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Observational study of quality of life in patients with headache, receiving homeopathic treatment

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Introduction

Homeopathic medical practitioners maintain that homeopathy is an efficient form of therapy. And yet, the clinical effects of homeopathic treatment are still under discussion in the field of biomedical research, because very few trials have been carried out according to methods that are accepted by conventional medicine. According to some, homeopathy cannot be compared according to the criteria commonly used in modern medicine. However, according to others, including the European *Homeopathic Medicine Research Advisory Group*, homeopathy can be studied scientifically, even if this is carried out with its own specificity.[1-3]

The specificity in homeopathy, that demands for methodological adaptations at variance with conventional study protocols, lies in the following aspects: a) the practitioner must take into consideration the patient's global and individual condition and this demands very wide experience and cannot be executed automatically on the basis of a diagnosis; b) the "medicine" is a substance given in very small, even infinitely small doses, where the therapeutic effects are presumed as experimental on healthy subjects ("provings") and this requires profound knowledge of Materia Medica; c) homeopathic methods generally envisage a "second prescription" based on the effects obtained after the first treatment; d) the outcome of the homeopathic treatment must be evaluated non only considering the main symptom that has normally led the patient to consult the doctor, but also taking into consideration the patient's "life quality" and other parameters like the dynamic change of symptoms ("Hering's rule").

It is because of this specificity, that the results of a clinical homeopathic research must be evaluated using instruments that examine the widest number

of variables concerning the health of the patient as a whole. For this reason it is considered important to calculate the state of health using standardised answers to standardised questions (self-reported questionnaires), an efficient and increasingly diffused method[4] that was also adopted in various complementary therapies[5] and homeopathy.[6,7] It has been also suggested[6] that the interpretation of the scores generated by pre-defined questionnaires may be problematic as the significance of changes in scores for different health concepts is likely to be interpreted differently by allopaths and homœopaths, particularly when these scores are being used to assess any overall change in health status. These problems claim for further studies in this field. In any case, it is essential that the instruments used in the survey be comprehensible, reliable from a psychometric as well as corporeal point of view, and that they be brief enough to be used in a medical surgery context.

Clinical research methods can be basically divided into two categories. The first is *experimental* research, where the treatments and choice of the samples for study are chosen and controlled by the researcher according to the question under investigation; and the second is non-experimental (or *observational*) research where the treatment and the sample choice are not pre-determined, or if so, only in a very minor proportion, by the researcher's intention. On one hand, experimental research is more reliable in order to establish the efficacy of a certain medicinal products or procedure (especially if this can be carried out under blind conditions and with adequate randomisation); on the other hand, observational studies provide the advantage of respecting with greater ease the actual conditions where therapies are applied. Generally, controlled and randomised trials are preceded by observational studies or uncontrolled trials in order to establish whether some treatment deserves further in-depth and experimental research.[8-11] Another important aspect to be taken into consideration is the greater value that is given to *prospective* observational study compared to *retrospective* study. This is because in the former case it is possible to evaluate with greater precision and reliability the number of enrolled patients and the number of drop-outs.

This study describes the results obtained from a *prospective observational* research program in the field of homeopathic treatment for patients suffering from migraine and chronic or recurrent headaches (here referred as cephalalgia). This condition causes a major impairment of the quality of life of affected people,[12,13] who often turn to homeopathy after having tried all types of conventional drugs. The scope of this program has been to use special questionnaires to evaluate the changes in life quality and symptoms in cephalalgic patients treated in the surgery by qualified doctors specialised in homeopathy. The protocol was set up and carried out by a group of homeopaths, most of whom are professors at the School of Homeopathic Medicine in Verona, in collaboration with the Medical Association (Ordine dei Medici Chirurghi e degli Odontoiatri) of Venice and with the Observatory for

Complementary Medicines (OMC), established in Verona under the initiative of the University and of the Medical Association.

We checked the application in the homeopathic practice of the short-form-36 (SF-36) health questionnaire, that has already been proven valid in various fields.[14-18] It is understood that this respects both the necessity for documentation that is as complete as possible concerning the physical and psychological symptoms, as well as the particularity of homeopathic treatment. Another objective of this study, was to evaluate the applicability of a monitoring system for the results of the homeopathic treatment applied in surgeries and basic medicine.

It has been envisaged to carry out the investigation on at least 50 cases, by a group of homeopaths who use the classical (single prescription) homeopathic treatment and high potencies of the medicinal products. This last point is important because of the regulation implications involved, considering that the medicinal products employed in this study are all included in the list of the products currently authorised by the Italian health ministry.

Methods

Type of study and criteria for inclusion

This clinical research was a prospective observational study, composed of an evaluation at the beginning of the treatment (first visit) and a second evaluation after 4-6 months. The second evaluation was independent of the number of visits the patient has had in the mean time. The criteria for inclusion were the following: patients of either sex, in an age range between 15 and 65, suffering from cephalalgia for a period of at least two years. Either patients diagnosed as suffering of migraine (with- and without aura) and those suffering of tension-type headache (groups 1 and 2 according to the International Headache Society)[19] were included. The criteria for exclusion from the study were painful syndromes in the head as a result of other pathology (trauma, vascular and metabolic disorders, non-vascular intracranial disorders, intake of substances or their withdrawal) and a high probability of insufficient compliance with homeopathic treatment or with the questionnaire because of psychic or character problems. The outcome was calculated according to the subjective clinical and symptomatological data obtained before and after treatment, using the SF-36 Life Quality questionnaire.

The study was carried out between June 1999 and December 2000 in the private professional medical surgeries of the practitioners (all medical doctors) who participated in the program (the authors of this paper, except P.B.), located in various towns in the Veneto and Lombardia regions. All the data was sent as prospective review to Prof. Paolo Bellavite of the OMC at the Department of

Biomedical Morphological Sciences of Verona University for the safekeeping of the questionnaires and the data processing.

Protocol

The patient was visited by the doctor who made his diagnosis and evaluated whether the patient could be eligible. The proposal to participate in the study was made to all patients eligible according to the criteria, without making any further choices (such as including only those patients where the doctor could feel he has found the correct remedy). After the patient had been informed of the characteristics of homeopathic therapy and of the research study, if he was willing, he gave his written consent to the therapy and to personal data management for research purposes. He received a questionnaire and was invited to fill in the questions according to the instructions, that were given orally and were also described on an appropriate sheet apart. In particular, the most relevant explanations were the following: a) that the patient must fill in the questionnaire alone, b) that he/she must feel completely free to answer all questions sincerely and objectively, c) that the information is processed in a completely anonymous manner and coded by independent observers, d) that the answers do not have any influence on the type of assistance provided by the doctor, e) that the questionnaire must be filled in completely and faithfully. Only when it was strictly necessary, and on the patient's explicit request, the doctor could help with the completion of the questionnaire.

The homeopathic remedy and the dose were not pre-established, but were adapted to each single patient according to individualized homeopathic prescription (see below for details). The prescribers decided also the potency following their usual practice, in any case they prescribed potencies above the 30c. The remedy, the dose, and the date of prescription were recorded in a register, and a copy was sent to the OMC together with the questionnaire. The patient was allowed to take his/her usual painkillers if necessary, but not other homeopathic remedies different from prescription. The doctor visited the patient the number of times he felt necessary. He was also available for phone calls for any possible urgent advice.

After 4-6 months (ideally 5 months) when the patient returned for a control check-up, he was given another questionnaire identical to the first one, that was filled according to the same criteria as that described above. During the second visit, the patient did not have a copy of the first questionnaire (since this could possibly influence his/her answers to the second one). In the case where the patients did not appear spontaneously during the 4 to 6 month period after the first visit, they were contacted by phone or by letter, asking to come to the surgery and at least fill in the questionnaire. This was sent immediately to the OMC for processing.

SF-36 and statistics

The SF-36 questionnaire[13,17,20] is composed of 36 questions that explore many aspects of the physical, psychic and relational health of the patient. In this study we have adopted the Italian version of the questionnaire, that was officially translated and validated by Apolone and Mosconi.[17] It should be emphasized that the questions in the large majority of cases concern symptoms or sensations experienced during the four weeks preceding the visit. The answers to these questions may be processed in order to obtain eight different scores, representing eight different concepts (or dimensions) related to health: physical functioning (PF), role limitations due to physical problems (RF), bodily pain (BP), general mental health (MH), role limitations due to emotional problems (RE), vitality (VT), social functioning (SF), general health (GH). These scores can be statistically evaluated. Table 1 summarizes the main concepts and the scales of the SF-36. According to the parameters expressed in this list it is obvious that this is an adequate instrument for evaluating the evolution of chronic illnesses and their impact on various aspects of life quality. Once the questionnaire has been completed, it was sent to the OMC immediately where it was registered and given a progressive number. All the transformations of the scores were executed with an algorithm programmed in "*Stata*" software. Because in many questions the distribution of the answers was not normal, the difference between results before and after treatment, were calculated with a non-parametric test and more precisely using the using the Wilcoxon matched-pairs signed-ranks test (pre-post therapy).[21,22]

Table 1. - The dimensions of health according to the SF-36 questionnaire

Life quality dimensions	**Lowest scores**	**Highest scores**
Physical functioning (PF)	Strongly limited in all physical functions including getting dressed and bathing	Performs all types of activity without limitation because of health problems
Role limitations due to physical problems (RP)	Difficulty with work or other daily activities because of physical health	No problems with work or other daily activities because of physical health
Bodily pain (BP)	Very strong and extremely limiting pain	No pain, or limitations due to pain
Mental health (MH)	Permanently nervous and depressed	Feels calm, serene, happy
Role limitations	Difficulty with work or	No problems with work

due to emotional problems (RE)	other daily activities because of emotional problems	or other daily activities because of emotional state
Vitality (VT)	Constantly tired and exhausted	Feels full of energy, vivacious, bright
Social functioning (SF)	Extreme and frequent interference with social activities through physical and emotional problems	Performs all social activities normally without interference due to physical or emotional problems
General health (GH)	Feels that personal health is bad and destined to worsen	Feels that personal health is excellent

Adapted from Ware and Sherbourne.[20]

Treatment

The method of medicine choice was individualized prescription according to classical homeopathy. In brief, the symptoms under evaluation (homeopathic symptoms) must reflect the particular details expressed by the patient compared to the pathological situation, rather than the typical symptoms of the pathology. For example a patient suffering from tension-type headache could present two symptoms at the same time: a) the headache improves after rest and b) the headache worsens if he drinks beer. The homeopath will give more importance to the latter symptom, since it is particular to that patient and not to the majority of cases of patients suffering from tension-type headache (vice-versa, improvement after rest is very common). Homeopathic symptoms of the patient collected in this manner must not be too many or too few (no less than three and a maximum of ten, but this may change according to the individual). When making symptoms choice, the homeopath will give preference to the symptoms that are expressed with clear intensity by the patient and that are present both at the time of the visit and during the previous months or years (historical symptoms). The prescription requires the use of the repertory and it is preferable (although not obligatory) to use a computerised repertory for easier symptom classification. Once the homeopathic symptoms have been chosen and a series of candidate remedies selected with the help of the repertory, the doctor will establish a prescription of one single medicine, by comparing the ensemble of the symptoms and the signs presented by the patient with the ensemble of the symptoms produced by various medicines proposed in the Materia Medica. When carrying out the follow-up, any new symptoms that may appear, are judged in homeopathic medicine according to the category synthetically expressed by the so-called Hering principle.

Results

Fifty-three patients were recruited during the research program, and OMC received the first forms of all 53 patients. Five patients did not complete the therapy for unknown reasons, and it was not possible to trace them for completing the second questionnaire. These five dropped out patients were included in the statistical analysis according to the intention-to treat as if they were unimproved (i.e. using the same scores of the first questionnaire also for the after-therapy values). The cases where the information from both questionnaires (before treatment and after the observation period) was available were 48. Of these, the following cases could not be included for evaluation: six cases were excluded because the two questionnaires (pre-post) bore the same date and were filled in during the second visit, therefore the first questionnaire was completed retrospectively. One was eliminated because the treatment was suspended because of pregnancy, another because the questionnaires were far from complete, another because his age was lower than that mentioned in the inclusion criteria. In total, the cases included in the

statistical evaluation were 44 (83% of total), 39 of which were complete (73.6% of total) and 5 of which responded only to the first questionnaire (9.4%) but were analysed according to the intention-to treat criteria. The group was composed of 36 women and 8 men with an average age of 37.5 ± 12.7 years (range 16 to 66 years). The period of the medical treatment, or the interval between the first and second questionnaire was 4.9 ± 2.9 months (range 1 to 15 months). A few patients did not answer all the questions leaving spaces now and then. Where these cases were sporadic (1-3 per questionnaire) the questionnaire was retained for analysis.

The medicines used as a first choice were as follows: 6 cases – *Natrum muriaticum*, 3 cases – *Staphysagria, Lycopodium, Lachesis* and *Nux vomica*, 2 cases *Pulsatilla, Arsenicum album, Stramonium, Sepia* and *Ignatia*, 1 case – *Nux moscata, Sulphur, Helleborus niger, Conium maculatum, Lac caninum, Thuya occidentalis, Sabadilla, Phosphorus, Arnica montana, China, Calcarea carbonica, Calcarea sulfurica, Bryonia, Carbo vegetabilis, Tuberculinum, Carcinosinum*. In 8 cases the medicine was changed during the treatment as follows: *Carbo vegetabilis* after *Nux moscata*, *Natrum muriaticum* after *Lycopodium*, *Sepia* after *Pulsatilla, Chelidonium* after *Nux vomica*, *Phosphoric acidum* after *Lachesis*, *Pulsatilla* after *China*, and *Pulsatilla* after *Nux vomica*.

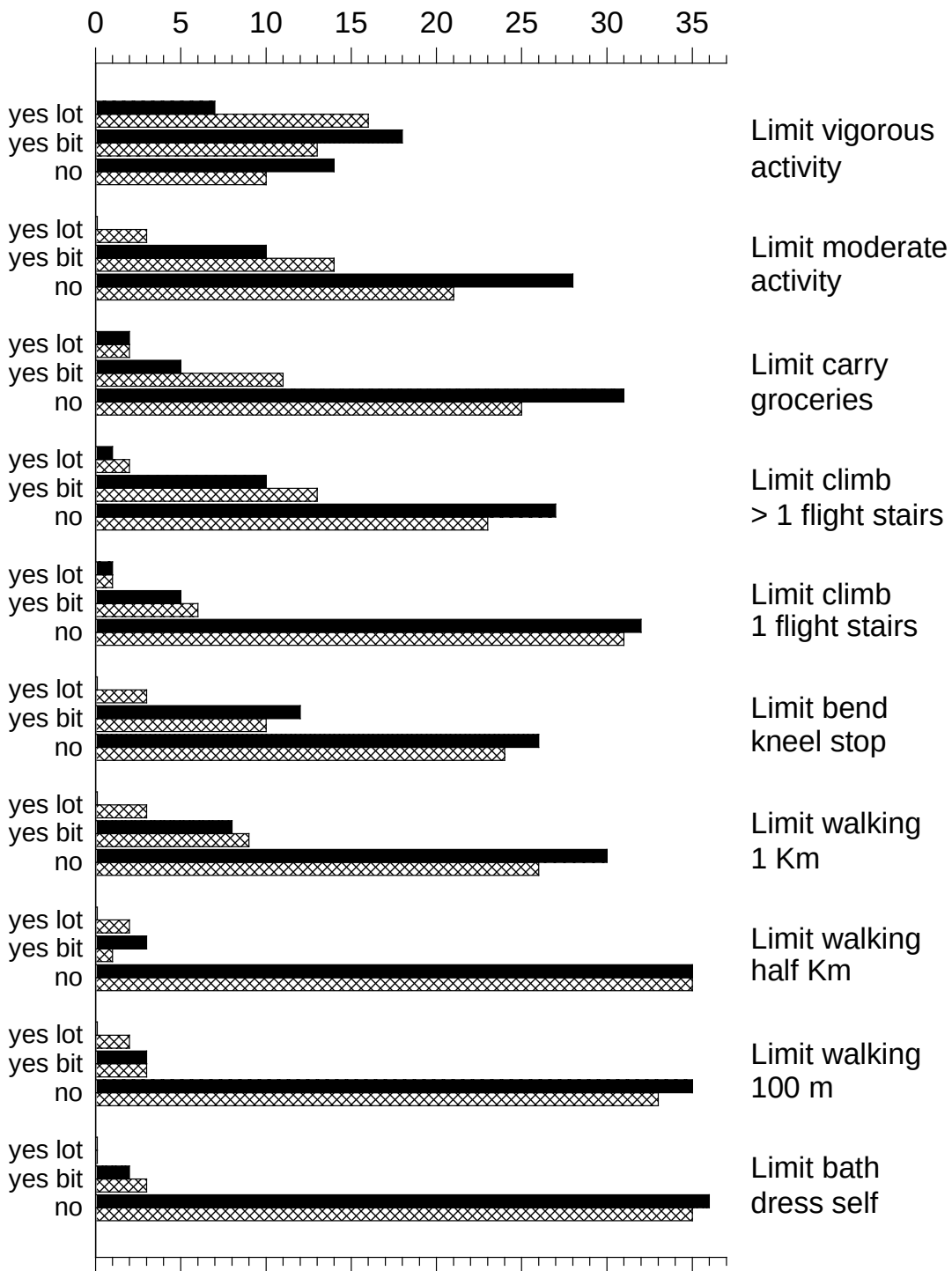
The patient's contribution in filling the form was quite simple and accepted willingly, taking between 10 minutes and a half hour. Only one patient refused to complete the questionnaire. Many patients (over 50%) asked some explanations from the doctor or the assistants in the surgery concerning the meaning of certain questions and the way to answer. These request regarded a maximum of one-two questions through the questionnaire. In these cases, the doctors and the assistants, according to the precise instructions of the protocol, provided only short explanations, without influencing the choice of the answer by the patient.

Answers to the questionnaire

The SF-36 questionnaire is composed of 36 questions, some of which are grouped according to 11 main topics, aimed at exploring many aspects of the patient's daily life as well as his/her symptoms. Questions 1 and 2, concerning general health, showed a clear and strong improvement in the post treatment period compared to the period before treatment. The number of cases where the state of health was declared as bad, dropped from 10 to 3 after treatment, and those with "very good health" rose from 0 to 7. The question n. 2 of the questionnaire, concerning a subjective evaluation of the patient's own health during the previous year showed a clear shift of judgements towards better health after treatment.

Figure 1. Frequency of patients' judgements of the limits in various physical activities caused by present health status. These data are from patients who completed both questionnaires.

▒ Before therapy ■ After therapy



ut normal physical activities according to the

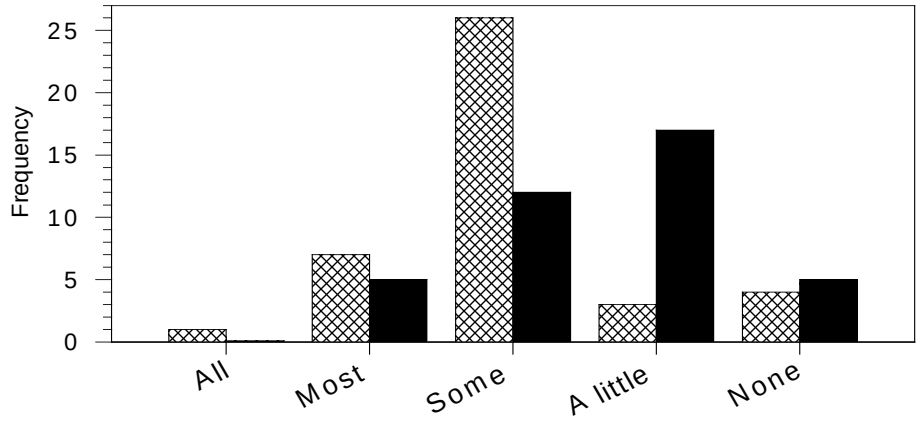
various parameters included in the SF-36 questionnaire. To the question: “Does your present state of health limit you in these activities? If so, how much?”, the patients replied in a way that showed an improvement after treatment, especially for vigorous (such as running, lifting heavy objects, participating in strenuous sports) or medium (such as moving a table, pushing a vacuum cleaner, bowling) physical efforts. The fact that the answers were graduated according to increasing physical effort (both for pre and post treatment) shows that the test is “dose-dependent”, and therefore is sensitive and suitable for quantitative evaluation of these parameters. On the whole, it is evident that the patients under survey were in reasonable physical health even before treatment, if we consider that most of them declared that they had no problems in carrying out the activities described. This seems coherent with the type of pathology under study and with the average age of the enrolled patients.

Even if the ability to perform physical efforts and the general state of health can be described as reasonable or good, the patients’ physical health has caused a number of problems at work and in other social activities all the same. In particular, the majority of the patients complained of difficulties in performing work and accomplished less than they would like. The information concerning physical pain (question n. 7 of the questionnaire) showed that the peak of patients judged it “severe” before the therapy and “mild” after therapy (data not shown).

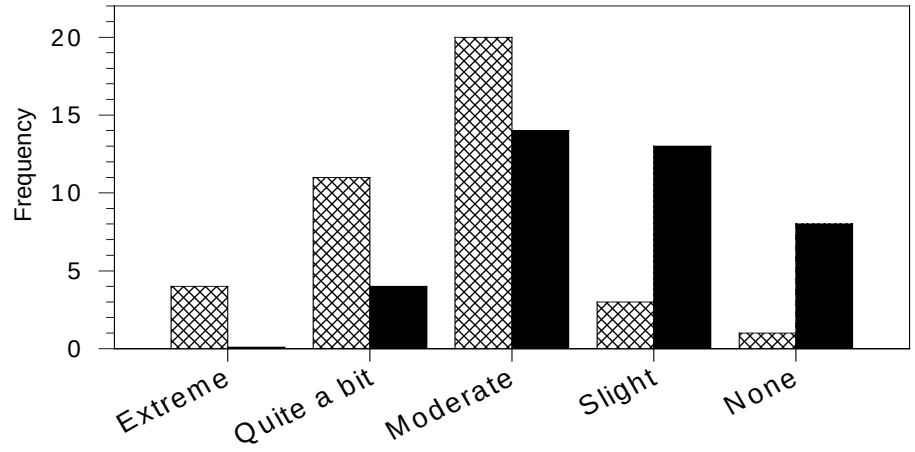
Several questions concerned the level in which the health problems (both physical and psychological) limited normal social activities.

Figure 2. Frequency of patients’ judgements of the interference on social activities by emotional problems (A) and by pain (B) and of the duration of that interference (C). These data are from patients who completed both questionnaires.

C - Interference of physical or emotional problems (how much time)



B - Interference of pain



ɔrtant parameter on life quality. None patient affected “quite a bit”, were strongly reduced o declared they were not affected at all (from by the pain (Figure 2B) was reduced after interfered slightly or not at all. In answer to es (Figure 2C), a wide range of the patients ous 4 weeks; after therapy, the largest group

Four questions of SF-36 explore the “vitality” levels, meaning vivacity and energy, both for psychological health and general well-being. The answers showed a definite improvement after therapy, especially in the reduction of the number of people who felt “worn out”, where the peak moved definitely from “some time” to “little”. The parameters concerning the so-called “mental health” also showed an improvement after treatment. Especially the question related to the fact that “nothing could cheer you up” registered a decided improvement after the therapy, whereas others questions asking whether the patient felt “nervous”, “calm”, “peaceful”, “downhearted” or “happy” showed only a slight improvement. This is in agreement with the fact that the main problem of these patients was related to pain and the interference of pain with general health and social activities. Another interesting observation appears the fact that after therapy most patients considered that the opinion that they would be more likely to fall sick than others, was false, meaning that they agreed with the trend towards improvement.

Dimensions of health status

The processing of the SF-36 scores, according to the international interpretation of the coded rules, permits the reduction of the set of questions down to eight fundamental “dimensions”, with the considerable advantage that this type of scoring can also be standardised in numerical scale form from a minimum of 0 (very bad health) to 100 (excellent health), to provide quantitative statistical evaluation. In general, the results of the calculations (Table 2) confirm the impressions obtained when observing the plain answers to each question.

Table 2. - Values of the eight dimensions of the SF-36 questionnaire before and after homeopathic therapy

SF-36 dimensions	N° of subjects	Mean (SD)		Median (5% - 95% percentile)		Condition after therapy N° of subjects (percent of total)			P PRE/POST	REFERENCE VALUES[2]	
		BEFORE	AFTER[1]	BEFORE	AFTER[1]	BETTER	WORSE	SAME[1]		Normal	Migraine
Physical functioning (PF)	43	79.3 (22.9)	85.6 (19.7)	85 (30-100)	85.6 (50-100)	20 (46.5%)	8 (18.6%)	15 (34.9%)	0.020	84.4 (23.1)	86.0 (19.4)
Role limitations due to physical problems (RP)	43	36.2 (38.6)	64.5 (38.7)	25 (0-100)	75 (0-100)	24 (55.8%)	5 (11.6%)	14 (32.6%)	0.0003	78.21 (35.9)	57.1 (40.9)
Bodily pain (BP)	44	37.8 (30.9)	57.4 (33.3)	36.5 (0-80)	57 (33-100)	28 (63.6%)	3 (6.8%)	13 (29.6%)	0.0000	73.7 (27.6)	48.5 (33.5)

		(20.9)	(22.3)	(0-80)	(22-100)	(63.6%)	(6.8%)	(29.6%)		(27.6)	(22.5)
Mental health (MH)	41	53.0 (16.9)	62.5 (17.7)	53.2 (28-76)	64 (36-84)	25 (61.0%)	8 (19.5%)	8 (19.5%)	0.0011	66.6 (20.9)	60.4 (18.2)
Role limitations due to emotional problems (RE)	43	37.9 (41.5)	65.1 (40.4)	33.3 (0-100)	66.6 (0-100)	21 (48.8%)	5 (11.6%)	17 (39.5%)	0.0011	76.2 (37.2)	57.3 (40.6)
Vitality (VT)	41	41.7 (16.3)	52.1 (19.6)	42.5 (10-65)	55 (15-80)	25 (61.0%)	5 (12.2%)	11 (26.8%)	0.0001	61.9 (20.9)	52.8 (18.9)
Social functioning (SF)	44	51.1 (18.8)	65.6 (21.9)	50 (25-87)	62.5 (25-100)	28 (63.6%)	5 (11.4%)	11 (25.0%)	0.0003	77.4 (23.3)	63.7 (22.4)
General health (GH)	43	53.5 (16.9)	62.4 (19.9)	52 (25-80)	65 (25-92)	30 (69.8%)	5 (11.6%)	8 (18.6%)	0.0002	65.2 (22.2)	59.6 (21.9)

[1]Includes data from 5 dropped-out cases that were treated as unimproved according to intention to treat (see text).

[2] Reference values for normal subjects are from a random sample (n=2031) of Italian adults, reference values for migraine are from a sample of 423 Italian adult patients affected by migraine.[13]

It can be seen that the average scores of the patients' dimensions before therapy were considerably low above all as far as pain (37.8/100) and the "role limitation" (36.2/100 and 37.9/100 for physical and emotional problems respectively) are concerned. However, the general physical capacity was fairly good (79.3/100), as already demonstrated in a semi-quantitative manner in the data shown in Figure 1. Therefore, in general, patients before therapy showed a reasonable to good level of physical activity, sufficient mental health, and sufficient general health, but there was strong suffering due to headache pain and the limits that this condition inflicts. The SD and the inter-percentile values were quite high, especially as the role limitations (RP and RE) are concerned, indicating that the impact of the disease on the life quality was heterogeneous in this group of patients.

After therapy, all scores rose and the results that were particularly noticeable were those of role limitation (these changed to 64.5/100 and 65.1/100 for physical and emotional problems respectively). There was also a change towards an improvement in the median values of the various parameters after therapy. Naturally the difference in the physical functioning limitations was

slight, because the starting point level was already reasonable or good. All the differences between pre/post treatment were statistically highly significant, with the strongest results in the “bodily pain” and “vitality” parameters ($p < 0.0001$).

Table 2 also shows the number and percent of patients whose conditions improved, worsened, or remained the same before and after therapy. More than 60% of the cases experienced an improvement where pain was concerned as well as in the limitations in social activities, in vitality and health in general.

The results concerning physical pain are particularly important, since they include the main symptom that brought the patient to consulting the doctor. Even though this questionnaire was not composed for some specific symptom type or area, it is obvious that the patients under observation were suffering from pain due to tension-type headache and migraine. Only in one single case did the doctor signal that the patient was affected with a tumour (that was not a brain tumour and was under conventional treatment) that worsened during the observation period. This case was included in the evaluation all the same, because tumours were not excluding criteria.

As a reference, the data from other independent studies done on Italian population are reported in the right-end two columns of Table 2. It can be seen that the SF36 scores at baseline in our cephalalgic patients are in the range or slightly lower as compared to the values which were reported in a group of subjects affected by migraine (no data for tension-type headache are available).[13] In our group after homeopathic treatment, the values of PF, MH and GH of patients became similar to the control averages, while the values of other parameters were still under the normal status, while considering that the comparison with the reference group is purely indicative.

Discussion

Although homeopathy is a form of medicine that is predominantly empiric and much research has been carried out over the past two hundred years, there is still no final agreement on the question of its proven efficacy, nor to the question of its possible action mechanisms. In fact, research that has been conducted according to criteria with completely acceptable methods is rare and the results are not incontestable. Also in basic research, many more problems have appeared than those that the experimentation was able to clarify. In the field of homeopathic treatment of headache, the evidence from randomized clinical trials (RCT) is still controversial.[23-27] It has been suggested that in the field of migraine, besides randomised controlled trials well performed outcome or audit prospective studies are likely to be useful in the long run in the objectifiation and quantification of the benefits of homeopathy.[28]

The object of this research was the homeopathic therapy in the field of migraine and chronic headaches, carried out at professional practice level. Because of the precise choice of method, it was necessary to respect the homeopathic type of follow-up that provides for an in-depth and often repeated conversation with the patient, as well as possible succession of different medicines, so this study was not carried out as a "blind study" with a placebo group, and therefore it cannot answer the question that is often considered crucial – "Does the homeopathic pharmaceutical act as a placebo?". On the other hand, it does face the question – that is probably more important from a practical point of view, concerning the method of verifying the effectiveness of the therapy on a common pathology, and testing it in the actual conditions where the treatment is applied. Therefore, an approach of this kind could bridge the distance between the results of clinical experimentation and the therapeutic decisions of single doctors, who often have to base their choices on personal experience only.

The basic question was aimed at discovering whether homeopathic treatment changes the state of health, evaluated according to the SF-36 questionnaire on the state of health, one of the most widely used instruments for measuring so called "life quality". This method was programmed on the basis of trustworthy theoretical and methodological conditions, and is the result of progressive experience in many international centres where it was elaborated. In Italy it has been very carefully translated and applied in many clinical situations.[16,17] The population standards are also well known. Data at baseline have shown that cephalalgic patients of our study suffered of severe impairment of their quality of life, with scores in the range or even lower than those reported by others for migraine patients.[13] A possible explanation of the low values at baseline (particularly as regards RP, BP and RE parameters) may be the fact that usually patients use to go to the homeopath after having unsuccessfully tried conventional painkillers and this may select the more severely impaired patients.

This experience would confirm the SF-36 questionnaire as a valid instrument for recording the changes in physical and emotional conditions during homeopathic therapy, a conclusion in agreement with previous reports.[7] The follow-up of the homeopathic treatment as shown in the questionnaire concerning the general state of health, permitted the doctors to register with sensitivity, precision, and selectivity, all the changes that took place, the way of dealing with a chronic condition mainly with painful symptoms, over a period of several months.

We would like to mention certain problems that arose with the running of this clinical research. The initial application of this method using a questionnaire in the private surgery did provoke a little incomprehension involving some getting used to the system by both doctors and patients. Many patients asked for explanations on certain questions; moreover, in six cases the second questionnaire was filled in at the same time as the first, making reference to the patient's memory of six months previously, thus demonstrating scarce attention to the respect of the protocol by the doctor.

There is no doubt that the results obtained from this observational study are positive, even though it is also necessary to maintain some caution, since it is well known that observational studies based on questionnaires cannot guarantee absolute

certainty on the efficacy of a certain treatment (in both conventional and complementary medicine) because of the intrinsic methodological limits. Naturally, the lack of a parallel control group is the main limiting factor in this type of research study and this prevents the distinguishing of the efficacy of the treatment from possible spontaneous improvement and/or from the co-related phenomenon called “regression towards the mean” (where the patient would tend to come to the doctor for the first visit at the moment the symptoms are strongest, while the following visits would represent the normal situation of his condition). However, as a partial answer to this objection, it should be considered that the inclusion criteria provided for cases of headache with at least a two year history, and therefore the disease under evaluation was a chronic situation which was relieved for most of the patients after a period of a few months of homeopathic treatment.

As far as the clinical results in terms of the patients’ subjective opinions are concerned, it has been demonstrated that the pain was considerably reduced in about 60% of the patients over the 5 month observation period, bringing a decided improvement in their daily lives, work and social activities. Only a minority of patients (6.8% to 19.5%) declared to have worsened after therapy. The number of drop-outs – those patients who did not complete the second questionnaire (about 10%) was quite low and substantially acceptable for this type of study. These data, that quantify the decrease of suffering and of limitations of daily life in over half of all patients enrolled in the study may be of obvious interest for any patient undertaking this kind of therapy.

Patients today want to be adequately informed, and want to make their decisions in full awareness of the situation. In this context, new developments in complementary medicine – among which homeopathy play an important role – are considered with increasing favour by the public. Therefore, there is necessity of improving data collection and exchange systems and the evaluation of therapy outcome with validated questionnaires of the life quality and patient satisfaction are important options for this documentation.[28-30] The work completed up till this point would encourage the continuation of this study that, with a minimum of involvement by the medical practitioner, has demonstrated that it can be easily carried out in private surgeries coordinated with an external and independent observatory. Lastly, this preliminary experience can provide help with the programming of studies in various pathologies and according to other therapeutic protocols.

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