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

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This study describes the results obtained from a prospective observational research of homeopathic treatment for patients suffering from headache (migraine with- and without aura and tension-type headache). Fifty-three patients were asked to complete the SF-36 questionnaire at the beginning of the treatment and after 4–6 months. The homeopathic medicine and potency were not pre-defined, but were adapted to each single patient according to individualised homeopathic prescription. Most patients (73.6%) completed the study. There was heterogeneity in the answers (patients in very poor health as well as those with only slight disorders). Analysis of the data according to the concept of 'intention-to-treat' showed that after therapy, the mean and median scores of all life quality dimensions rose. More than 60% of the cases experienced an improvement in pain and the limitations caused by pain, as well as in limitations in social activities and health in general. All the differences between pre/post post treatment were statistically highly significant, with the strongest results in the 'bodily pain' and 'vitality' parameters ($P < 0.0001$). *British Homeopathic Journal* (2001) **90,** 189–197.

Keywords: cephalalgia; migraine; observational study; prospective study; homeopathy; clinical research methods; quality of life

Introduction

Homeopathic medical practitioners maintain that homeopathy is an effective form of therapy. But the clinical effects of homeopathic treatment are still controversial in the field of biomedical research, because 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.[1–3]

The specificity of homeopathy, which requires methodological adaptations at variance with conventional study protocols, lies in the following:

(a) the practitioner must take into consideration the patient's global and individual condition. A prescription cannot be made automatically on the basis of a diagnosis;
(b) the 'medicine' is given in very small, even infinitely small, doses. The therapeutic effects are determined from experiments on healthy subjects ('provings'). This requires detailed knowledge of homeopathic Materia Medica;
(c) homeopathy generally envisages a 'second prescription' based on the effects obtained after the first treatment;
(d) the outcome of the homeopathic treatment must be evaluated not only considering the main symptom that led the patient to consult the doctor, but also the patients 'Quality of Life' and other parameters like the dynamic change of symptoms ('Hering's rule').

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Because of this specificity, the results of clinical research must be evaluated using instruments that examine a range of variables concerning the health of the patient as a whole. It is important to calculate the state of health using standardised responses to standardised questions,[4] adopted in various complementary therapies[5] and homeopathy.[6,7] It has been suggested[6] that the interpretation of the scores generated by questionnaires may be problematic as the significance of changes in scores for different health concepts is likely to be interpreted differently by conventional doctors and homeopaths, particularly when these scores are being used to assess overall change in health status. These problems call for further studies. In any case, it is essential that the instruments used 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 consultation context.

Clinical research methods can be 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. The second is non-experimental (or observational) research where the treatment and the sample choice are not predetermined, or if so, only to a minor degree, by the researcher. Experimental research is more reliable for establishing the efficacy of a medicinal product or procedures (especially if this can be carried out under blind conditions and with adequate randomisation). But observational studies have the advantage of respecting 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 the treatment deserves further, experimental research.[8–11] Another important aspect is the greater value of prospective compared to retrospective studies. This is because with *prospective* designs it is possible to evaluate with greater precision and reliability the number of enrolled patients and the number of drop-outs.

This report describes the results obtained from a prospective observational research programme of homeopathic treatment for patients suffering from migraine and chronic or recurrent headaches (collectively, 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. This programme used questionnaires to evaluate changes in life quality and symptoms in cephalalgic patients treated in routine practice by qualified doctors specialising in homeopathy. The protocol was designed and implemented by a group of homeopaths, most of whom are professors at the School of Homeopathic Medicine of 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 at the initiative of the University and of the Medical Association.

We used the Short Form-36 (SF-36) health-related Quality of Life questionnaire, which has been validated in various fields.[14–18] This respects both the necessity for documentation that is as complete as possible concerning the physical and psychological symptoms, and 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 primary care settings.

We planned 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. This last point is important because of regulatory implications, the medicinal products employed in this study are all included in the list of the products currently authorised by the Italian Ministry of Health.

Methods

Study design and patients

This was a prospective observational study, consisting of evaluation at the beginning of treatment (first visit) and a second evaluation after 4–6 months. The second evaluation was independent of the number of visits in the mean time. The criteria for inclusion were: patients of either sex; age range between 15 and 65; suffering from cephalalgia for a period of at least 2 y. Patients diagnosed as suffering from migraine (with- and without aura) or tension-type headache (groups 1 and 2 according to the International Headache Society)[19] were included. 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 psychological or character problems. The outcome was calculated according to the subjective clinical and symptomatological data obtained before and after treatment, using the SF-36 questionnaire.

The study was carried out between June 1999 and December 2000 in the private practices of the practitioners (all medical doctors) who participated (the authors of this paper, except PB) located in various towns in the Veneto and Lombardia regions. All data was sent to Professor Paolo Bellavite of the OMC at the Department of Biomedical Morphological Sciences of Verona University for safekeeping and data processing.

Protocol

The doctor made the diagnosis and evaluated whether the patient was eligible. The proposal to participate in the study was made to all patients eligible according to the criteria, without any further options (such as including only those patients where the doctor felt he had found the correct remedy). After the patient had been informed about homeopathy and the research study, if they were willing, they gave written consent to personal data management for research purposes. A questionnaire was given and the patient was invited to complete it according to the instructions, given orally and on an information sheet. In particular, the most important points were:

(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 will be processed in a completely anonymous manner and coded by independent observers;
(d) that the answers do not have any influence on the type of treatment 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 medicine and dose were not preestablished, but were adapted to each patient according to individualised homeopathic prescription (see below for details). The prescribers decided 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 analgesics if necessary, but no other homeopathic medicine. The patient visited the doctor the number of times it was felt necessary. Follow-up was also available for phone calls for urgent advice.

After 4–6 months (ideally 5 months) when the patient returned for a follow-up, he was given another questionnaire identical to the first one, to be completed according to the same criteria as 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). If patients did not appear spontaneously during the 4–6 month period after the first visit, they were contacted by phone or by letter, requesting them to come to the surgery or at least complete 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 translated and validated by Apolone and Mosconi.[17] Most of the questions concern symptoms or sensations experienced during the preceding 4 weeks. The answers to these questions are 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 summarises the main dimensions and scales of the SF-36. This is an adequate instrument for evaluating the evolution of chronic illnesses and their impact on

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 due to emotional problems (RE)	Difficulty with work or other daily activities because of emotional problems	No problems with work 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]

various aspects of life quality. Once the questionnaire had been completed, it was sent immediately to the OMC where it was registered and given a sequential number. All the transformations of the scores were executed with an algorithm programmed in '*Stata*' software. Because the distribution of many of the answers was not normal, the difference between results before and after treatment, were calculated with a non-parametric test, using the Wilcoxon matched-pairs signed-ranks test (pre/post therapy).[21,22]

Treatment

The method of prescribing was individualised 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 (improvement after rest is very common). Normally 3–10 such homeopathic symptoms per patient would be collected, although there is some variation. When selecting symptoms, the homeopath will give preference to the symptoms that are described as intense by the patient and 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. 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 and described in the Materia Medica. At follow-up, any new symptoms that may have appeared are evaluated according to the so-called Hering principle.

Results

Fifty-three patients were recruited during the research programme, and the 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 to complete the second questionnaire. These five 'drop-out' patients were included in the statistical analysis, in analogy with the intention-to-treat concept, as if they were unimproved (ie using the scores of the first questionnaire for the after-therapy values). Information from both questionnaires (before and after treatment) was available for 48 patients. 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 completed at the second visit, therefore the first questionnaire was completed retrospectively. One was eliminated because treatment was suspended because of pregnancy, another because the questionnaire was incomplete, another because his age was lower than that specified in the inclusion criteria. In total, 44 cases were included in the statistical evaluation (83% of total), 39 of which were complete (73.6% of total) and five of which responded only to the first questionnaire (9.4%) but were analysed according to the intention-to-treat principle. The group was composed of 36 women and eight men with an average age of 37.5 ± 12.7 y (range 16–66 y). The period of the medical treatment, or the interval between the first and second questionnaire was 4.9 ± 2.9 months (range 1–15 months). A few patients did not answer all questions, when three or less questions were unanswered the questionnaire was retained for analysis.

The medicines used as a first choice were as follows: six cases *Natrum muriaticum*, three cases *Staphysagria*, *Lycopodium*, *Lachesis* and *Nux vomica*, two cases *Pulsatilla*, *Arsenicum album*, *Stramonium*, *Sepia* and *Ignatia*, one 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 eight cases the medicine was changed during the treatment as follows: *Carbo vegetabilis* after *Nux moschata*, *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 generally accepted willingly, taking between 10 and 30 min. Only one patient refused to complete the questionnaire. Many patients (over 50%) asked for some additional explanation from the doctor or practice staff concerning the meaning of certain questions and answers. In these cases, the doctors and their staff, according to the instructions of the protocol, provided only short explanations, without influencing the choice of the answer by the patient.

Questionnaire responses

The SF-36 questionnaire is composed of 36 questions, 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 three after treatment, and those with 'very good health' rose from zero to seven. Question 2 of the questionnaire, concerning a subjective evaluation of the patient's own health during the previous year showed a clear shift towards better health after treatment.

Figure 1 shows details of the ability to carry out normal physical activities according to the parameters of the SF-36. 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 effort. 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 were in reasonable physical health 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 caused a number of problems at work and in other social activities. 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 showed that the greatest number of patients judged it 'severe' before the therapy and 'mild' after therapy (data not shown).

Several questions concerned the level to which health problems (both physical and psychological) limited normal social activities. Figure 2(a) shows that the patients were moderately disturbed in this important parameter of life quality. No patient declared himself 'extremely' affected. The patients who declared that their life was affected 'quite a bit', were reduced after treatment (from 10 to two), and there was an increase in those who declared they were not affected at all (from four to 11). The level of interference with work and other daily activities caused by the pain (Figure 2b) was reduced after homeopathic treatment and a number of patients reported that the pain interfered slightly or not at all. In answer to the question on interference of health state with social activities (Figure 2c), most of the patients (26/39) declared that their state of health had interfered 'some of the time' over the previous 4 weeks; after therapy, the largest group (17/39) reported that the problem had interfered 'a little'.

Four questions of the SF-36 explore the 'vitality' for psychological health and general wellbeing. The answers showed a definite improvement after therapy, especially the number who felt 'worn out', where the peak moved from 'some of the time' to 'little'. The parameters 'mental health' also showed an improvement after treatment. The question 'nothing could cheer you up' registered a particular improvement

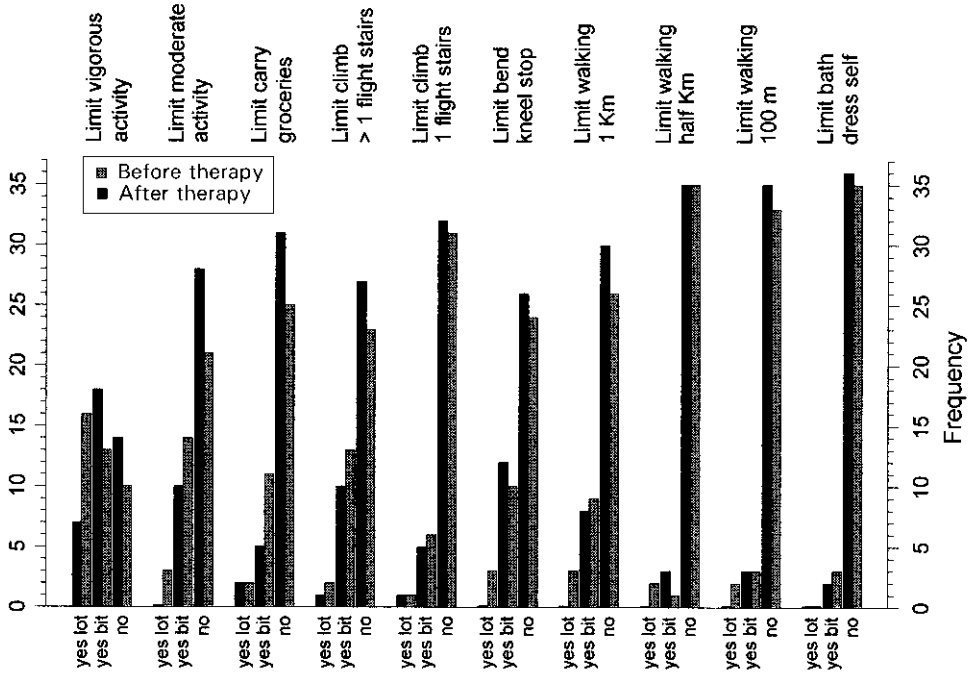

Figure 1 Frequency of patients' judgements of the limits in various physical activities caused by present health status. These data are from patients who completed both questionnaires.

after therapy. Other 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 is that after therapy most patients considered that the opinion that they would be more likely to fall sick than others was false, indicating that they agreed with the trend towards improvement.

Dimensions of health status

Processing of the SF-36 scores, according to agreed international interpretation, permits the reduction of the set of questions down to eight fundamental 'dimensions', with the advantage that this score can be standardised in numerical scale from 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 from the answers to each question. It can be seen that the average scores of the patients' dimensions before therapy were low particularly as far as pain (37.8/100) and 'role limitation' (36.2/100 and 37.9/100 for physical and emotional problems, respectively) are concerned. General physical capacity was fairly good (79.3/100). Therefore, in general, patients before therapy showed a reasonable to good level of physical activity, satisfactory mental health, and general health, but there was strong suffering due to headache pain and the limits that this condition imposed. The SD and the inter-percentile values were quite high, especially for role limitation (RP and RE), indicating that the impact of the disease on the life quality was heterogeneous in this group of patients.

After therapy, all scores rose. The results that were particularly noticeable were role limitation. There was also a change towards an improvement in the median values of the various parameters after therapy. The difference in the physical functioning limitations was slight, because the baseline was already reasonable or good. All the differences between pre/post treatment were statistically highly significant, with the strongest effects in the 'bodily pain' and 'vitality' parameters ($P < 0.0001$).

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

The results concerning physical pain are particularly important, since they include the main symptom that brought the patient to consult the doctor. Even though this questionnaire does not include any specific symptom type or area, it is obvious that the patients were suffering from pain due to tension-type headache and migraine. Only in one case did the

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

SF-36 dimensions	*No of subjects*	*Mean (s.d)*		*Median (5%–95%) percentile*		*Condition after therapy no of subjects (percentage of total)*			*P Pre/Post*	*Reference values*[b]	
		Before	*After*[a]	*Before*	*After*[a]	*Better*	*Worse*	*Same*[a]		*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 (20.9)	57.4 (22.3)	36.5 (0–80)	57 (22–100)	28 (63.6%)	3 (6.8%)	13 (29.6%)	0.0000	73.7 (27.6)	48.5 (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)

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

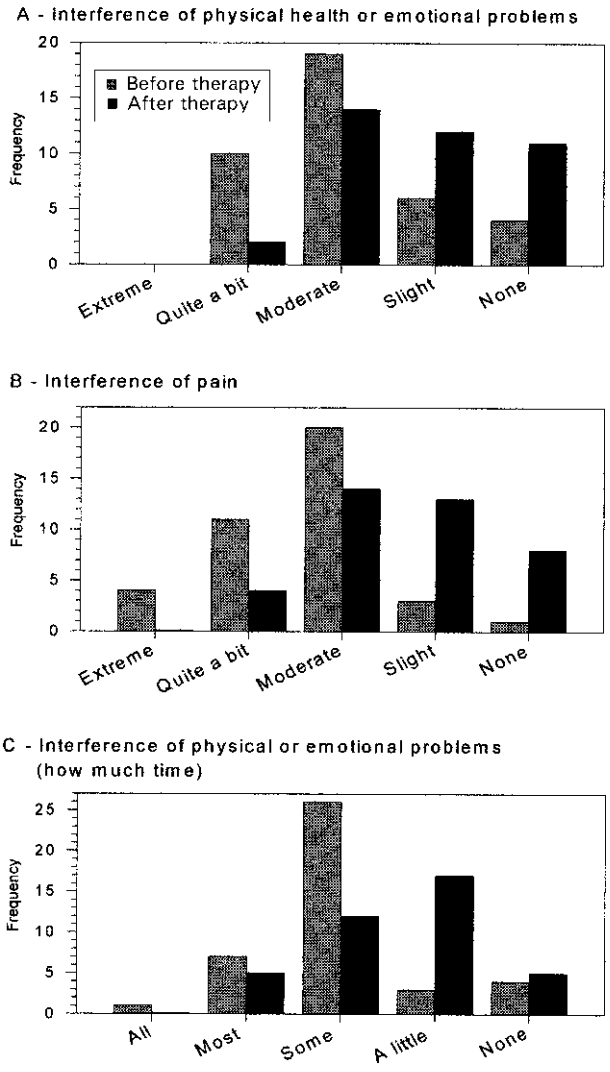

Figure 2 Frequency of patients' judgements of the interference on social activities by emotional problems (a) and by pain (b) and of the duration of that interference (c). These data are from patients who completed both questionnaires.

doctor signal that the patient was affected with a tumour (not a brain tumour and under conventional treatment) that worsened during the observation period. This case was included in the evaluation, because tumours were not in the exclusion criteria.

As a reference, the data from other independent studies done on an Italian population are reported in the right-hand 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 below normal.

Discussion

Although homeopathy is predominantly empirical and much research has been carried out over the past 200 y, there is still no agreement on the question of its efficacy, nor of its possible mechanisms of action. In fact, research that has been conducted according to criteria with completely acceptable methods is rare and the results not incontestable. Also in basic research, many more problems have appeared than experimentation was able to clarify. In homeopathic treatment of headache, the evidence from randomised clinical trials (RCT) is still controversial.[23–27] It has been suggested that in migraine, besides RCTs well performed outcome or audit prospective studies are likely to be useful in the long-term objectification and quantification of the benefits of homeopathy.[28]

The object of this research was the homeopathic therapy in migraine and chronic headaches, carried out at professional practice level. Because of the choice of method, it was necessary to respect homeopathic follow-up that provides for an in-depth and sometimes repeated conversation with the patient, as well as possible succession of different medicines, so this study was not carried out 'blind' 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 questions, probably more important from a practical point of view, verifying the effectiveness of the therapy in a common condition, and testing it in the actual conditions where the treatment is applied. Therefore, an approach of this kind could bridge the gap between the results of clinical experimentation and the therapeutic decisions of single doctors, who often base their choices on personal experience.

The basic question was to determine whether homeopathic treatment changes the state of health, evaluated according to the SF-36 health status questionnaire, one of the most widely used instruments for measuring so called 'Quality of Life'. This questionnaire has been systematically and internationally developed and validated. In Italy it has been translated and validated and applied in many clinical situations.[16,17] The population standards are also well known. Data at baseline have shown that cephalalgic patients in our study suffered a severe impairment to 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 that patients often go to the homeopath after having unsuccessfully tried conventional painkillers, this may select the more severely impaired patients.

Our experience confirms the SF-36 as a valid instrument for recording the changes in physical and emotional conditions during homeopathic therapy, a

conclusion in agreement with previous reports.[7] Follow-up concerning general state of health, permitted the doctors to register with sensitivity, precision, and selectivity, all the changes that took place, in a chronic condition mainly with painful symptoms, over a period of several months.

We would like to mention certain problems that arose during this clinical research. The initial application of this method using a questionnaire in private practice did provoke some misunderstanding from 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 scant attention to the respect of the protocol by the doctor.

There is no doubt that the results obtained from this observational study are positive, but it is 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 limits of the method. The lack of a control group is the main limiting factor in this type of research study and prevents the distinguishing of the efficacy of the treatment from possible spontaneous improvement and/or from the related phenomenon 'regression to the mean' (where the patient would tend to come to the doctor for the first visit when 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 of least 2 y duration, and therefore the disease under evaluation was a chronic situation.

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%–19.5%) declared themselves worse after therapy. The number of drop-outs—those patients who did not complete the second questionnaire (about 10%) was quite low and 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 are 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 plays an important role—are considered with increasing favour by the public. Therefore, there is the 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 practices coordinated with an external and independent centre. Lastly, this preliminary experience can provide help with the design of studies in various pathologies and according to other therapeutic protocols.

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