

Survey To Determine the Effect of the Static Magnetic Device, LadyCare, on Menopause Symptoms - A Summary of Results

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Introduction

Menopause can be a challenging stage of life. Hot flashes are associated with a decreased quality of life (Groeneveld et al, 1996) and are a primary reason that midlife women seek medical care (Anderson et al, 1987).

According to a recent Gallup Poll, 80 percent of menopausal, post menopausal or surgically menopausal women reported having some symptoms of menopause. Among the women who had symptoms, the most common were: hot flashes (72%), irregular periods (50%), emotional responses (49%), changes in sexual relationship (31%).

There is strong evidence from randomized controlled trials that oestrogen therapy is highly effective in controlling vasomotor symptoms (Manson & Martin, 2001) and urogenital symptoms (Cardozo et al, 1998). The benefits of HRT to prevent osteoporosis appear to be confined to current or recent users, and it is unlikely that taking oestrogen therapy in the first decade after the menopause protects against fractures later in life (median age of hip fracture is 80 years) [Ettinger & Grady, 1993]. The use of HRT to control menopause symptoms is not without risk. There are definite increased risks of venous thrombo-embolism and endometrial cancer (Grady et al, 1995), and probable increased risks of breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormone replacement therapy, 1995) and ovarian cancer (Rodriguez et al, 2001). It is uncertain whether it has any protective effects against cardiovascular disease (Hahn et al, 1998; Herrington et al, 2000) or cognitive decline (Mulnard, 2000).

It is understandable given the above reported side effects why there has been more reluctance recently on the part of women to take HRT and more caution on the part of doctors to issue it so freely.

A previous double blind placebo-controlled study reported that the static magnetic device called LadyCare (LC), designed for application over the pelvic region, significantly reduced dysmenorrhoea in women (Eccles,2005). The current study was prompted by anecdotal reports from women wearing the LC device, that their menopause symptoms were significantly improved. It was decided to explore this further by conducting a survey to see how common this effect might be in a larger group of women who were experiencing menopause symptoms.

Methods

508 subjects with Menopause symptoms responded to an advert placed in the *Daily Mail* newspaper offering a free trial of the LC static magnetic device (see description of device below). No exclusions were made but they had to be experiencing symptoms that had been attributed to Menopause. Subjects were asked to complete a questionnaire that requested them to report the duration of symptoms and to rate their symptoms (on a scale of 0-5 (where 1 represented very mild symptoms, not causing much interference, and occurred occasionally and 5, more severe symptoms that were majorly intrusive on a daily basis); prior to and after 1, 2 and 3 months of using the device.

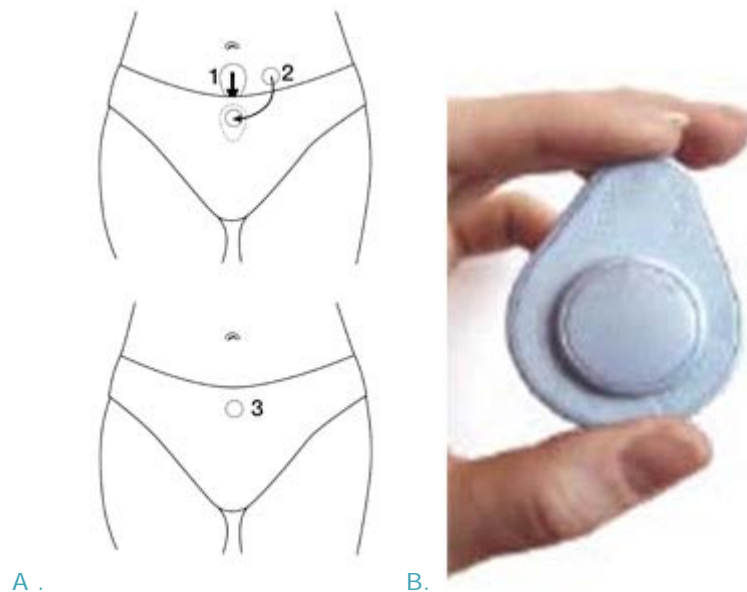
In particular, the level of each symptom was graded according to the following scale:

- 0 = None at all
- 1 = Very mild, does not cause much interference, occurs occasionally
- 2 = Mild, causes some interference on a fairly regular basis
- 3 = Moderate, causes definite interference on a fairly regular basis
- 4 = Significant, causes definite interference on a regular basis
- 5 = Severe, and is majorly intrusive on a daily basis

The LadyCare Device

The LadyCare (LC, see photo A below of the device) magnetic device is designed for attachment to the underwear by magnetic force. LC is plastic coated and is comprised of two parts. The pear-shaped piece is worn inside of the ladies' underwear, directly against the pelvis.

The LC contains a 20-mm x 5-mm iron neodymium-boron magnet within the pear-shaped piece.



The second part is a circular plastic case that contains a neodymium-boron magnet with directional plate adherent to its outside. This second part positioned on the outside of the underwear (as shown in **B**) attaching securely with the force of the magnetic field (manufacturer's patent). This patented directional plate increases the magnetic power of the negative pole (standard scientific notation) of the magnetic field into the body.

Results

Twenty three different symptoms rated were rated in this way (see Table 1 below). Patients were instructed to wear the device 24 hours a day (except during bathing) for the duration of the 3 months. Results were analysed by an independent statistician.

Table 1	Median Level Symptom level change after LC	% Symptom Reduction achieved after LC	Time to achieve maximum reduction of symptom (months)
Hot flashes	3 to 2	33%	1
Heart palpitations (feeling your heart racing)	1 to 0	*	2
Irritability	3 to 2	33%	1
Mood swings, sudden tears	3 to 1.5	50%	2
Loss of libido, sex drive	3 to 2	33%	2
Anxiety	3 to 1	67%	3
Marked fatigue	4 to 2	50%	3

Feelings of doom, dread	3 to 1	67%	2
Vaginal dryness	2 to 1	50%	1
Inability to concentrate	3 to 2	33%	1
Trouble sleeping	4 to 2	50%	2
Urinary incontinence upon sneezing, laughing	2 to 1	50%	1
Itchy, crawly skin	1.5 to 0	*	2
Sudden weight gain	3 to 1	67%	3
Hair loss	0 to 0	-	-
Stomach problems: indigestion and gas	3 to 0	100%	2
Painful and sore muscles, tendons and joints	3 to 2	33%	2
Breast soreness, tenderness	2 to 1	50%	1
Irregular vaginal bleeding	1 to 0	*	1
Disturbing lapses of memory	3 to 2	33%	1
Increased muscle tension	3 to 1	67%	2
Painful intercourse	1 to 0	*	1
Bladder infections	0 to 0	-	-

As it appears from the median score values, shown in the table above the benefits from LC became apparent from the first month of use. In particular, for each symptom a highly statistically significant finding ($p < 10^{-5}$) was obtained after the 1st month of use, indicating that the level of suffering was reported to be highly statistically significantly lower after the use of LC.

Summary of Findings

508 subjects rated their menopause symptoms on a 5 point scale prior to and after at 1, 2 and 3 months after wearing the LC device.

23 of the most common symptoms were rated

Average age of respondents was 49.7 ± 0.199 [1] years

Median duration of menopause was 2.1 (1.3, 2.5)[2] years

21 of 23 symptoms were reduced highly statistically significantly ($p < 10^{-4}$) after the 1st month of use of LC.

The graphs show that symptom relief was maintained after 3 months of use.

The other 2 symptoms were rated as zero across the group to begin with and so no change could be determined in this cohort

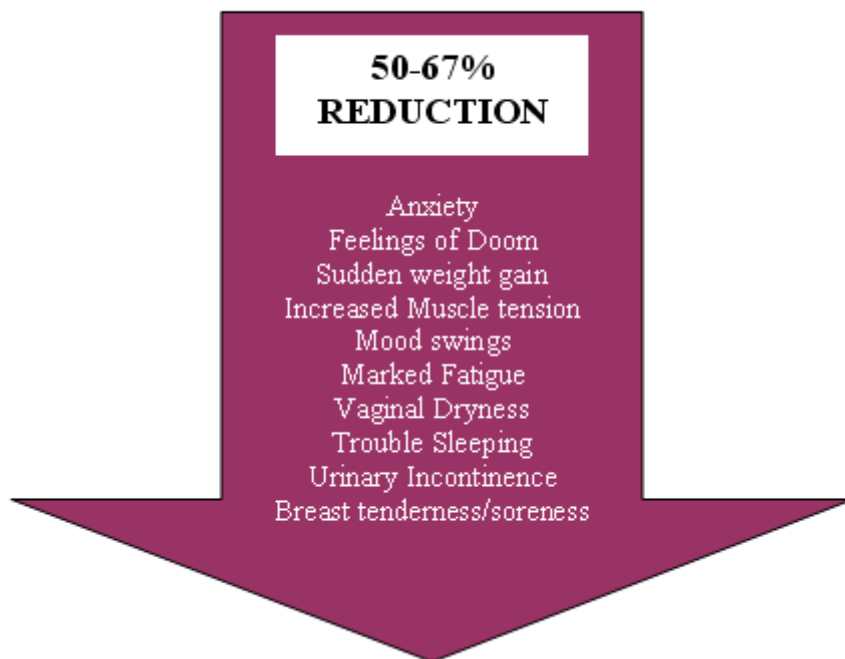
Women reported that the following symptoms were reduced by 50 to 67% across the group:

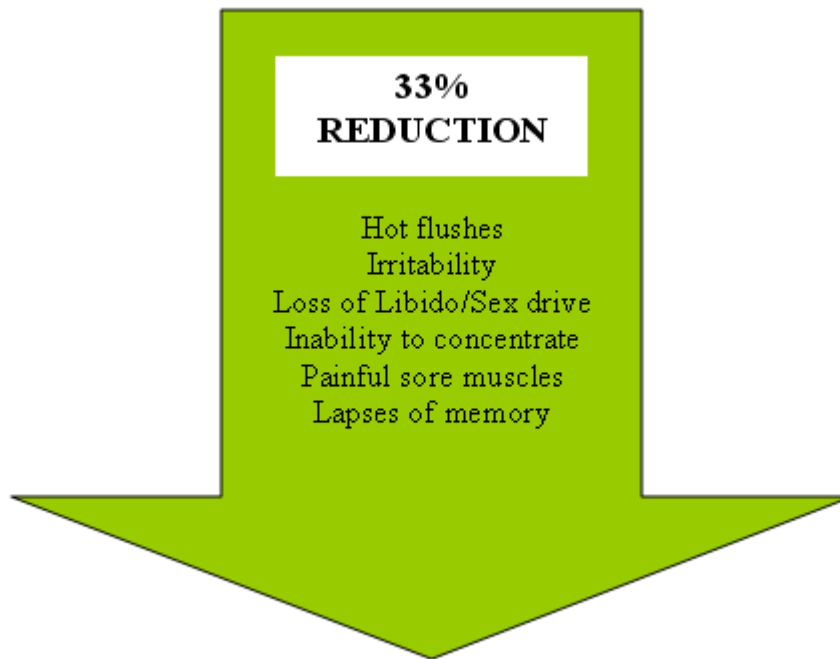
- Anxiety
- Feelings of Doom
- Sudden weight gain
- Increased Muscle tension
- Mood swings
- Marked Fatigue
- Vaginal Dryness
- Trouble Sleeping
- Urinary Incontinence
- Breast tenderness/soreness
- Stomach problems (bloating and gas) - reduced 100%

Women reported that the following symptoms were reduced by 33% across the group:

- Hot flashes
- Irritability
- Loss of Libido/Sex drive
- Inability to concentrate
- Painful sore muscles
- Disturbing lapses of memory

Table 1 shows the exact reported level of reduction in all the 23 symptoms in the group. The above may be best represented graphically as below.





8.1% of women surveyed had had a hysterectomy. This did not seem to affect the response to LC. There was no statistical difference in reduction of symptoms between those who still had a uterus and those that did not.

7.1% of women surveyed were taking HRT. This did not seem to affect the response to LC. There was no statistical difference in reduction of symptoms between those who were taking HRT and those that were not.

19.1% of the group lost weight. Median weight loss was 14 pounds (8, 17 pounds)[3] over the 3 months.

29% of women reported a return of their periods after using LC.

Comment:

This study was designed as a consumer survey. The results are consistent with a large body of anecdotal evidence received from women who reported a reduction of their menopause symptoms after using the LC device. On the basis of these encouraging results a formal placebo-controlled trial is now being planned. As part of the latter, we will assess female pituitary and ovarian hormone profiles to investigate possible mechanisms of action.

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[1] (mean ± SE)

[2] (25th, 75th quartiles)

[3] (25th, 75th quartiles)

I'm younger looking, improved skin tone and less drawn looking, although I've just lost approx 8lbs. More in control of emotions, more confident and relaxed. Would hate to be without LadyCare at this traumatic time of life.

C Sharp

Thank you for this product – I had tried several alternative remedies for the menopause and this is the only product that has helped – more than that relieved the hot flushes to a bearable level. I am sure it will be a success on the market. I have recommended it to friends and the nurse at my GP surgery, who was very interested in it for her other patients.

J Thomas

My quality of life and mood has greatly improved. I feel like my old self again.

C Tait

I feel more energetic, probably because I have slept better during the nights even in the hot weather. I do not want to resort to HRT so this LadyCare has been just what I need.

J George

I have generally felt much brighter. My main benefit was vaginal dryness, which has improved tremendously. I am quite amazed at the overall improvement it has made to me.

J Douglas

I no longer take any medicine for menopausal symptoms, only LadyCare. I was paying up to £30 every 6 weeks for tablets.

S Ashdown

My inability to concentrate has decreased dramatically. The hot flushes have been non-existent. My energy levels have been boosted tremendously. My memory has improved greatly – many thanks.

I Walton

I felt more energetic and just more positive, no more feelings of doom and gloom. Not so tired, weepy, depressed. I'm just so positive now. No more hot sweats – even in this heatwave. I think it's marvellous. I run a language school as you can imagine this is a busy time for me. However, I still have so much energy, which in August is unusual – my sex life is also amazing!!!

J Verrall

