

New Facts about the Munich Headache Study

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Abstract: Since its publication, the Munich headache study by Walach (Walach 1997 and 2000) has been the subject of controversial discussion. [Particularly by Vithoulkas (Vithoulkas 2002/1 and 2002/2), but also by Kösters (Kösters 1998) and others.] In spite of this, even in homeopathic circles, Walach's study is still regarded as a serious scientific trial with negative implications for classical homeopathy and has influenced all meta-analyses since published. As a result, it "damaged homeopathy more than anything else that had so far surfaced in medical journals" (Vithoulkas 2002/1 p. 32) and has become a main pillar of Walach's interpretation of homeopathy as "non-causal" or "magical", (Walach 1999 p. 292) contradicting Hahnemann's original principles.

This has recently prompted Seiler to carry out a detailed review of Walach's study. (Seiler 2006/1 and 2006/2) This shows that Vithoulkas's original criticism that the verum group was suffering from homeopathic aggravations can be proven to be correct. Walach's data concerning the therapeutic reactions of verum and placebo have been interchanged for the most part and are interpreted in a clinically inadequate manner; moreover, an essential error in randomization has been overlooked and the clinical parameters for migraine have been used inappropriately. The following text includes a review of the history and the most important critical aspects of the Munich study.

Keywords: homeopathic headache studies, double-blinded studies, interpretation of homeopathy, Walach's Munich headache study – a critique

1 *The legendary migraine study of Brigo and Serpelloni*

This trial was published in 1991 by the Italian homeopathic researcher, Dr. med. B. Brigo, in cooperation with Dr. med. G. Serpelloni.¹ Its aim was to prove the efficiency of high potencies in severe chronic cases in a strict double-blinded setting. For that purpose, Brigo selected chronic migraine patients with a mean age of 37.5 years. Only patients with a first medication of Lachesis, Natrium muriaticum, Silicea and Sulphur were admitted to the study. Randomization was perfect and the patients were allowed to continue their usual allopathic medication and dietary habits. Homeopathic medication was administered in C 30 at intervals of 14 days. Changing the remedy was allowed and this possibility was used in most cases. The duration of the study was four months.

Its results were spectacular: headache frequency, the most important clinical parameter in migraine studies, displayed about a 70% reduction in the homeopathic verum group. The comparison group taking placebo showed only 20% reduction.

This almost too brilliant Italian result clearly sur-

passes an average homeopathic practitioner's daily experience with severe chronic migraine cases.² Possibly it just reflects the extraordinary homeopathic skill of Dr. Brigo with the assistance of some statistical luck.³ Nevertheless, the data were double-blinded and statistically highly significant. Therefore, they provided further proof that homeopathic remedies potentized far beyond the number of Avogadro are effective in chronic cases.

2 *The Munich headache study – a differently conceived reconstruction with paradoxical results*

Some years later Prof. Dr. phil. H. Walach, et al., decided to re-examine Brigo's results.⁴ However, they

2 See also Vithoulkas 2002/2 p. 186.

3 For a detailed discussion see Seiler 2006/1 p. 15ff.

4 Walach's first report (explicitly mentioning Brigo's trial of 1991 as a starting point) was published in 1997 (Walach 1997); the detailed data of the study were only published some years later (Walach 2000). The Walach-Vithoulkas dispute, the most important controversy about the Munich-study, was published in 2002 with open results (Vithoulkas 2002/1 and 2002/2, Walach 2002/1 and 2002/2). So the debate is still far from being resolved and, in consideration of new scientific arguments, there appears to be justification for reopening this important discussion even

1 Brigo.

inexplicably chose a very different setting, which will be discussed below in some detail.

The results of the Munich study were a shock for the homeopathic world and a triumph for its adversaries: both placebo and verum showed virtually the same, only very slight reduction in headache frequency amounting to about 6%, much less even than Brigo's placebo rate of 20%. What was even worse, Walach's placebo group showed a clear tendency to achieve better results than homeopathy.

A further strange finding was that all the placebo results displayed far more fluctuations than verum. Walach was unable to interpret this phenomenon.⁵

In this article, we will try to show that these paradoxical results of the Munich study can be explained by its inadequate conceptualization, homeopathic long-term aggravations, and an essential error in randomization.

3 Problematic use of the parameter "headache frequency" in the Munich study

One of the main differences between Brigo's and Walach's trial is the fact that the Munich study was not confined to migraine patients but included all kinds of severe chronic headache, particularly permanent tension headache. Indeed, more than one-third of Walach's patients (37%) suffered from permanent headache.⁶

In spite of this fact, Walach uses the term "headache frequency," which is normally restricted to pure migraine studies, as the primary parameter in his mixed study.⁷ This is already quite problematic. As every practitioner knows, patients with permanent tension headache, by definition, do not suffer from the periodic pain attacks with pain-free intervals characteristic of migraine. As a result, permanent sufferers who are successfully treated first feel a reduction in their pain intensity, which may later result in their headache ceasing to be permanent and becoming periodic. Per contra, migraine patients who are being successfully treated experience a reduction in their headache frequency right from the outset. This reduction may even precede the lessening of pain intensity.

Walach tries to avoid this problem by using a statistical maneuver. Instead of asking his patients about the frequency of their pain attacks, as is usual in migraine studies, he defines his "headache frequency" as the "number of positive answers to the question: Did you suffer from headache today?"⁸ over a certain period of time. This naturally means that the "headache frequency" of all his permanent sufferers is registered as "daily

attacks." In this way, all permanent headache patients in the Munich study were transformed into migraine patients – merely with seven "attacks" a week!

This confusion of chronic migraine and permanent tension headache is not just a statistical problem, but essentially affects the clinical significance of the Munich study. Since permanent headache that is getting better will only show a reduction in frequency at a much later date than migraine, it becomes evident that the change in Walach's parameter "headache frequency" is slower and less distinctive than would be the case in pure migraine trials.

4 Advanced age of the patients further slowed down the reactivity of the Munich study

Age was an additional factor slowing down the reactivity of the Munich-study. The mean age of Walach's patients was substantially higher than Brigo's (48.5 vs. 37.5 years) and the duration of their suffering longer (23 vs. 16.3 years). This difference was even greater in the verum group. The mean age of Walach's verum patients was 51 years (Brigo's 37) and they had been suffering from headaches for a mean of 23 years (compared to 14 years in Brigo's study).

In his first critique, Vithoukaskas mentioned the fact that it would be very difficult to obtain useful results with such a problematic collective in a trial lasting merely a few months.⁹ This was also the opinion of the physicians conducting the Munich study.¹⁰

How slow the reactivity of the Munich study really was, particularly in regard to frequency reduction, can be shown by comparing its placebo results with those of pure migraine studies. In comparable studies, the placebo results should be roughly the same irrespective of the verum medication administered because the placebo patients all get the same medication, viz. nothing. As mentioned above, the reduction in migraine frequency in Brigo's Italian placebo group was about 20%; other pure migraine studies show about 15%.¹¹ In Walach's study, however, as mentioned above, the placebo reduction in "headache frequency" was only about 6%.

5 Unrealistically high "headache frequencies" at the beginning of the trial

Furthermore, in Walach's study, because of the many patients suffering from "daily attacks," there was also an exceedingly high initial "headache frequency" of more than 16 per month.¹² What is even more remarkable is that during the six-week observation period without medication that preceded the medication phase

some years later (Seiler 2006/1). The results of the discussion Walach-Seiler (Walach 2006 and Seiler 2006/2) are integrated in this article.

5 Walach 1997 p. 125.

6 Walach 2000 p. 70.

7 Walach 1997 p. 119.

8 Walach 1997 p. 120.

9 Vithoukaskas 2002/1 p. 33.

10 Seiler 2006/1 p. 30.

11 Seiler 2006/1 p. 26.

12 Seiler 2006/1 p. 37. Walach 2000 S. 83 ff. The best representation of graphs can be found in Gauss 1994 p. 52 ff.

of the Munich study, the “headache frequency” of the placebo group showed an isolated, inexplicable rise to about 18 attacks per month.

These values are, of course, clinically absolutely unrealistic. Brigo recorded 10 attacks per month among his severely afflicted Italian patients, which was already a very high value, whereas other homeopathic migraine studies show just 4-5.¹³

However, this passes almost unnoticed because Walach never explicitly mentions his artificially inflated “headache frequencies.” He restricts the use of this questionable term to the summary of his main publication and other general conclusions where absolute numbers do not have to be given. In his circumstantial analysis and in the only detailed graph published in his main article,¹⁴ however, he carefully avoids the term “headache frequency” and more correctly speaks of the “percentage of patients with headache per day.” The rather complicated method of calculating the corresponding “headache frequency” from this extremely unclear expression¹⁵ is not explained.

6 *Walach’s more appropriate parameter, “pain intensity,” showed the most paradoxical results*

Apart from his problematic “headache frequency,” Walach, of course, also registered the parameter “pain intensity,” which is better adapted to permanent pain. As expected, this indicator reacted more distinctly.

However, in contrast to the exceedingly high initial values of Walach’s “headache frequency,” the initial average pain intensity of his patients was much lower than in pure migraine studies. Walach reports only 15 mm on the VAS scale whereas Brigo indicates 87 mm and Straumsheim 53.7.¹⁶

This divergence can again be explained by Walach’s mix of migraine and permanent tension headache patients. Chronic tension headache never usually reaches the very high pain score of severe migraine attacks. What is more, the migraine patients’ days free of symptoms may even have been registered as zero pain values. If this were the case, the sensitivity of the Munich study would have decreased even further.

Be that as it may, in spite of its very low basic value, Walach’s more reliable parameter “pain intensity” yielded a clearer result than his “headache frequency.” However, this made the paradoxes in his study more apparent in equal measure: During the observation period, there was an even more pronounced increase in

the pain score of the placebo group from 15 to 20 mm VAS whereas verum once more remained practically stable.¹⁷ Then, in the treatment phase, the comparison group showed a considerable reduction of 23.5% from this elevated basic value. This is decidedly more than the 6% displayed in “headache frequency.” Verum, on the other hand, only showed 7.5% reduction in pain intensity, which is also somewhat more than in “headache frequency” (6%), but at this point clearly less than the placebo group.¹⁸

If placebo shows better results than verum in a study, this must be due to one of the following two causes:

1. A hidden artefact of randomization makes the placebo group decidedly more sensitive to positive environmental factors of the study than verum. In this case the trial concerned evidently becomes useless.

2. The verum medication has caused a real aggravation. Naturally, this can happen, particularly in a homeopathic trial, but in this case correct application of the well-selected remedy and appropriate length of the study make it possible to avoid this risk.

These two factors can have a combined effect of course. In the following, we will show that this was most probably the case in Walach’s study.

7 *An obvious error in randomization*

The complicated process of randomization is carefully documented in Walach’s study. Unfortunately, it resulted in a rather considerable difference in the size of the groups. Of the total 98 patients, 61 were allocated to the verum group, compared to only 37 in the placebo collective. This disequilibrium made the study more susceptible to artefacts from the outset.

Walach had already noted an apparent lack of clinical homogeneity in his two groups. Before the trial, 75% of the verum group were taking allopathic remedies whereas this was only the case with 58% of the placebo group.¹⁹ The authors of the Munich study were unable to state a reason for this discrepancy.

Another inconsistency which corresponds to that mentioned above is not noted however. Before the trial, 27% of the placebo patients underwent psychotherapy or similar psychosomatic treatment compared to just half of that amount (14%) in the verum group.

So, in spite of the careful randomization, in the small comparison group we find a clear tendency to prefer psychotherapy to drugs. How can this be explained? A look at the distribution of the occupational groups among verum and placebo gives us the clue to this strange phenomenon. Through a very rare coincidence, with the almost incredible low probability of only about 1:350, all the patients belonging to crea-

13 Straumsheim and Whitmarsh, summarized in Seiler 2006/1 p. 19 ff.

14 Walach 1997 p. 123. Walach 2000 p. 83ff. The best graphs are presented by Gauss 1994 p. 52 ff.

15 Seiler 2006/1 p. 37.

16 Seiler 2006/1 p. 48. The value of Straumsheim is particularly interesting as this study is a control of Walach’s with a similar conception but with migraine patients only.

17 Seiler 2006/1 p. 48. Walach 2000 p. 83ff. The reason for this strange phenomenon will be discussed below.

18 Seiler 2006/1 p. 48.

19 Walach 1997 p. 121.

tive-artistic professions (art, media, etc.) happened to be allocated to Walach's small placebo group.²⁰ As a result, these six people represented the second largest occupational group²¹ in the comparison group of only 37 patients. Consequently, the verum group was dominated by more prosaic people tending to practice rather down-to-earth professions.²² As artists professionally have to be more sensitive than other people, this group difference most probably explains the increased psychosomatic susceptibility of the placebo collective which - amongst other things - made it prefer psychotherapy to drugs.

This artefact of randomization was increased by another accidental imbalance. Of the six patients belonging to paramedical professions, no less than five were allocated to Walach's small placebo group. This disproportion is, admittedly, somewhat less improbable than that of the artists but still very noteworthy. Nurses and medical assistants tend on average to be more sensitive to medical influences than other people. So, finally the number of psychosomatically potentially more sensitive patients in Walach's placebo group grew to almost one third (11 of 37).²³

8 *Walach's more sensitive placebo group noted higher diary values*

During the purely observational six-week period without new medication, all patients had to keep a detailed diary of their complaints. The end result of this diary run-in was taken as the basis value for the subsequent three-month medication phase. As already mentioned, during this period the placebo values showed an isolated increase of about 10% in "headache frequency" (from about 16.5 to 18) and about 30% in pain intensity (from about 15 to 20) while the verum values remained practically stable.

This strange phenomenon can now be explained. As we have seen above, artists and nurses, who were clearly overrepresented in the placebo collective, usually exhibit more psychosomatic sensitivity than other people. So when starting a detailed diary without receiving any new medication, this group most probably tended to display more introspection and self-observation than the verum group causing them to note down higher scores for their symptoms (= diary effect).

9 *Important changes in allopathic medication and withdrawal from coffee affected verum somewhat more than placebo*

After the observation period, the three-month treatment phase was started. In contrast to Brigo, Walach's

patients were now forced to change their allopathic medication in significant aspects.²⁴ These changes naturally applied to both groups, but the verum patients, who were more liable to take drugs, were probably affected somewhat more. This might also have contributed to the lack of positive reaction of the verum group during the treatment period.

Furthermore, in contrast to Brigo, Walach's patients now had to cut out coffee completely.²⁵ Coffee restriction is unfortunately documented somewhat inconsistently by Walach. However, it seems clear that although it had partially begun in the observation period, it was only strictly controlled in the treatment period.²⁶

At least theoretically, it could be that an increased susceptibility of the placebo people to coffee withdrawal might have caused the isolated rise in their parameters during the observation phase. This, however, is very improbable for two reasons:

1. All registered complaints concerning coffee withdrawal were noted by members of the verum and not by the placebo group.²⁷

2. Another homeopathic migraine trial, the Norwegian Straumsheim study, also included a purely observational phase, but coffee withdrawal only started during the treatment phase. Nevertheless, this study also shows an augmentation in the number of attacks from about 4 to more than 5 per month recorded in the diaries.²⁸ So surely the diary effect occurs independently from coffee withdrawal and is mainly due to psychological factors.

The increased sensitivity of the Munich verum group to coffee withdrawal can be explained by the fact that coffee is the best phytotherapeutic remedy for headache and that this collective generally showed more drug dependency. Accordingly, persistent symptoms stemming from coffee withdrawal might also have contributed to the negative result of the homeopathic collective in the treatment phase.²⁹ However, as we shall see, there are other more important explanations for this.

10 *Problematic application of Q-potencies with risk of long-term aggravations*

In Walach's study, instead of a single doctor deciding about the constitutional remedy to be given, the decision was made by a group of homeopathic physicians. Furthermore, in contrast to Brigo, these

20 Seiler 2006/1 p. 31.

21 Walach's 98 patients were subdivided into 14 different occupational groups (see attached table).

22 Seiler 2006/1 p. 31.

23 Seiler 2006/2 p. 11.

24 2006/1 p. 30 - 31.

25 2006/1 p. 30.

26 Seiler 2006/2 p. 13 - 14.

27 Seiler 2006/1 p. 38-39 and 45.

28 Seiler 2006/1 p. 24. But in contrast to Walach's study this increase was distributed among both groups about equally because of the well balanced randomization.

29 For a detailed discussion of this question see Seiler 2006/2 p. 11-14.

homeopathic physicians were allowed to select their remedies without any restriction.³⁰

After beginning with their medication, patients underwent a first routine control after six weeks, which was followed by a second treatment period of the same length and concluded with the final examination. However, they were free to contact their doctors at any time and changes in medication could be initiated whenever prescribed. But this option was used seldom: during the entire trial only ten new prescriptions were issued outside the routine controls.³¹ Furthermore, even when changes in medication for routine controls were included, new prescriptions were clearly less frequent than with Brigo.³²

In addition, the Munich physicians were free to choose among C- and Q-potencies. This is an important fact as finally 65 (30%) of the overall 217 documented prescriptions for Walach's 98 placebo and verum patients were Q-potencies.³³ Q-potencies are usually administered daily and need more stringent case management than with the Kentian method, to which the control frequencies of the Munich study were adapted. Hahnemann controlled even his chronic patients treated with Q-potencies regularly at much shorter intervals of one to two weeks and frequently changed his prescriptions.³⁴ In his first discussion with Walach, Vithoulkas also stressed the necessity of prescribing a sequence of different remedies when treating patients with severe chronic headache.³⁵

In the Munich study, however, in at least some cases, Q-potencies were administered unchanged once or even twice daily during a whole treatment interval of six weeks without regular control in between.³⁶ In addition, as mentioned above, extra-consultations involving a change of prescription were rare.

If Q-potencies are administered in such a way, even long-term aggravations can easily occur. In addition, Vithoulkas, in his first critique of Walach's study, already mentioned that in very severe chronic cases long-term aggravations may occur even when using the correct Kentian technique.³⁷

We shall see that the pattern of therapeutic reactions reported by the homeopathy group makes it almost certain that this was the case with a relevant number of patients.

30 But this not only is an advantage. Particularly problematic constitutions like *Sepia* for instance were excluded from Brigo's study. Concerning the collective choice of the homeopathic medication, see also Vithoulkas' critics 2002/1 p. 33 and 2002/2 p. 186.

31 Seiler 2006/1 p. 35, Walach 2000 p. 79.

32 Seiler 2006/1 p. 36.

33 Seiler 2006/1 p. 33 and Walach 2000 p. 121.

34 Seiler 1988 p. 188 - 224.

35 Vithoulkas 2002/1 p. 32 and indicated again on p. 33.

36 Seiler 2006/1 p. 35.

37 Vithoulkas 2002/1 p. 32 and 2002/2 p. 186.

11 *Interchange of the data concerning the therapeutic reactions of verum and placebo groups*

After each of the two six-week treatment periods, patients were asked to note any side effects resulting from the treatment in their diary. First, they had to reply to the general question of whether they felt side effects, with "yes" or "no," and then were asked to give specifications if applicable. Twenty-two homeopathy patients (36.1%) and 17 participants in the control group (45.9%) replied "yes" once or twice, and many of them (17 of verum or 27.9%, 12 of placebo or 32.4%) also noted details of their reactions.³⁸ These specifications are, of course, of great importance in attempting to answer the question of whether verum suffered from specific homeopathic aggravations or not.

In view of the importance of these data, we compared Walach's list of specific reactions³⁹ with the original published by Walach's statistician Prof. Gauss.⁴⁰ To our great astonishment, we found that in most cases (80%) Walach's data of placebo and verum were interchanged.⁴¹ This very remarkable error has been explicitly confirmed by Gauss.⁴²

This mistake clearly confirms that Walach's analysis of the specified reactions of verum and placebo was rather careless. Without giving any concrete argument (not to mention statistics), he simply notes that exactly 50% of the specifications given by both groups could be interpreted as typical homeopathic reactions.⁴³ So, according to Walach, there was absolutely "no difference between the two groups".⁴⁴

Hence, one could conclude that his confusion regarding the patients' data was not of great significance. However, a careful analysis of the adjusted data will show the contrary.

12 *Aggravations in the first half of the trial were much more frequent among the homeopathy group*

38 Seiler 2006/1 p. 39. So in contrast to the absolute numbers we find a slight preponderance of the placebo collective both with the total number of side effects and the detailed notices. This can once more be explained by the increased psychosomatic susceptibility of this collective which made it more suggestible particularly to non-specific placebo or rather "nocebo" side effects in spite of the fact that verum most probably suffered from more and more severe therapeutic reactions objectively. But the pattern of appearance and the quality of the therapeutic reactions were very different in the placebo collective and the homeopathy group (see below).

39 Walach 2000 p. 100 - 101.

40 Gauss p. 70 - 72

41 Seiler 2006/1 p. 40.

42 Personal letter to Seiler.

43 Seiler 2006/1 p. 40.

44 Walach 2000 p. 102 and confirmed again strictly in his discussion with Vithoulkas 2002/1 p. 37.

After correcting Walach's error, we could analyze the specified notes about the therapeutic reactions in detail. They were listed in the following manner: if a patient noted several symptoms of different organ systems (e.g., digestive and circulatory problems in the same patient), they were counted separately. Symptoms noted by the same patient both in phase I and II of the treatment period were also noted separately. This resulted in our finding 27 specifications of therapeutic reactions with verum and 20 with placebo.

There is already an astonishing difference between verum and placebo when analyzing the pattern of occurrence of these specified symptoms, either in phase I or II. Of the 27 therapeutic reactions of the homeopathy group, no less than 21 were registered in the first period of treatment. This is an overwhelming majority of 78%.

In the control group, however, only 8 of the 20 detailed symptoms (40%) were noted in phase I. So, with homeopathy we find a relationship of early to late phase reactions of 21:6 or 3.5:1 whereas with placebo only 8:12 viz. 0.7:1.

If the homeopathy and control group had been equal in their reaction pattern, these coefficients should, of course, be about the same and accordingly their ratio about 1:1. But in Walach's trial we find a significant difference in this relationship of 3.5:0.7 versus 5:1.

This clearly proves that the homeopathy group suffered more in phase I of the treatment. To a certain extent, this can be explained by the forced changes in chemical and phytotherapeutic medication affecting verum somewhat more than placebo as discussed above. But it will be shown below that most probably homeopathic aggravations were responsible for at least some of these early therapeutic reactions.

The slight increase in placebo or rather nocebo "side-effects" in phase II of the trial is typical. It is well known that the positive reaction to placebo medication is always strongest at the beginning of treatment. Subsequently, disappointment sets in more or less rapidly and consequently complaints increase. Brigo's study already showed that with migraine patients: the placebo effect became weaker after two months.

13 *The homeopathy group suffered significantly more from typical homeopathic aggravations*

To judge a symptom as a typical homeopathic reaction, Seiler classified the specified therapeutic reactions in seven categories according to their homeopathic importance. This resulted in the following ranking list:

1. Initial aggravation followed by explicit amelioration

Verum: 1 case.

This patient noted with an exclamation mark that she

or he was "worse for three days, then well!"

Placebo: No such records.

II. Old symptoms returning after a longer period of absence

Verum: 2 cases

a. Return of depression after a longer phase of stability.

This was so severe that the patient's family judged it to be unacceptable.

b. Unbearable headache for two days exactly noted with date. This had never happened to such a degree since the birth of the patient's son two years earlier.

Placebo: No such records.

III. Symptoms explicitly marked as new or unusual

Verum: 2 cases

a. Menstruation four days earlier than usual which had never happened before.

b. Unusual pattern of headache for four days exactly noted with date.

Placebo: No such records.

So, all five symptoms typical of the first three categories of typical homeopathic reactions were noted in the verum group. Even considering the difference in group size (61 verum, 37 placebo), this ratio of 5:0 in favour of the homeopathy group still remains at about 3:0.

IV. Probably new, characteristic and striking symptoms

Verum: 8 cases⁴⁵

Placebo: 2 cases

If we add this category, which is still typical for a homeopathic reaction, the preponderance of the homeopathy group increases further to a ratio of 13:2 = 6.5:1. Considering the difference in group size we still find a ratio of about 4:1.

It is only in the following groups of symptoms which are less characteristic of homeopathic remedy that the ratio of homeopathy to placebo changes to an increasing preponderance of placebo.

V. Possibly new but poorly characterized and non-specific symptoms

Verum: 7 cases

Placebo: 7 cases

In this group of symptoms, which also includes typical negative placebo or nocebo reactions, we find a relationship of 1:1. Considering the difference in group size this coefficient even increases to 1.7:1 in favor of placebo.

⁴⁵ In the interests of brevity, the detailed description of the symptoms is no longer given. A complete list with the details of all symptoms is published in Seiler 2006/1 p. 41-46.

VI. Aggravation of current symptoms (in most cases headache) without explicit amelioration

Verum: 2 cases

Placebo: 4 cases.

As expected in this category, which includes the most typical kind of nocebo reaction, we find a clear dominance in the control group.

VII. Symptoms marked by patients explicitly as insecure or caused by other reasons than medication

Verum: 5 cases.

Placebo: 7 cases.

Of course, this classification of symptoms has some arbitrary aspects and could be framed in a somewhat different way as well. Nevertheless, the outcome of any exacting analysis would be about the same: typical homeopathic reactions were decidedly more frequent within the verum group.

How could such obvious differences between the therapeutic reactions of verum and placebo pass unnoticed in the analysis of the Munich study?⁴⁶ Maybe Walach was just unable to see what he did not want to see. In his vehement dispute with Vithoulkas about the influence of homeopathic aggravations on the outcome of his study, he even went so far as to call homeopathic aggravation "a myth."⁴⁷ This statement could only come from someone lacking true experience in classical homeopathy. A good homeopathic practitioner sees aggravations among his patients on a day-to-day basis.⁴⁸ So it seems important to the authors of this article that future important homeopathic studies should only be monitored and analyzed by the most experienced homeopathic practitioners and not by mere theoreticians.⁴⁹

14 *The analysis of the Munich study must be revised*

So the paradoxical findings of the Munich study can be explained in the following way:

I. Placebo group

During the diary run-in without medication, the placebo group, which was psychosomatically more sensitive, noted higher scores than verum in all parameters and consequently reached more elevated starting

values. Once treatment began, this group, for the same reason, showed a decidedly positive placebo reaction with clear amelioration.

Only at the end of phase II, with decreasing placebo effect, did this amelioration turn into a final aggravation of all parameters. However, this third distinct fluctuation of the placebo values did not reach the elevated starting point seen at the end of the diary run-in period.

Consequently, in spite of the very low reactivity of Walach's study, there remained a slightly positive result in favor of placebo.

II. Homeopathy group

In contrast, the homeopathic verum group consisting of more down-to-earth people recorded almost stable scores during the diary run-in.

This, surprisingly, did not change greatly during the treatment phase. So we have to conclude that antithetical factors were cancelling each other out in the treatment phase:

- On the negative side, we surely have to take into consideration, as explained above, homeopathic aggravations that were potentially severe and long lasting. Furthermore, the verum group, being more dependent on drugs, suffered at least somewhat more than the placebo group from the significant changes in allopathic medication and the total coffee withdrawal imposed by the Munich study.

- On the positive side, we surely have to take into consideration a certain placebo effect in the homeopathy group too. However, for the reasons mentioned above, this factor has to be weighted somewhat less than for the placebo group. Furthermore, in spite of the problematic setting of the Munich study and the difficulties already mentioned, we also have to take into consideration at least a small number of patients who, without prolonged initial aggravation, showed positive reactions to their well-selected and correctly administered homeopathic remedy.⁵⁰ However, for the reasons given above, these positive therapeutic reactions were neither frequent nor striking.

In this way, we can explain why the positive factors were cancelled out almost completely by the negative, and the verum group showed merely a very slight amelioration which remained even below that of the placebo group.

Finally, we can only confirm Vithoulkas's earlier statement that chronic headaches are not the ideal subject for a homeopathic trial of a few months duration.⁵¹ Brigo's splendid result remains an isolated case, but it

46 The evident fact of the disproportionate distribution of the early and late therapeutic reactions remains hidden by a rather strange statistical representation of the data (Seiler 2006/1 p. 42-43)!

47 Walach 2002/1 p. 37.

48 Documented by Vithoulkas in his discussion with Walach 2002/2, p. 186.

49 A positive example of integrating strictest university standards with profound homeopathic skill and knowledge is the newly published study with ADS-children by Heiner Frei (Frei 2006).

50 For instance, the patient mentioned above under 13/1. But only one patient in the whole study group explicitly reported this typical pattern of homeopathic healing!

51 Vithoulkas 2002/1 p. 32-33.

has to be strictly re-emphasized that it has never been exactly replicated. Other double-blinded homeopathic migraine studies with a different, more Walach-like setting, had to struggle with less severe, but similar difficulties to those experienced in the Munich study.⁵² Nevertheless, a careful analysis shows that both these trials, in spite of generally being qualified as negative by Walach and others, yielded significantly positive partial results in favor of homeopathy.⁵³ Therefore, after definitively qualifying Walach's trial as defective, it can be said that all three remaining double-blinded homeopathic migraine studies (Brigo, Straumsheim and Whitmarsh) at least partially showed positive results.⁵⁴

15 *Walach's non-causal or magical interpretation of homeopathy – a superfluous and inappropriate assumption*

As mentioned above, the seemingly controversial results of homeopathic trials and particularly the negative outcome of his important Munich study led Walach to interpret homeopathy as being non-causal in the sense of the statistical Copenhagen interpretation of quantum mechanics.⁵⁵ This implies that homeopathy functions in a way that is similar to sorcery and could never be proven by classical scientific methods, such as double-blind trials. However, a critical meta-analysis of homeopathic studies⁵⁶ shows the contrary. In spite of the fact that double-blind trials are not the ideal test for a holistic method like classical homeopathy,⁵⁷ the results of Frei,⁵⁸ Jacobs,⁵⁹ Reilly⁶⁰ and others together with the present definitive proof of the invalidity of the Munich headache study show that the efficacy of homeopathy can be satisfactorily proven providing the trial is well-conceived. This experimental evidence already makes Walach's assumption superfluous.

Furthermore, Walach's theory lacks sound foundations on the theoretical level too. It is well known that Einstein, still considered to be the major physicist in modern science, strictly refused to accept the purely statistical approach to physical reality postulated by Bohr's Copenhagen interpretation of quantum me-

chanics right up to his death: "God doesn't play dice!" Well-founded alternatives have been elaborated by de Broglie and Bohm, and the real physical meaning of quantum theory still remains one of the most puzzling open questions in modern physics.⁶¹

It is unnecessary to say that Hahnemann, an undisputed representative of the Age of Enlightenment, in spite of his belief that the essence of potentiation is the activation of a universal life force slumbering in matter, strictly saw homeopathy as a rational science and not an occult mystery! Life energy and science at Hahnemann's time were not yet as strictly separated as – unfortunately – they are today. Hahnemann's renowned predecessor in bioenergetic medicine, F.A. Mesmer, whose healing magnetism is integrated in the Organon,⁶² had already elaborated the very interesting physical theory that matter is nothing other than a dynamic manifestation of life energy.⁶³

It is still too little known that this theory not only gives us a useful model of high potencies but also a new possibility to elucidate the controversial hidden parameters postulated by Einstein, de Broglie and Bohm to reintegrate quantum mechanics into classical causal physics.⁶⁴ Therefore, it is a major mistake to connect the non-causal statistical interpretation of quantum mechanics, possibly one of the more important errors of modern physics, to homeopathic science, as Walach has done. On the contrary, modern physics should learn from homeopathy!

Conclusions

1. The Munich headache study by Walach, et al., has to be considered invalid by the following reasons:
 - The data concerning the reactions of the patients have been interchanged for the most part and are interpreted in a clinically inadequate manner.
 - An important error of randomization was overlooked.
 - The sensitivity of the study has been decreased substantially by intermixing migraine and permanent headache.
2. The effectiveness of homeopathy can be proven by double-blinded studies too, particularly also by migraine-studies, provided the experimental conception is appropriate. This makes Walach's non-causal, respectively magical interpretation of homeopathy superfluous.

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63 Mesmer 1814.

64 Seiler 1986, shortly outlined and discussed in Seiler 2006/1 p. 53 – 55.

52 Whitmarsh (1997) and Straumsheim (2000) discussed in detail in Seiler 2006/1 p. 19 – 27.

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54 As an example of a well designed, but not double-blinded homeopathic migraine trial we mention the recent study of Kivellou, Vithoulkas, et al. (Kivellou 2006). This study of 12 months' duration showed a very distinct, statistically highly significant reduction of migraine frequency and pain intensity. It is planned that it will be followed by a double-blinded randomized trial with similar conception.

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