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ORIGINAL PAPER

Treating hot flushes in menopausal women with homeopathic treatment–Results of an observational study

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Objective: **There is great controversy concerning treatment for menopausal symptoms. We evaluated homeopathic treatments for hot flushes and their effect on quality of life in menopausal women.**
Methods: **Open, multi-national prospective, pragmatic and non-comparative observational study of homeopathic treatments prescribed and their effectiveness, observing their impact on quality of life.**
Results: **Ninety-nine physicians in 8 countries took part in this study and included 438 patients with an average age of 55.**
Homeopathic medicines were prescribed to all patients; 98% of the prescription lines were for homeopathic medicines. *Lachesis mutus, Belladonna, Sepia officinalis, Sulphur* and *Sanguinaria canadensis* were the most prescribed. A non-homeopathic treatment and/or food supplement prescribed for 5% of the patients.
This observational study revealed a significant reduction ($p<0.001$) in the frequency of hot flushes by day and night and a significant reduction in the daily discomfort they caused (mean fall of 3.6 and 3.8 points respectively, on a 10 cm visual analogue scale; $p<0.001$).
Ninety percent of the women reported disappearance or lessening of their symptoms, these changes mostly taking place within 15 days of starting homeopathic treatment.
Conclusions: **The results of this observational study suggest that homeopathic treatment for hot flushes in menopausal women is effective. Further studies including randomized controlled trials should be conducted.** *Homeopathy* (2008) **97,** 10–15.

Keywords: homeopathy; hot flushes; homeopathic treatment; observational study; menopause

Introduction

The menopause is defined by at least 12 months of amenorrhea in women aged at least 50 (with or without a measured increase in serum level of FSH), negative testing for progesterone in women aged at least 45[1] or bilateral oophorectomy in women of child-bearing age.

Hot flushes (or flashes) are sudden sensations of intense heat, mainly affecting the upper part of the body and lasting for 1–5 min on average. They may be accompanied by facial redness, perspiration that is sometimes heavy, palpitations, anxiety, irritability and nocturnal sweating. The physiological mechanism

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[1]Testing for progesterone is said to be negative in the absence of withdrawal bleeding after the administration of a progestational treatment for 10 days per month for at least 3 consecutive months.

governing hot flushes is not precisely known. During the menopause has started, 8 women in 10 report hot flushes of varying intensity, which may affect their sleep and quality of life.[1,2] These hot flushes are the main reason for instigating hormone replacement treatment (HRT). According to the survey undertaken in April 2004 by the ''Société Française d'études par Sondage'' (Sofres—French Society for Studies via Surveys), on behalf of the ''Agence Nationale d'accréditation et d'évaluation en Santé'' (Anaes—National Agency for Health Accreditation and Evaluation), 25.5% of menopausal women aged 45–70 in December 2003 were taking hormone replacement treatment. The iatrogenic consequences of these treatments is a major public health issue.[3]

Although they may have an effect on hot flushes, soya derivatives, specifically phyto-oestrogens' are products for which the risks have not been evaluated and are not monitored, and which do not meet health and safety requirements for medicinal substances. The ''Agence Française de Sécurité Sanitaire des Produits de Santé'' (Afssaps—French Health Products Safety Agency) does not recommend soya derivatives alone to treat hot flushes.[3]

Hot flushes and their consequences in menopausal women can be treated with homeopathic treatment. *Lachesis mutus, Sulphur, Sepia officinalis*, *Belladonna, Glonoinum, Sanguinaria canadensis* and *Amylium nitrosum* are the medicines most commonly indicated for the treatment of hot flushes in menopausal women.[4]

Several studies have been published evaluating homeopathy (individualized or not) in menopausal symptoms, particularly in women who have suffered from breast cancer.[1,5–7] Jacobs *et al*'s study was a randomized, double-blind study versus placebo performed over 1 year with 83 women suffering from breast cancer; patients received either individualized homeopathic treatment or a homeopathic complex or a placebo. This study did not show any significant difference between the three patient groups relative to the severity and frequency of hot flushes although there was a positive trend in the ''individualized homeopathic treatment'' group during the first 3 months of the study. But there was a significant improvement in quality of life in the 2 groups of patients taking homeopathic treatment compared with the group who received the placebo.[5]

Thompson *et al* conducted a prospective observational study with 45 women suffering from breast cancer. The homeopathic approach (individualized treatment) was evaluated in this study. The authors concluded that there was a significant reduction in symptoms linked to oestrogen deficiency between the start and end of the study.[6]

A second study by Thompson *et al* was a randomized, double-blind study versus placebo which was performed over 4 months with 57 women suffering from breast cancer; individualized homeopathic treatment was compared with a placebo: this study did not show any significant difference between the 2 patient groups for the criteria evaluated.[7]

Literature reviews and observational studies have also been published on alternative and complementary treatments for menopausal symptoms[8–10] and hot flushes.[2,11,12] These studies show that some complementary treatments can be beneficial to patients and recommend that further randomized clinical studies be performed to confirm these results.

The homeopathic strategy is therefore a valid part of the therapeutic arsenal, particularly in the current context where hormone replacement therapy is being questioned and vigilance required on the use of food supplements based on soya isoflavones alone.[13–24]

In this context, we decided to perform an observational study with physicians prescribing homeopathic medicines. The study objective was to evaluate homeopathic treatment for hot flushes in menopausal women in terms of prescribed medical treatment, effectiveness and impact on quality of life.

Method

Study design

An open, multi-national pragmatic, prospective, non-comparative observational study of the practice of physicians prescribing homeopathic drugs was organized in 2005 with physicians from 8 different countries.

Recruitment of investigating physicians

This observational study was proposed to 157 physicians who prescribe homeopathic medicines. The physicians, GPs or gynaecologists, were recruited on a voluntary basis if they were interested.

This study was observational and each physician remained totally free regarding to his prescriptions and his treatment choices so it was not necessary to ask the advice of an ethics committee.

Patient selection

Inclusion criteria:

- women aged over 45;
- established menopause;
- suffering from hot flushes;
- not taking either homeopathic treatment or hormone treatment to reduce their hot flushes;
- not taking Raloxifene.

Patients using topical hormone treatment for vulvo-vaginal trophic disorders linked to the menopause were included in the study.

We defined established menopause as follows:

- at least 12 months of amenorrhea in women aged at least 50;
- or testing negative for progesterone (ie the absence of withdrawal bleeding after administration of a

progestational drug for 10 days per month over at least 3 consecutive months) in women aged at least 45;
- or when a bilateral oophorectomy had been performed on a previously menstruating woman.

Exclusion criteria:

- patients not meeting the inclusion criteria;
- patients suffering from hormone-dependent cancer.

Evaluation criteria

The patients were assessed twice during the study: at the inclusion visit and at the final visit.

Clinical effectiveness

The evolution of clinical symptoms and the diurnal and nocturnal frequency of hot flushes was evaluated as follows:

(1) The evolution of the patients' clinical condition was measured at final visit by a question with four responses: disappearance (no symptom), improvement (lessening of symptoms), no change (same symptoms) or aggravation (deterioration of symptoms).
(2) Diurnal frequency of hot flushes, compared at the inclusion visit and the final visit. We measured the percentage of patients who reported 0 to 5, 6 to 10 or more than 10 hot flushes per day, at each visit.
(3) Nocturnal frequency of hot flushes, compared at the inclusion visit and at the final visit. We measured the percentage of patients who reported 0 to 5, 6 to 10 or more than 10 hot flushes at night, at each visit.
(4) The percentage of patients who suffered from daily hot flushes was compared at the inclusion visit and at the final visit of the study.
(5) These measures were recorded by physicians who questioned patients for retrospective recall.

Quality of life

The evolution of the impact of hot flushes on quality of life was measured by two different visual analogue scales, graded from 0 to 10.

One scale measured the discomfort caused during daytime with the question: ''When you have a hot flushes during the day, how would you describe the discomfort in your life?'' A score of 10 indicates the most disturbed day life.

The other scale measured the effect on sleep by using the question: ''When you have hot flushes at night, how would you describe the consequences on your sleep?'' A score of 10 indicates the most disturbed sleep.

These scales were recorded by patients at the inclusion visit and at the final visit of the study. These scales were specifically developed for the study but were not validated.

Duration of the study

The period of inclusion in the study was from 17 January to 30 June 2005.

Follow-up was provided between 2 and 6 months following the inclusion visit, depending on the physician's practice.

Statistical analysis

The results analysis was per protocol because it concerns all patients who adhered strictly to the protocol, particularly relative to respecting the inclusion criteria.

The statistical analysis was performed using tests appropriate for the variables, ie:

- for qualitative variables: Chi-squared test (χ^2);
- for quantitative variables: Student's test.

Alpha risk was set at 5%.
No subgroup analysis was performed.

Results

The physicians

Ninety-nine physicians in 8 countries took part in this observational study: 53 French, 23 Tunisian, 9 Brazilian, 5 Polish, 3 Bulgarian, 3 Portuguese, 2 Moroccans and 1 Italian.

The patients

A total of 489 patients were included in this study. We analysed the data for 438 case files. The 51 case files excluded are explained by:

- 33 lost to follow-up;
- 18 cases did not meeting the inclusion criteria;

The geographical distribution of the patients was as follows: 241 France (55%), 102 Tunisia (23%), 32 Brazil (7%), 32 Poland (7%), 14 Bulgaria (3%), 7 Morocco (2%), 5 Portugal (1%) and 5 Italy (1%). The average age of the patients was 55 (45–76).

The patients were followed at the inclusion visit and at the final visit depending on the physician's practice. The average duration of follow-up was 98 days. 11% of patients were followed-up in 60 days, 66% of patients were followed-up from 60 to 120 days, 17% of patients were followed-up from 120 to 180 days and 6% of patients were followed-up later than 180 days.

Medical treatments

Since this was an observational study, each physician remained totally free regarding to his prescriptions and treatment choices. Participating physicians prescribed a total of 1506 prescription lines for 438 patients, ie 3.4 medications per patient, on average. One prescription line corresponds to one medication prescribed to one patient at the inclusion visit.

Medications were given simultaneously or sequentially depending on the physician's practice. Homeopathic treatment was prescribed for all the patients. Homeopathic treatments covered 98% of the prescribed medication (1475 prescription lines). Five percent of patients (22 patients) also received non-homeopathic medication (notably minerals) and/or food supplements (notably soya-based). These treatments covered 2% of the total prescriptions (31 prescription lines).

Table 1 shows the 12 homeopathic medications most prescribed during this study; the main ones are: *Lachesis mutus, Belladonna, Sepia officinalis, Sulphur, Sanguinaria canadensis* and *Glonoinum. Lachesis mutus, Sepia officinalis* and *Sulphur* were most often prescribed at a dilution of 9 cH, whereas *Belladonna, Sanguinaria canadensis* and *Glonoinum* were more frequently prescribed at a dilution of 15 cH. Sixty-five percent of the 438 patients received *Lachesis mutus* and 43% received *Belladonna. Sepia officinalis, Sulphur, Sanguinaria canadensis* and *Glonoinum* were prescribed for 26%, 25%, 21% and 15% of the patients, respectively.

Table 2 shows the 16 homeopathic medications most prescribed for the 83 patients who noted a disappearance of their symptoms. *Lachesis mutus, Belladonna, Sepia officinalis, Folliculinum, Sanguinaria canadensis, Sulphur and FSH* were the main homeopathic treatments prescribed for these patients. Table 3 shows the 16 homeopathic medications most prescribed for the 301 patients who noted an improvement in their symptoms. *Lachesis mutus, Belladonna, Sulphur, Sepia officinalis, Sanguinaria canadensis, Glonoinum* and *FSH* were the main homeopathic treatments prescribed for these patients.

Clinical effectiveness

At the inclusion visit, 89% of patients suffered from daily hot flushes. This percentage was reduced to 39% at the final visit ($p<0.001$). Thus more than 50% of the patients suffering from daily hot flushes at the beginning of the study, no longer suffered daily from them at the final visit. At the inclusion visit, 46%, 38% and 16% of the patients experienced 0 to 5, 6 to 10 and more than 10 hot flushes per day respectively, compared to 90%, 8% and 2% of patients, respectively at the final visit (see Figure 1). The number of diurnal hot flushes fell significantly between the inclusion and follow-up visits ($p<0.001$). At the inclusion visit, 69%, 23% and 8% of the patients, experienced 0–5, 6–10 and more than 10 hot flushes per night respectively, compared to 93%, 5% and 1% of patients, respectively, at the final visit (see Figure 2). The number of nocturnal hot flushes fell significantly between the inclusion and follow-up visits ($p<0.001$). Ninety percent of the women (384 patients) noted

Table 2 The 16 most prescribed homeopathic medications for the 83 patients who noted a disappearance of their symptoms

Names of homeopathic medications prescribed for the patients who noted a disappearance of their symptoms	*Number of lines*	*%*	*Total (%)*
Lachesis mutus	51	18.35	18.35
Belladonna	41	14.75	33.09
Sepia officinalis	35	12.59	45.68
Folliculinum	15	5.40	51.08
Sanguinaria canadensis	15	5.40	56.47
Sulphur	14	5.04	61.51
FSH	13	4.68	66.19
Glonoinum	12	4.32	70.50
Thuja occidentalis	11	3.96	74.46
Ignatia amara	8	2.88	77.34
LH-RH	8	2.88	80.22
Natrum muriaticum	5	1.80	82.01
Luteinum	5	1.80	83.81
Progesteronum	4	1.44	85.25
Amylium nitrosum	4	1.44	86.69
Lycopodium clavatum	3	1.08	87.77
Others	34	12.23	100.00
Total homeopathic medications	278	100.00	–

Table 1 The 12 most prescribed homeopathic medications

Names of homeopathic medications	*Number of lines*	*Total medications*		*Total homeopathic medications*	
		%	*Total (%)*	*%*	*Total (%)*
Lachesis mutus	298	19.79	19.79	20.20	20.20
Belladonna	190	12.62	32.40	12.88	33.08
Sepia officinalis	130	8.63	41.04	8.81	41.90
Sulphur	110	7.30	48.34	7.46%	49.36
Sanguinaria canadensis	92	6.11	54.45	6.24	55.59
Glonoinum	67	4.45	58.90	4.54	60.14
FSH	66	4.38	63.28	4.47	64.61
Folliculinum	63	4.18	67.46	4.27	68.88
Ignatia amara	53	3.52	70.98	3.59	72.47
LH-RH	46	3.05	74.04	3.12	75.59
Thuja occidentalis	45	2.99	77.03	3.05	78.64
Amylium nitrosum	40	2.66	79.68	2.71	81.36
Others	275	18.26	97.94	18.64	100.00
Total homeopathic medications	1475	97.94	–	100.00	–
Total medications	1506	100.00	–	–	–

Table 3 The 16 most prescribed homeopathic medications for the 301 patients who noted an improvement in their symptoms

Homeopathic medications prescribed for patients with improved symptoms	*Number of lines*	*%*	*Total (%)*
Lachesis mutus	217	21.34	21.34
Belladonna	121	11.90	33.24
Sulphur	81	7.96	41.20
Sepia officinalis	78	7.67	48.87
Sanguinaria canadensis	70	6.88	55.75
Glonoinum	45	4.42	60.18
FSH	42	4.13	64.31
Folliculinum	40	3.93	68.24
Ignatia amara	38	3.74	71.98
LH-RH	30	2.95	74.93
Thuja occidentalis	30	2.95	77.88
Amylium nitrosum	28	2.75	80.63
Nux vomica	16	1.57	82.20
Pulsatilla	11	1.08	83.28
Natrum muriaticum	10	0.98	84.27
Actaea racemosa	10	0.98	85.25
Others	150	14.75	100.00
Total homeopathic medications	1017	100.00	–

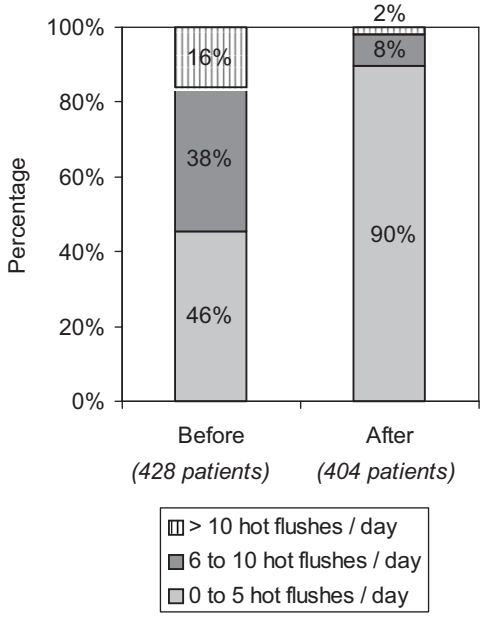

Figure 1 Diurnal frequency of hot flushes

either the disappearance or lessening of their symptoms (Table 4). Favourable evolution was determined by disappearance or improvement of patients' symptoms (self-assessment). This favourable evolution occurred most frequently within 15 days of starting the treatment (Table 5).

Quality of life

Concerning the discomfort caused during daytime, the mean score was 6.1 (SD = 2.3) at the inclusion visit and 2.5 (SD = 2.0) at the final visit ($p<0.001$). Concerning the disturbance to sleep, the mean score was 6.2 (SD = 2.6) at the inclusion visit and 2.4

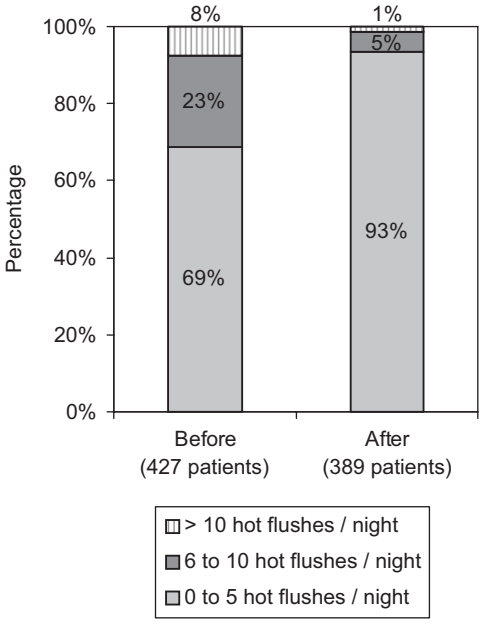

Figure 2 Nocturnal frequency of hot flushes

Table 4 Evolution of the patients' clinical condition

Evolution of clinical condition	*Patients*	*%*
Disappearance	83	19.39
Improvement	301	70.33
No change	34	7.94
Deterioration	10	2.34
Total	428	100.00
Missing values	*10*	

Table 5 Time taken for favourable evolution of clinical condition

Time taken for favourable evolution of clinical condition	*Patients*	*%*
Within 15 days	152	40.64
15 days to 1 month	134	35.83
More than 1 month	88	23.53
Total	374	100.00
Missing values	*10*	

(SD = 2.3) at the final visit ($p<0.001$). Quality of life therefore significantly improved during the study period, with a fall of 3.6 and 3.8 points, respectively, in the 2 items measured on a visual analogue scale.

Discussion and conclusion

We performed an observational study with physicians who prescribe homeopathic treatments; this was not a comparative study of two groups of patients receiving different treatment, which is its main limitation.

During the study, patients were allowed to take other medication and products in addition to those prescribed by the participating physicians. Of the 83

patients who noted a disappearance of their symptoms, 32 (39%) had taken other products, mainly soya/yam-based phytotherapies (10 patients). Of the 301 patients who noted a lessening of their symptoms, 137 (46%) had taken other products, mainly soya/yam-based phytotherapies (48 patients). Of the 44 patients who noted no change or an aggravation of their symptoms, 18 (41%) had taken other products again, mainly soya/yam-based phytotherapies (11 patients).

These last data lead us to suppose that the consumption of products other than the homeopathic medication did not affect the results because the proportion of patients who took other products was comparable in each group of results.

It would be interesting to perform a randomized, double-blind comparative study using an appropriate method to evaluate the homeopathic medication effectiveness (with a validated tool like Greene Climateric Scale for example) in the treatment of hot flushes in menopausal women.

In conclusion, the results of this observational study suggest that homeopathic treatment is effective for hot flushes. Further investigation is justified.

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