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Research Paper

Menopausal Symptoms: an Osteopathic Investigation

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SUMMARY

The aim of this placebo controlled osteopathic study was to investigate the effect of 'Fox's low-force' osteopathic techniques on 30 subjects with menopausal symptoms. The results showed a significant reduction of symptoms in the treated group. An unexpected finding was that testosterone levels were lowered (p=0.028) in the treated group whereas the control group levels were unaffected.

INTRODUCTION

For some women the transition from one phase of life to another, via the menopause, is an uneventful affair. For others, the daily round of distressing symptoms so affects the quality of their lives that they are driven to search for some means of relief. Typical the symptoms women experience are panic attacks, hot flushes, night sweats, depression, irritability, joint pain, palpitations, insomnia, urinary frequency, fatigue, and headaches. Symptoms, once established, can persist long after the menopause.

Yet these symptoms are not solely confined to the female climacteric; they feature in many other conditions, and are experienced by both men and women. Irritability, fatigue and insomnia are found in depressive illness whilst sweating, palpitations, insomnia, urinary frequency, headaches and panic attacks are common in stressed states. Fatigue, sweating, bladder dysfunction, depression and joint pain are symptomatic of myalgic encephalitis (ME) and fatigue, panic attacks, palpitations and sweating are present in hypoglycaemia. In premenstrual syndrome, irritability, fatigue and depression are common and urinary frequency, depression and irritability are found in primary dysmenorrhoea.

Similar symptoms occur as a result of drug therapy, as in the case of Sucralfate, where back pain and insomnia are experienced. Fatigue, headache and flushing are some of the side effects of Amlodipine Besylate. Irritability and depression can occur with Zopiclone, and Nifedipine has been found to cause flushing and urinary frequency. Atropine Sulphate and Belladonna Alkaloids can produce palpitations and flushing, whilst headaches and insomnia can result from taking Enoximone. In fact, the body responds to all stressed states, in a primaeval and stereotypical way, via the neuro-endocrine system.

Yet another stressful condition arises from chronic strain of spinal joints because of the local and constant neurological irritation. Since many women of menopausal age may well suffer from some form of chronic joint dysfunction, be it luminal or sub-liminal, the authors have suggested that cranial osteopathy combined with 'Fox's low-force' osteopathic manipulation, which gently effects a reduction in local irritation of the neurological system might alleviate some symptoms of the menopause, due to

the close relationship between the neurological and endocrine systems.

This theory was tested in a pilot study By Cleary and Fox. 26 subjects with premenstrual or menopausal symptoms were investigated. Examination revealed them all to have areas of chronic joint dysfunction within the pelvis and spine, which were manifested by recurrent episodes of neck or back pain or headaches. However, several subjects were surprised to discover they had areas of joint tenderness and limitation of movement as instances of back and neck pain had been short-lived. A newly developed 'low-force' technique, described below, was used as treatment, and consisted of gently relieving joint stiffness and tenderness from the pelvis, spine and cranium.

The results showed that headaches, back, and joint pain were relieved. Additionally, every premenstrual and menopausal symptom was also affected, with some symptoms being removed for periods ranging from 5 to 12 months. Subject were surprised by the effectiveness of the gentle techniques, and many said they could not tell when treatment was being applied.

This preliminary investigation prompted a larger, placebo-controlled study of the effect of this type of osteopathic treatment on women displaying menopausal symptoms. This paper reports the results.

METHODS

The study conducted between September 1991 and June 1992, asked, 'Can "Fox's low-force" osteopathic techniques reduce menopausal symptoms and, secondly, can the treatment affect hormone levels?'

The methods used in this study are referred to as Fox's low-force techniques to differentiate them from any other low-force technique. They were developed early in 1986 by one of the authors, (JPF). They follow standard osteopathic principles to restore mobility, but differ from conventional techniques in several ways; the most important being that only a few grammes of force is required. A finger or thumb is used to deliver the low-force to the spinous process in a direction that will relieve the restriction. The techniques have been designed to gently treat the spine, peripheral joints and ribs. They relax the joint's protective mechanism, via the muscle spindle, by increasing the resting length of the muscle, thereby improving mobility. The 'force' required to relax the muscle is so low that it does not extend to adjacent joints or surrounding tissues.

A placebo employs the same method, but the force is delivered to a joint adjacent to a restricted joint, where it will have no effect. The techniques also differ from conventional osteopathic techniques in that patients are not required to assist the practitioner by adopting a particular position, or use their own muscle power. Their spines are not twisted or compressed as there is no need for their joints to be 'clicked'. They are simply required to sit or lie in a position that they find comfortable and, as a result, are generally unaware that they have received treatment.

Thus, the use of these techniques made this clinical trial possible as they enabled a control placebo group to be used.

Subjects

The subjects were recruited by articles in local and national newspapers. 15 were given the trial treatment and 15 a placebo. All of the volunteers completed the study.

Any woman between the ages of 50-60 years with menopausal symptoms who had menstruated less

than 4 times in the previous 12 months was eligible provided she accepted the conditions of the study. However, the following criteria excluded some volunteers:

- Women found to be non-menopausal as a result of FSH/LH analysis.
- Women taking hormone replacement therapy, or who had done so in the preceding 18 months.
- Any woman with a debilitating medical condition, such as multiple sclerosis, ME or cancer.
- Any women who had undergone facial or spinal surgery.
- Women taking medication likely to affect their hormonal or sympathetic systems, such as thyroxine, or beta-blockers.
- Any past or present patient of the researchers.

Volunteers were randomly selected for experimental or control groups by choosing an envelope containing a serially numbered piece of paper, placed in an envelope by an independent randomiser. Even numbers received the trial treatment and odd numbers received a placebo. Only the authors were aware of the significance of the choice.

The spine, pelvis and cranium of each volunteer was examined. Every subject was found to have more than one area of joint strain. In the study group, the spine and pelvis of each subject was treated by the low-force techniques, and the cranium by cranial techniques following mechanical principles. The control group received the placebo, (described in Methods). Each subject attended the surgery once a week for 10 consecutive weeks, after which there was a 5 week gap. The study was then completed on week 15. All subjects received a similar 'treatment' time of 30 minutes.

Measurements

Each subject was asked by the independent assessor (see Acknowledgments) to complete a symptom questionnaire a few days before the study began and at week 15, in which she was asked to grade her symptoms on a scale from 1 to 10. (1 being nothing and 10 being unbearable) (see note at end). A symptom questionnaire was also completed each time she attended the surgery, when she was asked to record the highest level each symptom had reached in the previous week. After completing the final questionnaire the subject was informed whether or not she was in the experimental group.

In addition, 3 blood samples of 20 ml each were taken, the first a few days before the trial began, the second at week 5, and the final one at week 15. 11 hormone levels were studied; oestradiol, follicle stimulating hormone, lutienizing hormone, thyroxine, testosterone, sex hormone binding globulin, prolactin, cortisol, IGF/1, thyroid stimulating hormone, and growth hormone.

Ethical permission was given by Harrow Area Health Authority.

Statistical Methods

The change in menopausal symptom scores from week 1 to week 10 and from week 1 to week 15 were compared between the groups using the Mann Whitney U test. The same method was used to analyse the change from week 1 to week 15 for hormonal data. The statistical analysis was performed using Minitab software. For women with neck and headache at the start of the study, the percentage of improvement was compared between the groups using a Kruscal-Wallis test, exact p-values were used because of low numbers.

RESULTS

15 women received the trial treatment and 15 women received the placebo. 7/15 (47%) of the trial group and 8/15 (53%) of the control group believed they received the trial treatment.

Menopausal Symptoms

The figure shows the median and 95% confidence intervals of the average symptom scores for each group, at each week of the measurement. In the study group the average symptom scores decrease rapidly, while in the control group there is only a slight decrease. The change in the study group between week 1 and week 10 was greater than the control group for the average symptom score (p=0.005).

Table 1 compares the results between week 1 and week 10 for each group, and shows that the study group had a much greater reduction in symptoms than the control group from week 1 to week 10, hot flushes (p=0.016), night sweats (p=0.021), urinary frequency (p=0.021), and depression (p=0.042).

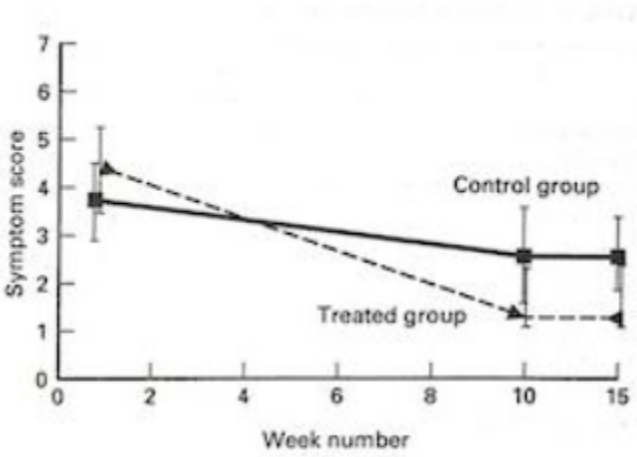

Fig. Medians for average menopausal symptom score, and Wilcoxon 95% CI.
Note: The confidence intervals on the graph are for each group separately, whereas the p value is testing the null hypothesis that the difference between the medians is zero. If this test is significant then the confidence interval for the difference between the medians would not include 0, but the confidence intervals for each group separately may still overlap.

Table 1 – Difference between menopausal scores, between the 2 groups, at week 10 and week 1

	Control		Study			
Menopausal symptom	**Median**	**(Range)**	**Median**	**(Range)**	**p value**	**W ***
Hot flushes	0	(-8 to 3)	-2	(-6 to 0)	0.016	290.5
Night sweats	0	(-8 to 2)	-4	(-9 to 2)	0.021	288.0
Insomnia	-1	(-5 to 2)	-2	(-8 to 0)	0.098	272.0
Urinary frequency	0	(-3 to 3)	-1	(-4 to 0)	0.021	285.5
Depression	0	(-5 to 2)	-2	(-5 to 1)	0.042	280.5
Irritability	-1	(-5 to 3)	-2	(-5 to 0)	0.184	264.5

Average -0.34 (-3.50 to 1.33) -2.66 (-5.50 to -0.83) 0.005 w=301.5 * Test statistic for Mann Whitney U test, W, which is the sum of the ranks for the control group.

Table 2 compares the results between week 1 and week 15 for each group. After a period of 5 weeks without treatment, similar results were observed for the changes between week 1 and week 15, with the exception that for urinary frequency and depression the reduction was not significantly different between the groups. However, insomnia was further reduced in the study group to p=0.018 compared to the control group.

Hormones

Table 3 compares the differences between the 2 groups, between week 1 and week 15. Of the 11 hormones studied there was a significant difference in testosterone levels between the groups with a p=value of 0.028. There was a median change in the control group of 0.0 whilst in the study group testosterone levels were reduced by 0.2 nmo1/L.

Table 2 – Difference between menopausal scores, between the 2 groups, at week 15 and week 1

	Control		Study			
Menopausal symptom	**Median**	**(Range)**	**Median**	**(Range)**	**p value**	**W ***
Hot flushes	0	(-7 to 2)	-2	(-6 to 0)	0.007	296.5
Night sweats	0	(-7 to 4)	-3	(-9 to 2)	0.016	291.0
Insomnia	0	(-5 to 4)	-4	(-9 to 0)	0.018	289.0
Urinary frequency	0	(-5 to 3)	-1	(-5 to 0)	0.168	265.5
Depression	0	(-6 to 1)	-1	(-7 to 1)	0.290	257.5
Irritability	-1	(-5 to 5)	-2	(-5 to 0)	0.271	259.0

Average -0.34 (-3.54 to 1.83) -2.34 (-5.50 to -1.00) 0.002 W=308

Table 3 – Hormonal analysis compared between the 2 groups from week 1 to 15

	Median change from assessment 1		Point estimate of difference	94.5% CI for difference		P value
	Control	**Study**				
Cortisol	-7.000	21.000	-46.000	(-160.000	58.100)	0.395
Prolactin	2.000	3.000	-22.000	(-99.900,	35.100)	0.481
IGF 1	0.050	-0.050	0.070	(-0.080,	0.220)	0.254
Oestradiol	0.000	-2.000	14.000	(-0.100,	91.100)	0.086
LH	-0.200	0.100	-0.800	(-6.800,	4.900)	0.694
PSH	3.700	7.900	-6.800	(-40.300,	11.800)	0.407
Testosterone	0.000	-0.200	0.200	(-0.000,	0.400)	0.028
SHBG	0.000	-10.000	8.000	(-4.000,	21.000)	0.198
Thyroxine	4.000	1.000	1.000	(-8.000,	7.000)	0.677
TSH	0.000	0.200	-0.200	(-0.600,	0.100)	0.144
GH	0.000	0.000	-0.100	(-1.600,	1.500)	0.770
Test/SHBG ratio	0.100	0.000	0.000	(-5.000,	0.799)	0.803

P Values are adjusted for ties.

Table 4 – Volunteers in both groups with chronic neck pain and/or backache at week 1, which had

been present for more than 2 years, and resulted in periods of exacerbation of ache, and the percentage reduction at week 15

		Neckache		Backache	
		Control	Study	Control	Study
Week 1		6	8	4	8
Week 15	No reduction in ache	4	1	1	0
	25% reduction	1	0	1	0
	50% "	0	1	1	0
	75% "	0	2	0	4
	100% "	1	4	1	4

Neck and back pain

Table 4 shows the effects on neck and backache between week 1 and week 15 in both groups. The reduction in pain was greater in the study group: ($p=0.04$) for neck pain, and ($p=0.016$ for back pain).

Symptoms

Table 5 shows the symptom level at week 1 and week 15 in the study group and control groups. The study group had a higher symptomatic level at week 1 than the control group. It took an average of 5 treatments to reduce the study group's symptom levels to either grade 1 (no symptom) to grade 2.

Table 5 This table shows the symptom levels for both groups at week 1, i.e. before the trial commenced, and week 15, i.e. 5 week after the trial ceased.

Study Group												
	HF Weeks		NS Weeks		INS Weeks		UF Week		D Weeks		IRR Weeks	
Vol no.	1	15	1	15	1	15	1	15	1	15	1	15
2	6	2	4	2	3	1	6	1	4	1	5	1
4	3	2			8	2	5	2	6	2	2	2
6	73	1	10	1					4	1	6	1
8	4	1	5	2	7	1	2	1				
10	6	1	6	2								
12	6	5	8	5	6	5	9	7	10	3	6	5
14	5	5	3	5	8	4			6	4	7	4
16	3	2	2	2	5	1	6	2			3	1
18	2	1	8	2	8	1	5	1	5	2	5	1
20	5	4	5	2	3	1	2	3	5	5	8	7
22	3	1	6	1								
24	3	1	2	1	5	1	4	1	3	2	6	1
28	8	2	8	2					2	1		
30	7	1	10	2	10	1	5	2	4	1	5	1
32	4	1	6	2	8	1					6	2

Control Group												
	HF Weeks		NS Weeks		INS Weeks		UF Week		D Weeks		IRR Weeks	
Vol no.	1	15	1	15	1	15	1	15	1	15	1	15
1	5	1			2	2	8	8			2	1
3	2	2			2	1	0	2	2	1	2	1
5	8	4	8	4	4	4	0	3	4	1	4	1
7	9	2	9	2	5	3	0	4				
9	2	1	6	2	8	3	7	2	5	2	7	2
11	7	7	2	6	5	4	7	4	5	2	6	1
13			4	4	4	4					3	4
15	5	5	10	8	7	7	6	4	5	4		
17	3	5	2	4	5	4	6	3			3	2
19	0	3	3	4	5	4	5	4			3	1
21	2	2	4	5	0	2	0	2	2	2	6	4
23	3	5	4	5	4	8	5	3	3	4	2	7
25	5	5	4	5	3	3			0	2	2	2
27	5	2	5	3	5	1	6	2				
29	3	5	4	6	4	2			3	1	2	1

DISCUSSION

These results show clearly that the majority of menopausal symptoms were relieved following the trial low-force osteopathic and cranial treatment. It can be said that the parameters used in this controlled study eliminated the likelihood that the results were due to subjective or psychosomatic influences on the volunteers. Both the study and the control groups received identical treatment times, both had similar physical contact and both were given equivalent consultations with the independent assessor during which time their symptoms were discussed at length. Additionally, the placebo group provided an excellent control, since at the end of the trial, about half the subjects in both groups guessed wrongly the treatment they had received.

It has not been possible to identify the mechanism by which the menopausal symptoms were affected in this study. What can be stated is that the treatment reduced neurological irritation at spinal level, reduced spinal ache, increased joint mobility and reduced areas of cranial tenderness; all of which would reduce stress on the neurological system. On palpation, all the volunteers had areas of spinal tenderness and some had areas of cranial tenderness. Those volunteers who at consultation mentioned that they suffered with headaches and migraines were not aware of tender areas on their spines or crania until they were revealed by palpation. There were volunteers who did not have back or neck ache, but experienced general stiffness, who also had areas of spinal tenderness. All areas of facilitation or cranial tenderness had to be relieved to achieve a reduction of menopausal symptoms.

In the study group, 5 volunteers suffered frequent headaches, some once a week. Of these, 4 had their headaches relieved; the one whose headaches remained, had no relief in her menopausal symptoms either. The fifth volunteer who had suffered migraine attacks for 35 years, had them relieved. In the control group, 2 had frequent headaches and 2 frequent migraines. There was some relief in their headaches, but no relief in the migraine attacks. There was a marked difference in the relief in back and neck pain between the two groups (Table 4).
An interesting result came from the hormonal level studies, where testosterone levels were reduced by a significant level in the treated group. The reduction of circulating testosterone can be ascribed to a fall in ACTH levels which in turn indicates a reduction of stress.

The first blood test, taken before the study commenced, revealed that 4 volunteers had greatly increased levels of oestradiol yet suffered hot flushes and night sweats; 3 were in the study group and their E2 levels were 939, 766 and 486 Pmo1/L. These levels were within normal parameters, (<100 Pmo1/L), when the second blood sample was tested at week 5. All their symptoms, including those of one of the volunteers, who graded night sweats at 10, were relieved (grade 1). The fourth volunteer was in the control group, and had an E2 measurement of 790 Pmo1/L at week 1. This again was reduced to normal by the second blood test; her sweats remained the same, one symptom worsened, one reduced from grade 4 to grade 3, one increased from grade 1 to grade 3 and one, irritability, was relieved.

These results and those of the first study clearly show that the methods used significantly reduced menopausal symptoms and it is not considered necessary to carry out a larger study. However, this study could be duplicated by any osteopath proficient in the use of the techniques employed.

Acknowledgments

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References

1. The Merck Manual, 14th ed. New Jersey; Merck, Sharp and Dohme Labs, 1982.
2. Black's medical dictionary. 13th ed. London: A & C Black, 1981.
3. Shreeve, C. Overcoming the menopause naturally. London: Century Arrow, 1986.
4. Steptoe, A. Appel, A. eds. Stress, personal control and health. Chichester: Wiley, 1988.
5. Rose N. ed. Essential psychiatry. Oxford: Blackwell Scientific, 1988.
6. Macintyre A. ME action campaign. Wells, ME Action, 1993.
7. Chamberlain, Ogilvie. Symptoms and signs in clinical medicine, 9th ed. Bristol: Wright, 1978.
8. British national formulary, no 21. London: Pharmaceutical Press/British Medical Association, 1991.
9. Anthony C. P, Thiboedeau G. A. The textbook of anatomy and physiology, 11th ed. St Louise: Mosby, 1983.
10. Hoag J. M, Cole W. V, Bradford S.G. Osteopathic medicine. New York: McGraw-Hill, 1969.
11. Symposium on functional implications of segmental facilitation. J Am Osteo Ass 1955: 54: 277-282.
12. Cleary C, Fox J. P. Osteopathy and menopausal women. Compl Ed Res 1990: 4(3): 60-61.
13. Korr I. M, Propriereceptors and somatic dysfunction. J Am Osteo Ass 1975: 74: 638-650.
14. Minitab reference manual. Release 8. PC version. Pennsylvania: Minitab, 1991.

Note added in proof

Copies of the questionnaires: 1) at the start of the trial; 2) at each weekly visit; 3) at the end of the trial (week 15), may be obtained from the authors.