

GMC (General Medical Council) Registration Number: 3586952

*Doctors, Nurses, Pharmacists, Health Professionals
Stockist of LadyCare & Mn8*

I have been asked by LadyCare Lifetime Limited to submit my professional opinion and overview of the data, submitted here with. As well as a Doctor of Pharmacology (PhD) I am a Medical Doctor and a Member of The Royal College of Physicians (MRCP) UK, I run a private Medical clinic on London's Harley Street specialising in non-invasive medicine.

I can confirm that I carried out all of the trials submitted for review and wish to stipulate that LadyCare Lifetime Limited and/or Derek Price, the managing director and inventor, had no influence over the outcome of the results shown. My staff and I carried out all the trials independently within our clinical environment. Furthermore, all of the data was analysed by an independent third party statistician.

LadyCare

There is no doubt that menopause can be a challenging time both psychologically and physically for many women. 80% of woman of menopausal age will suffer some degree of symptoms and many of these are majorly intrusive to everyday functioning. Since 2002 when the Women's Health Initiative (WHI) Study was published, there has been a significant decline in the number of women taking HRT and also doctors have become more careful in prescribing it due to the well-established increased risks of breast cancer, stroke, pulmonary embolus and cardiovascular disease associated with its long-term use. The need for an effective and safer alternative therapy for menopause has become paramount.

I conducted a large 508 women survey to investigate the effect of LadyCare on women who complained of menopause symptoms. Again, the data was analysed by an independent third party statistician. The data showed a significant reduction in the majority of common menopause symptoms. After reviewing the results of the survey, I would be bold enough to say that the LadyCare device may prove to be one of the greatest natural solutions for the alleviation of menopause symptoms.

For your convenience I summarise the key findings of the survey below:

- **There was a 50-67% reduction in Anxiety, Feelings of Doom, Sudden weight gain, Muscle tension, Mood swings, Marked fatigue, Vaginal dryness, Difficulty sleeping, Urinary incontinence, Breast tenderness/soreness**
- **There was a 33% reduction in Hot flushes, Irritability, Loss of libido/sex drive, Inability to concentrate, Sore muscles, Lapses of memory**

- **These improvements were noted after one month of wearing LadyCare and the benefits were even more significant after 3 months**

Other observations were:

- 8.1% of women surveyed had had a hysterectomy. This did not seem to affect the response to LadyCare
- 19.1% of the group lost weight. Average weight loss was 14 pounds (6.4kg)
- **NO UNTOWARD EFFECTS WERE NOTED**

Finally, having established what seemed to be a fairly consistent benefit to women with menopause symptoms the obvious question was how LadyCare could possibly be working. I postulated that because the effect was rapid in some women, as early as within 24 hours that it was unlikely to be a hormonal mechanism as this would almost certainly take longer. I set out to investigate a more plausible mechanism.

NEW Mechanism of Action of LadyCare in relief of Menopause symptoms

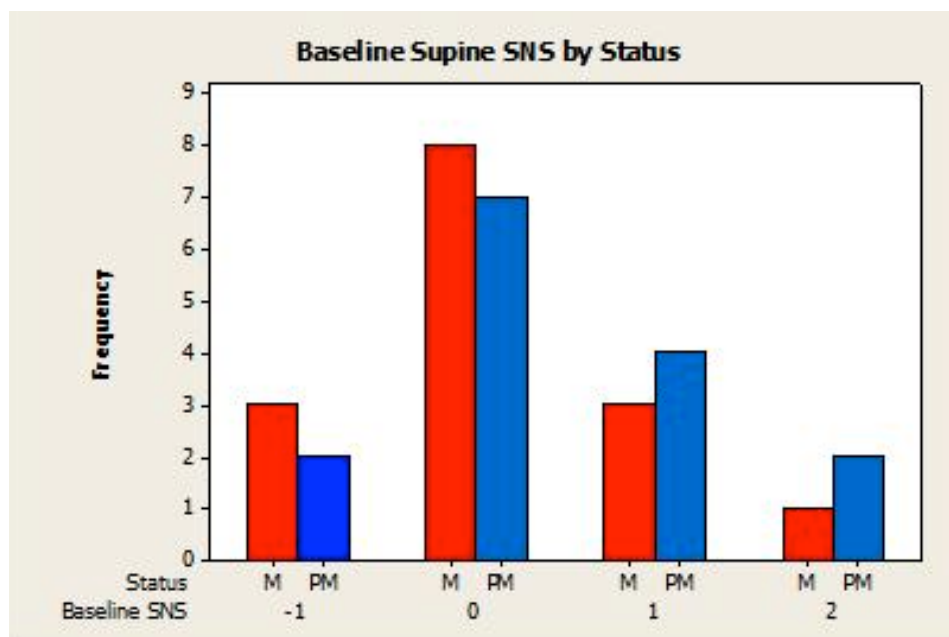
Because sweating is under the control of the autonomic nervous system (ANS), more specifically the sympathetic division (fight-flight/stress reactor system), I proposed that this was a likely target for the LadyCare mechanism of action.

There are 2 divisions of the ANS, the Sympathetic division (SNS) which is the fight-flight stress reactor system of the body e.g. when we perceive a threat the heart beats faster and the pupils dilate to allow more light for enhanced visual acuity and faster reactions. In contrast, the Parasympathetic division (PNS) is responsible for REST and DIGESTION. The latter is the repair and regulatory system of the body and tends to have the opposite effect to the SNS. For example, the SNS speeds the heart rate while the PNS slows it down. The 2 systems work together to regulate all our organ systems. I proposed that LadyCare may be acting by somehow re-balancing ANS activity.

In order to investigate this hypothesis I studied the ANS activity in 35 British police women with menopause symptoms. Because sweats/hot flushes are the most likely symptom to be related to ANS imbalance, all volunteers had to have hot flushes as one of their menopause symptoms.

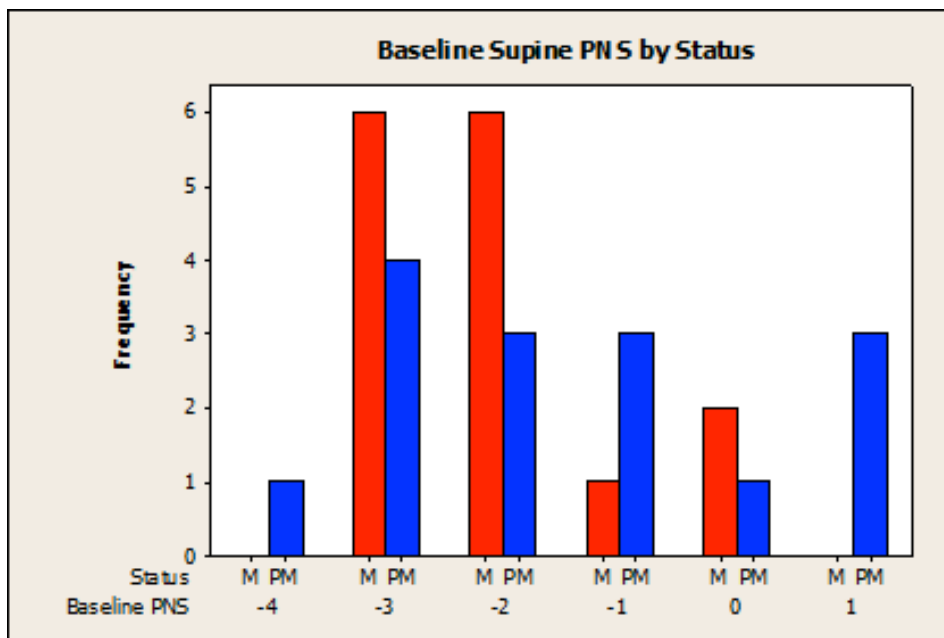
A recognised non-invasive method for measuring ANS activity is by Heart Rate Variability (HRV). Close inspection and measurement of the heart rhythm reveals that the heart beat from one to the next is not even. The measured time between each heart beat varies beat to beat. This variation is a reflection of a tonic influence of the SNS (speeding the heart) and PNS (slowing the heart down). Measuring HRV is therefore a convenient way of measuring ANS activity. A 5-6 minute heart rhythm recording is taken from which computer analysis is able to derive quantitative measurements of both SNS and PNS activity.

Results: Many of the police women in the study were sceptical that a device attached to their underwear could make any difference to their symptoms. However, 70% of the women in the study reported alleviation of their menopause symptoms one month after wearing LadyCare continuously. Although all of the women volunteers had menopause symptoms, approximately half of them were in fact peri-menopausal and not menopausal i.e. they were not 12 months free of periods. It is well known that women can experience menopausal symptoms well before the onset of cessation of their periods. Data for menopausal women and peri-menopausal women was separated for analysis...hence the 2 colours in the graphs shown next.

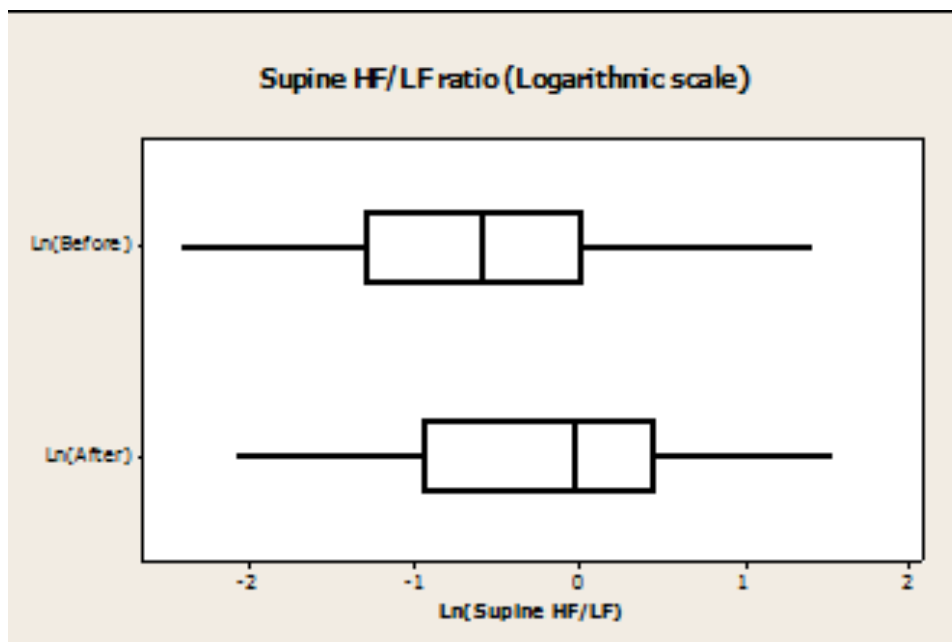


This graph above shows SNS activity in the volunteers before the use of LadyCare. M= Menopausal women, PM = Peri-menopausal women.

The zero point is neutral SNS activity so if you imagine a curve following the bar chart you can see that there is a tendency to slight SNS dominance in these women.



The graph above is however much more interesting. Notice the colours are reversed on this graph. Again the zero point is neutral PNS activity. What is clear is that in the peri-menopausal group and mores the menopausal group have a deficit in PNS activity. Effectively this would result in a preponderance of SNS activity over PNS activity and is a logical explanation for the occurrence of hot flushes in menopausal and peri-menopausal women. This represents A NOVEL FINDING. It is the first report of a clear autonomic nervous system imbalance in menopause (this has now been filed as part of a patent application, sees below and is PATENT PENDING). Does LadyCare redress this imbalance in ANS.? The answer is YES it does (See below).



After statistical analysis.....the answer became obvious as shown in this graph. The upper bar is the ratio of PNS to SNS before LadyCare and the lower bar is after LadyCare. The difference is highly statistically significant ($p < 0.017$). LadyCare wear has significantly increased the proportion of PNS activity.

This is a plausible explanation of how LadyCare may be working to correct hot flushes and other menopause symptoms.

It is also a plausible explanation of how MN8 may relieve dysmenorrhoea (period pain) since an increase in PNS activity would lead to relaxation or reduced contraction of uterine muscle and reduction of uterine artery spasm. (PNS activity antagonising the SNS-mediated uterine contraction and arterial constriction)

Mn8

A randomized double blind placebo controlled trial (published in the peer-reviewed journal, JACM, in 2005), demonstrated the following:

- There was a significant reduction ($p < 0.02$) in pain in the MN8 group compared to the placebo group
- 70% of the subjects in the MN8 group had at least a 50% reduction in pain
- 47% of whom had a > 75% reduction in pain
- 26% obtained complete pain relief with various combinations of conventional therapies.
- 18% of women experienced some side effects after taking painkillers. (dizziness, drowsiness, tiredness, light-headedness, nausea and upset stomach)
- **MN8 – NO SIDE EFFECTS WERE REPORTED**
- 71% reported a decrease in irritability
- 58% reported a reduction in PMS symptoms
- 54% reported a reduction in water retention and bloating
- 38% noticed a reduction in spots

Furthermore, a survey of 193 longer-term users of MN8 (the survey was conducted to establish the longer-term efficacy and safety of MN8). All were women who had Primary dysmenorrhoea with an average duration of 11.6 years i.e. they were all fairly long-term sufferers of period pain.

. The survey demonstrated the following:

- Average pain level was 8.2 ± 0.11 on a rating scale of 1-10
- MN8 caused a statistically significant reduction ($p < 0.0001$) in pain level
- MN8 led to a significant reduction consumption of painkillers ($p < 0.0001$)
- MN8 led to a significant reduction in irritability ($p < 0.0001$)

- MN8 caused a significant reduction in breast tenderness ($p < 0.0001$)
- MN8 caused a significant reduction in bloating and water retention ($p < 0.0001$)
- Mn8 led to a significant reduction in spots ($p < 0.0001$)
- MN8 use led to a significant ($p < 0.0001$) reduction of 54% in time taken off work
- 90% of those using MN8 for more than 1 year were still having pain relief
- NO LONGTERM USE SIDE EFFECTS OBSERVED were observed with long-term use of MN8

To summarise, I have been able to establish that both MN8 and LadyCare are effective in relieving period pain and menopause symptoms respectively. My latest research, as yet unpublished, has demonstrated a novel mechanism of action that could explain both of these clinical benefits. The latest research on mechanism of action will be submitted for publication and there is a 'patent pending' over this new discovery.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Nyjon K. Eccles', with a long horizontal flourish extending to the right.

DR NYJON. K. ECCLES BSc MBBS MRCP PhD