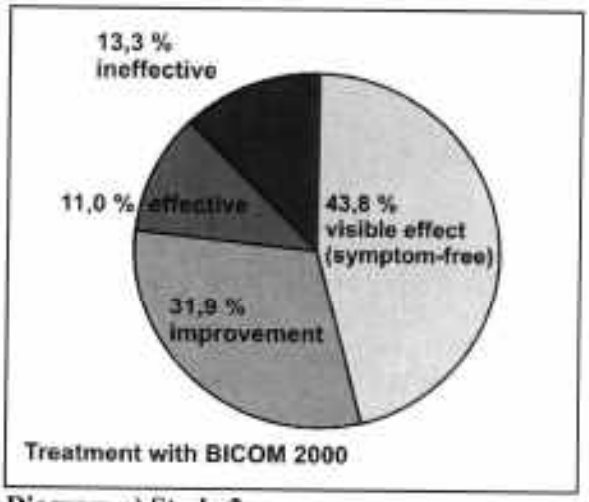

Diagram a) Study 2

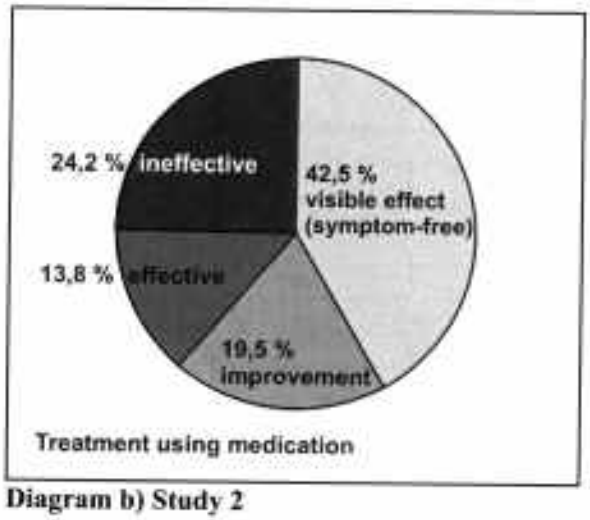

Diagram b) Study 2

Assessment: "Conventional treatment with medication is, at least in treating symptoms, extremely

[2] Study of a group of patients (not randomised)

effective. It is therefore astonishing that BICOM treatment achieves the same if not a better level of efficacy. The study design has a high **level of evidence 3**, which means that the results must be considered as proof of efficacy."

Study 3:

Single group cohort study with serial observation of 154 allergy patients from June 2002 to January 2004. Dermatitis, rhinitis, allergic conjunctivitis and asthma were treated. Immediately before and during treatment no anti-allergy medication was taken.

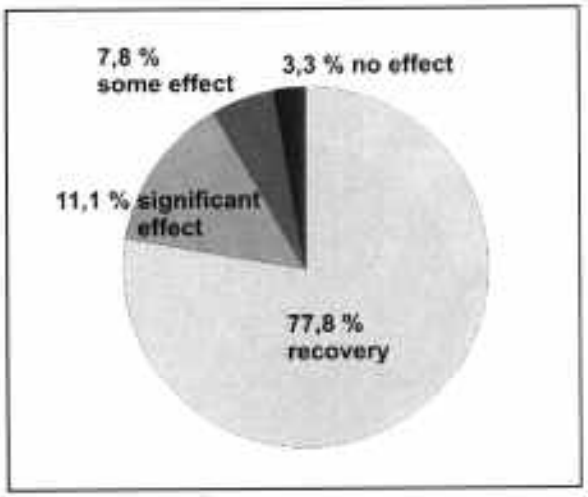

Diagram Study 3

Study carried out by: Yuan Ze, Huang Jiali, Wang Haiyan and Yu Chunyan, Xian Department of Paediatrics, Central Hospital, Xi'an.

Following treatment 120 out of 154 patients (= 78 %) recovered fully (symptom-free for 6 months). No undesirable effects were reported.

Extract from the assessment: **Level of evidence 4/5.** This is based on diagnoses which, if using conventional medical treatment, in practical terms may only be controlled to a certain extent with long-term medication (e. g. corticoids) which has a number of side effects.

The results were looked at and analysed 6 months after patients received treatment.

Study 4:

Cohort study with serial observation of 1639 patients with different allergy diagnoses. These are patients who had all been unsuccessfully treated in the past with standard medication.

The study was carried out in the Paediatrics Dept. of the Central Hospital in Xi'an, China.

Autoren: Ze Y. und Haiyan W.

Extract from the assessment: The patients had been treated in the past with various medications with little success. No recurrence of symptoms 6 months after BICOM therapy meant, for this period at least, that patients were cured. Spontaneous healing, placebo effects and similar cannot explain the percentage of patients who made a recovery in this allergy area. **Level of evidence 4-5.**

Results of Study 4

Disorder	Total number of cases	Recovery	Clearly effective	Effective	Ineffective	Recovery rate	Overall effectiveness
Eczema	188	176	8	2	2	94 %	97 %
Urticaria	352	266	42	30	15	75 %	87 %
Contact dermatitis	158	137	12	6	3	87 %	94 %
Neurodermatitis	55	30	8	10	7	55 %	70 %
Perspiration	183	160	10	12	1	87 %	93 %
Allergic rhinitis	165	140	14	5	6	85 %	94 %
Asthma	187	155	5	24	3	83 %	86 %
Spast. muscle twitching	146	120	20	2	4	82 %	96 %
Allergic conjunctivitis	80	66	10	2	2	83 %	95 %
Neurodermatitis	125	103	16	2	3	82 %	95 %
Overall	1639	1353	145	95	46	83 %	91 %
In %	100 %	82.6 %	8.8 %	5.8 %	2.8 %	–	–

Study 5:

Single group cohort study of 200 patients from a total of 248 questionnaires sent out. Patients with a longer case history (as well as various treatments prior to this): allergically related skin disorders (neurodermatitis, eczema, pruritus), allergic conjunctivitis, allergic intestinal disorders, allergic respiratory disorders, pollen allergies.

Author: Hennecke, J.

Treatments were carried out without allergen abstinence.

Extract from the assessment: Despite possible distortion of the result it can be assumed that a substantial number of patients were symptom-free (80.6 % return rate from the postal questionnaire). The number of symptom-free or improved patients can certainly not be explained by placebo effects or misdiagnosis. **Level of evidence 4/5.**

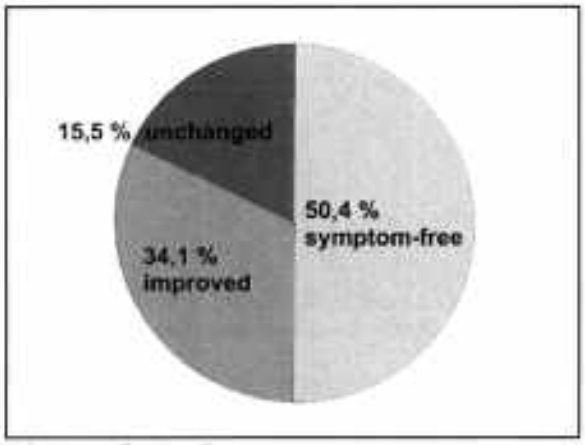

Diagram Study 5

Study 6:

Prospective randomised parallel 2-group study with 2 x 14 patients with liver cell damage.

The 2 groups were made up of patients with liver cell damage who had been diagnosed at least one year before. The enzyme values in the control group were almost unchanged around the median value and also remained largely pathological in individual patients (see the diagrams on following page).

In the group treated with BICOM a considerable improvement can be seen in the median. The individual values are normalised in most of the patients. The differences between the groups are both substantially and statistically significant.

Authors: Machowinski, R. und Gerlach, I.

Assessment: The study does not only show significant differences from the control group but the effects are also quite considerable and of medical significance. The design of the study, awarded a **level of evidence 1**, suggests a statistically sound and quite considerable level of efficacy for this indication.

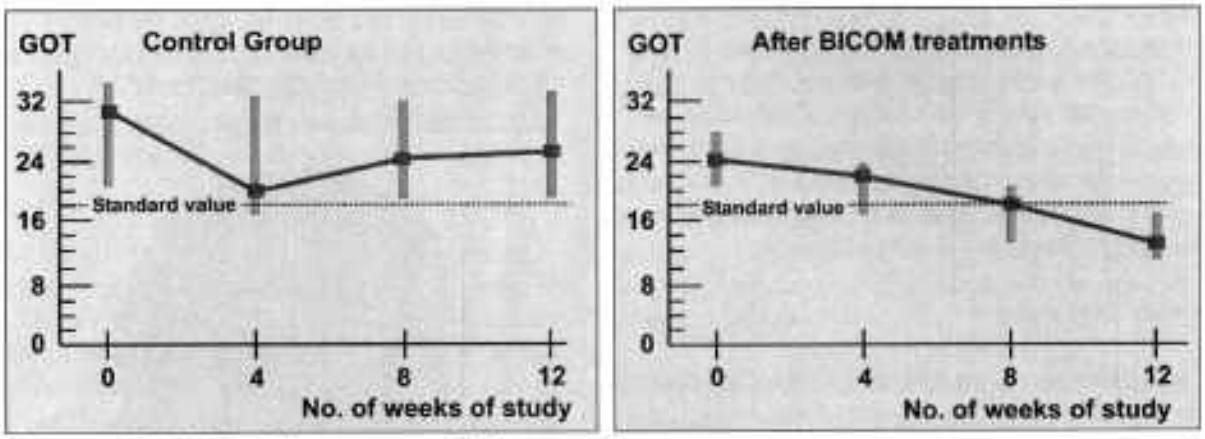

Diagram a) Study 6 – Liver enzyme GOT

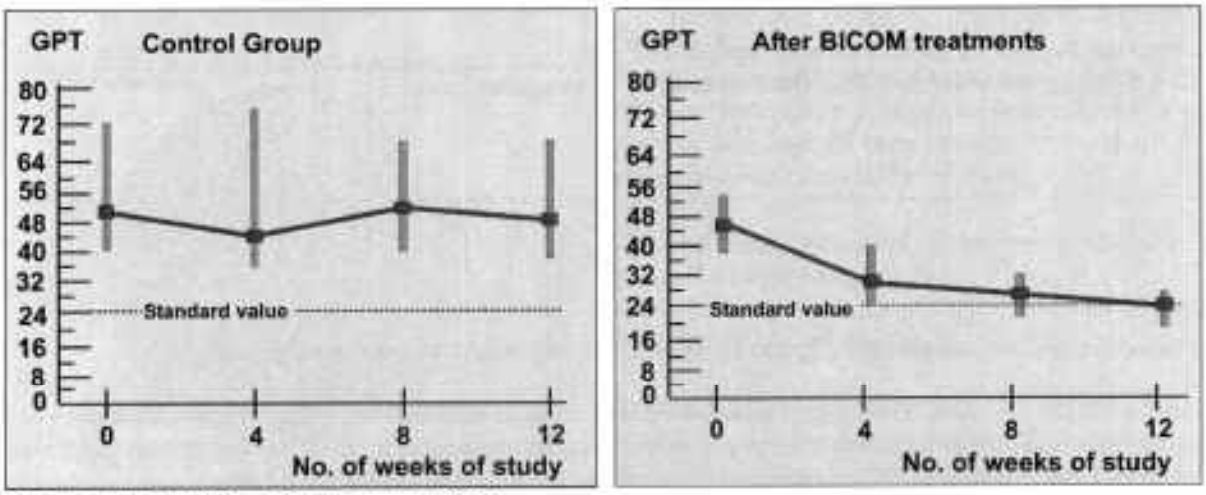

Diagram b) Study 6 – Liver enzyme GPT

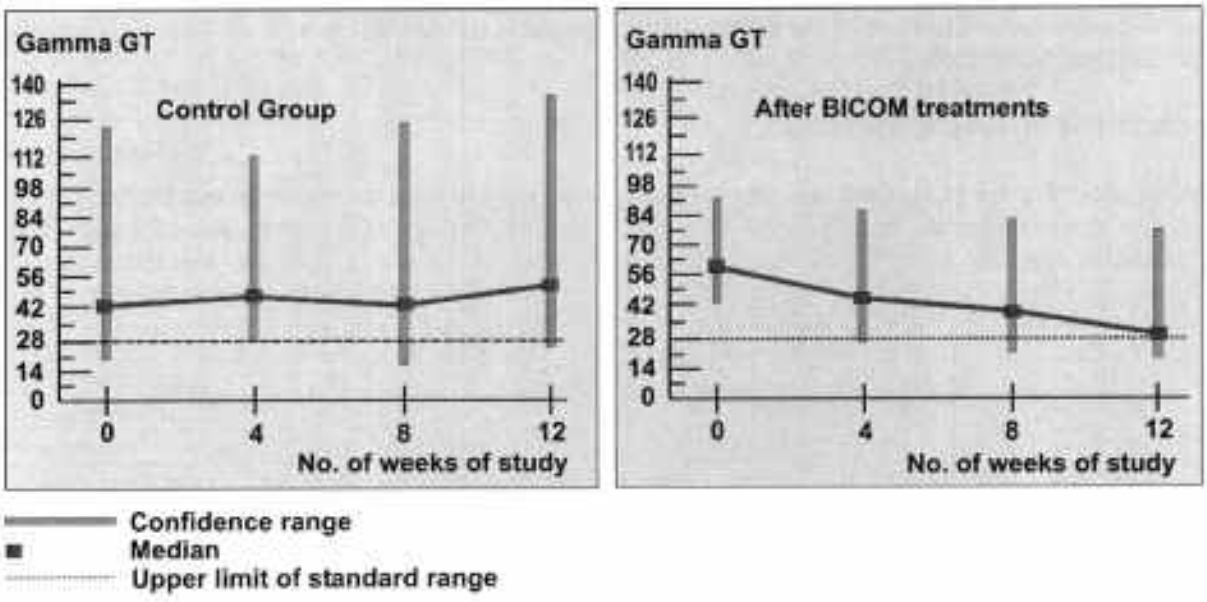

Diagram c) Study 6 – Liver enzyme Gamma GT

Study 7:

Two groups of athletes, not randomised, 12 patients in each group, suffering from overstrain syndromes associated with high performance athletes.

Study carried out by: Papez, B. J. and Barovic, Maribor Teaching Hospital, Slovenia, Dept. of Medical Rehabilitation.

The control group was treated with ultrasound as well as cryotherapy and electro-stimulation treatment. The test group only received BICOM bioresonance therapy.

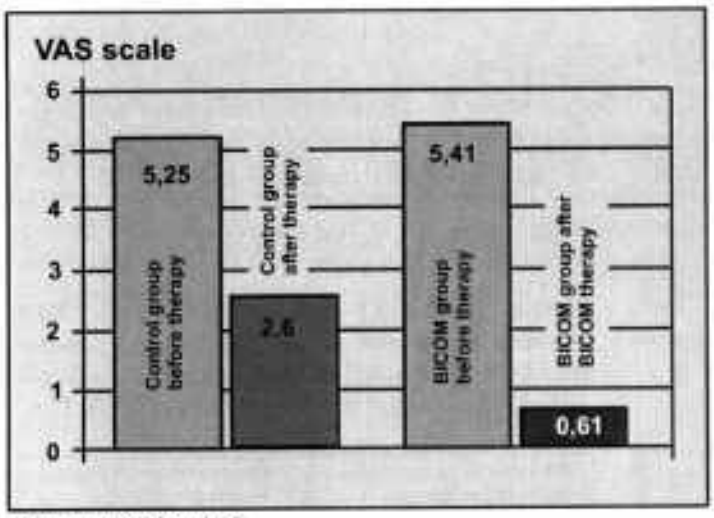

Diagram a) Study 7

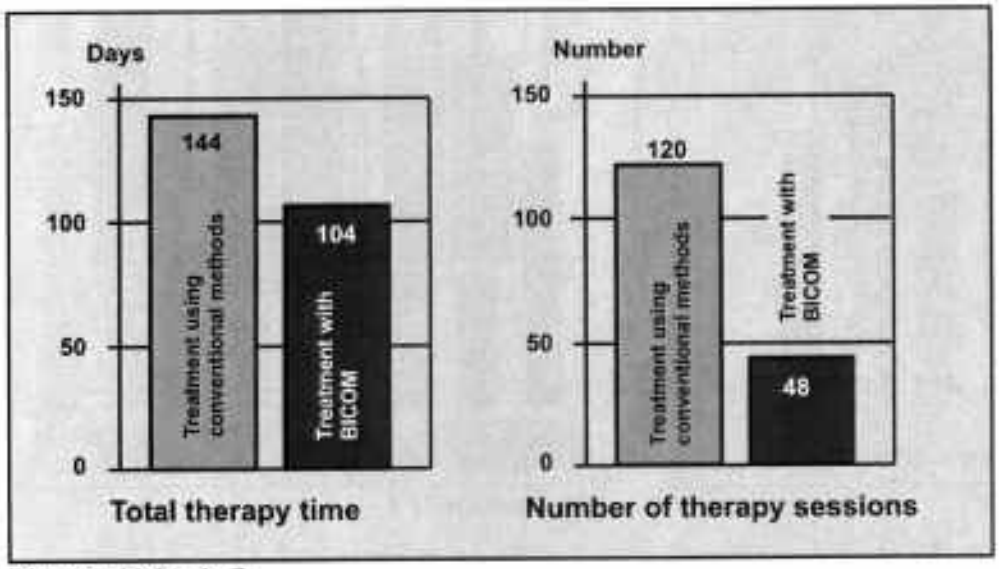

Diagram b) Study 7

Assessment: "Based on the 8-point **level of evidence** scale, the study is awarded **level 2** in terms of design i. e. providing strong evidence. In this sense the efficacy is shown to be statistically significant. The extent of the efficacy is also considerable both in terms of length of therapy and pain score."

Study 8:

Controlled pre-clinical in-vitro study. Summary illustration of in-vitro modulation of the phagocyte activity of human polymorph nuclear leucocytes through BICOM resonance therapy. A total of 50,000 blood samples were treated and checked using various program parameters.

The study was carried out by O. Osadchaya et al. at the Kavetzky Institute for Experimental Pathology, Oncology and Radiobiology at the Ukraine State Academy of Sciences. **Level of evidence 1.**

The phagocytic activity of human phagocytes in donor blood was statistically significantly altered through BICOM treatment. In-vitro study – controlled study.

The study shows clearly different and reproducible results using various program parameters. The phagocytic activity of human phagocytes in donor blood was altered through BICOM treatment to a statistically significant extent.

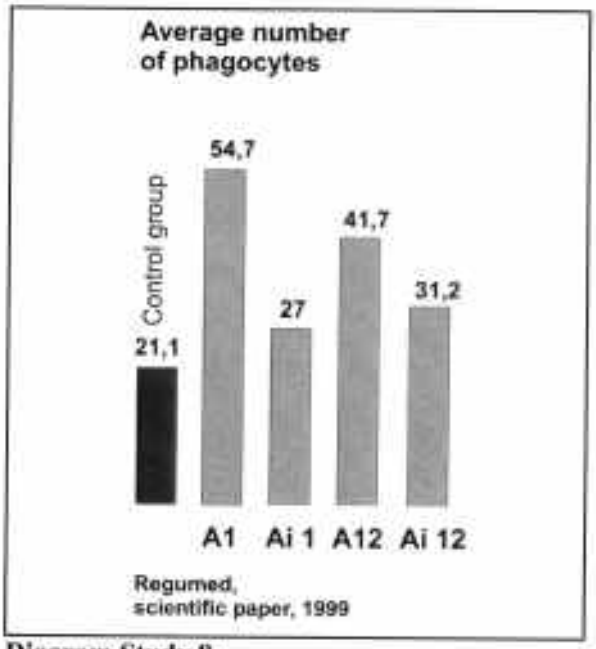

Diagram Study 8

The first bar shows the number of phagocytes in the donor blood. The blood was placed in 10 test tubes in the input cup and 10 ampoules with the same donor blood were also placed in the output cup. "Treatment" was carried out using different therapy programs. A and Ai denote the type of therapy and the additional figures show the amplifications. The next four bars show the number of activated phagocytes following each BICOM therapy session.

Study 9:

Controlled pre-clinical in-vitro study: investigation into the reproduction of the immune system of radioactively contaminated mice.

Carried out by D. Sakharov et al.

Through BICOM treatment it was possible to return the immune systems of mice weakened by radioactivity in Chernobyl to a statistically significant and relevant normal level. **Level of evidence 1.**

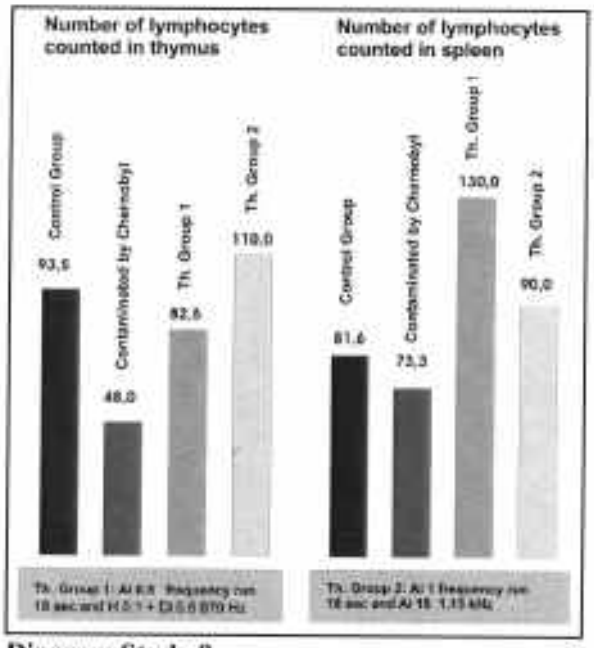

Diagram Study 9

Study 10:

Comparative diagnostic study:
BICOM bioresonance therapy versus prick test.

31 subjects were each tested with a prick test and BICOM test for mites, grasses, olive, wall pellitory.

The study was carried out by Giannazo E., Valenti S., Puzzo D. from the Physiology Dept, Chair of Biophysics at the University of Catania. 31 double readings were taken on 4 occasions.

The biometric assessment: The BICOM device is certainly suitable as an objective procedure for carrying out allergy testing. It would be desirable to carry out further investigations in which the accuracy of both the prick tests and the BICOM tests could be determined using a "gold" standard and discussed accordingly. **Level of evidence 1.**

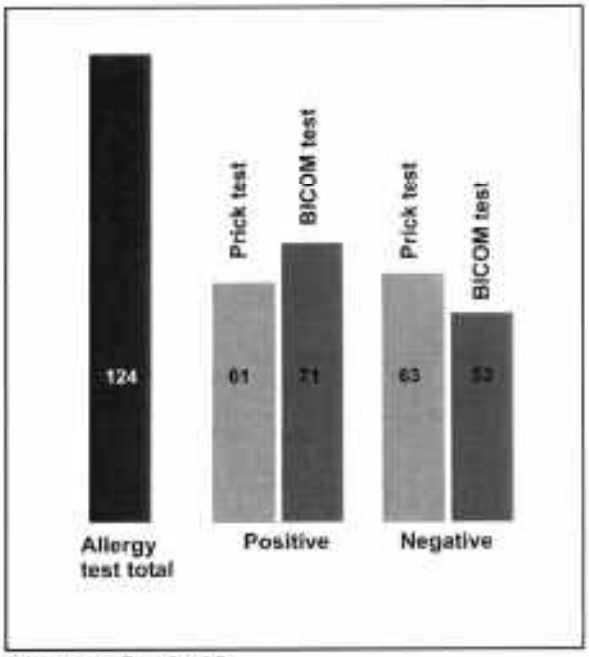

Diagram Study 10

Study 11:

Single group cohort study with clearly defined efficacy criteria.

The study is sufficiently representative with 79 patients taking part. Included in the study are eczema, ongoing dermatitis, nettle rash and psoriasis.

The study was carried out by Dr. Du Xia et al.

The efficacy was assessed using a 4-point scale. The follow-up observation after 1 year is notably long and increases confidence in the results of the study in terms of evidence-based medicine.

Result: Recovery in 74.7 % of treated cases and a visible effect in a total of 89.9 % of cases observed.

Assessment: The study was given a **level of evidence 5.**

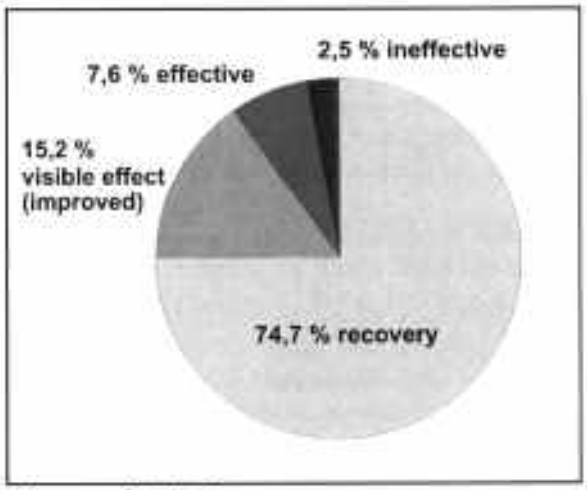

Diagram Study 11

Study 12:

Single group cohort study with clearly defined efficacy criteria. Despite the lack of a comparison group there appears to be a clear indication of the efficacy (Diagram 12).

The study comprised 150 patients in total, made up as follows: 95 patients with asthma and nasal catarrh, 20 patients with asthma only, 25 patients with nasal catarrh, 5 patients with skin eczema, 5 patients with other allergies.

This study was carried out by Dr. Feng Y. et al.

Extract from the biometric/medical assessment:
There appears to be a clear indication of the efficacy despite the lack of a comparison group since the successful results significantly outweigh the anticipated random effect. The credibility of the diagnoses for inclusion is supported by reference to relevant criteria. **Level of evidence 5.**

Efficacy was checked using a 3-point scale. In 60.7 % of cases all symptoms had disappeared. The general efficacy was proven at 94.7 % and a long-term recovery could also be seen in this study.

Treatment comprised 5 to 8 sessions. It was considered to be finished if all allergies tested negative in a renewed check. The observation period covered 5 to 8 sessions.

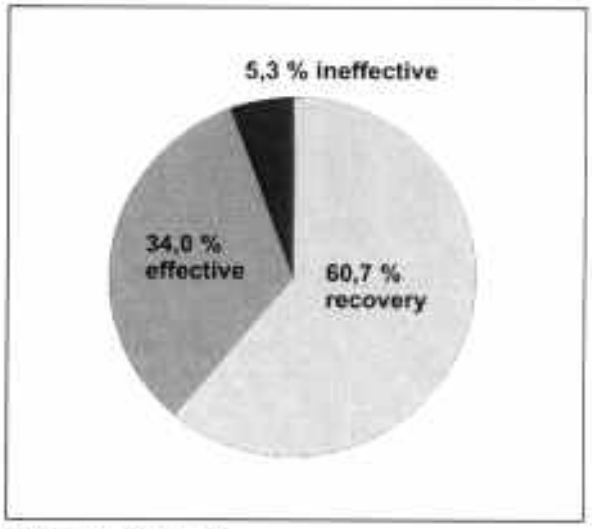

Diagram Study 12

Study 13:

Prospective randomised controlled parallel group study (Diagram 13).

The patients were distributed into 3 groups.

Group 1: BICOM treatment for children with first-time diagnosis
Group 2: BICOM treatment for children who were previously unsuccessfully treated with medication
Group 3: Control group, children with first-time diagnosis, treatment with medication

181 patients with allergy-related colds and allergic bronchial asthma were included in this study.

The study was carried out by Dr. Huang S. et al.

The efficacy was assessed using a 3-point scale: significant effect, effective, ineffective. The success rate is shown in the following diagrams.

This study is awarded a **level of evidence 1-2** based on the comparison groups available.

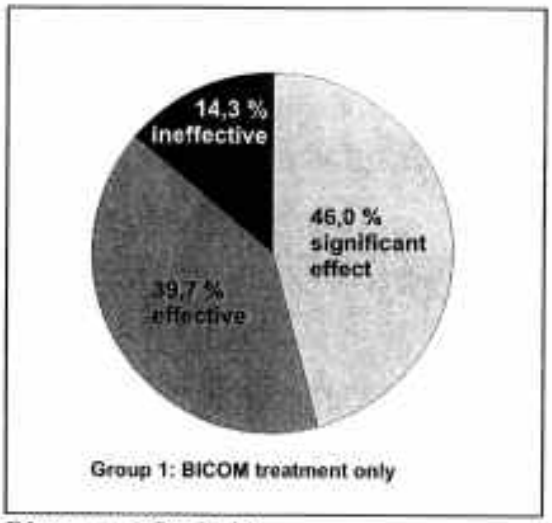

Diagram a) Study 13

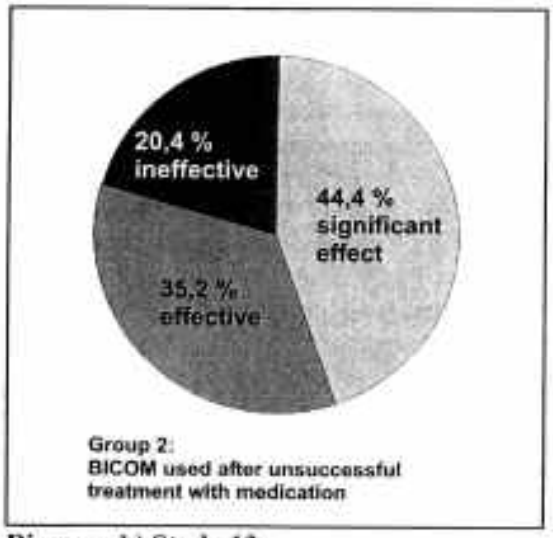

Diagram b) Study 13

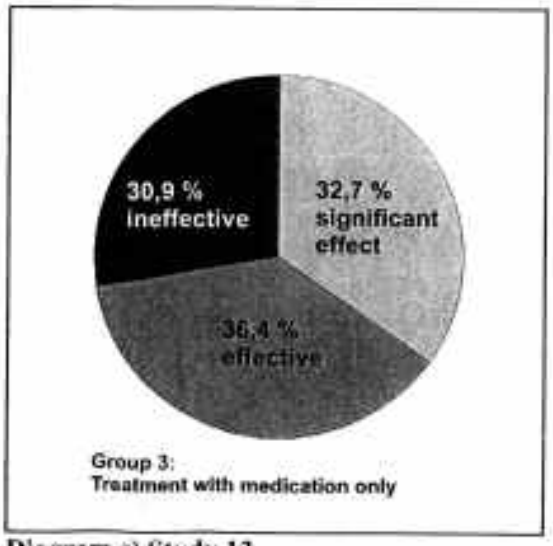

Diagram c) Study 13

Study 14:

Single group cohort study. 56 patients across all age groups suffering from nettle rash took part in this study.

It was carried out by Dr. Xu M. et al.

The results were assessed on a 4-point scale: recovery, clearly effective, effective (with relapse) and no effect.

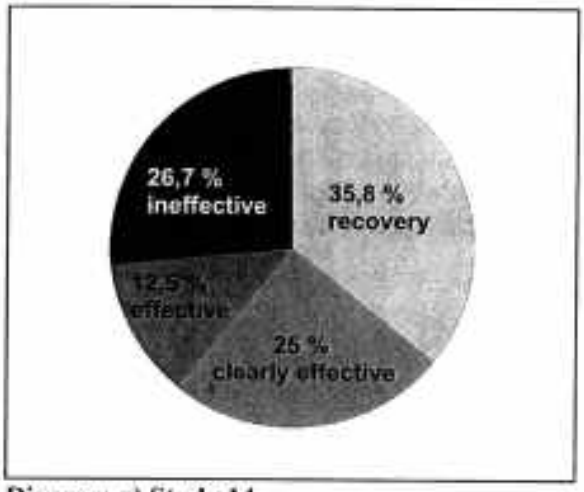

Diagram a) Study 14

The success rate for full recovery (35.8 %) and improvement (25.0 %) is 60.8 %.

It is interesting to note the breakdown into age groups, where the efficacy rate in the 1 to 15-year-old patients is the highest at 90 %, followed by the 16 to 30-year-olds at around 69 %. This study has a **level of evidence 5**.

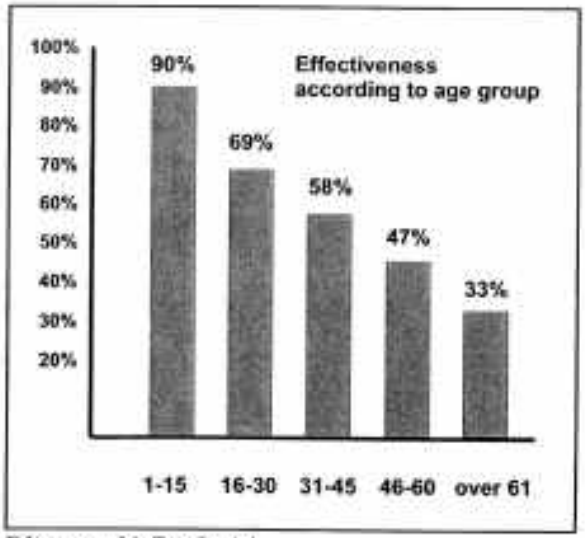

Diagram b) Study 14

Study 15:

Single group cohort study with 54 patients across all age groups with nettle rash (urticaria), carried out by Zhang X. et al.

The success rate for this study is 66.67 % (40.75 + 25.92), as can be seen in the following diagram.

Extract from the biometric/medical assessment:
Again we have a single group cohort study with defined efficacy criteria. The design is again similar to the usual observational studies used in Germany based on the conclusions described for the work of Du X. et al. The study is sufficiently representative with 54 patients taking part. As the authors themselves concede, the study is not adequate for long-term assessment.

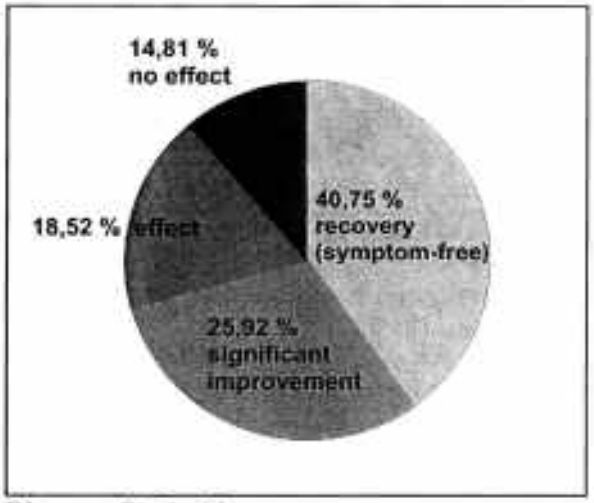

Diagram Study 15