

Intervención RDM acupuntura intradérmica para los sofocos durante el período climatérico. Estudio piloto

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Original

RESUMEN

Objetivo: Los síntomas climatéricos son una alteración que se presenta en el 80% de las mujeres, siendo los procesos vasomotores los más frecuentes, con una duración de hasta 7 años. Sintomas que padecen la mitad de la población.

Para estos síntomas no existe ningún medicamento probado sin efectos adversos. En este artículo se presenta un estudio de casos con Intervención RDM acupuntura intradérmica para la reducción de estos síntomas en 6 meses. Se realiza un estudio descriptivo de serie de casos. Exponemos 13 casos, mujeres con una presencia de sofocos elevada y con una permanencia de los mismos de una media de 5,2 años. Se mide a través de la escala MRS y se observa que la intervención mejora en un 100%, siendo significativa la mejora en la calidad de vida.

Este estudio se ha utilizado para diseñar un ensayo clínico doble ciego en una tesis doctoral en la URJC.

Metodología: Estudio de serie de casos descriptivo en mujeres con síntomas vasomotores. La intervención RDM se aplica durante 6 meses, realizando una captación y formación inicial a la mujer, entrenamiento durante 4 semanas en la que se la entrena en la técnica y posteriormente un seguimiento mensual. Su evolución se mide con test MRS desde el inicio y mensualmente.

Resultados: Se inicia la intervención en 20 mujeres y finalizan 13 mujeres. De las cuales el 100% de los casos tiene una mejora porcentual en el computo de los síntomas asociados al periodo climatérico según el cuestionario autoregistrado de MRS.

Conclusión: El estudio demuestra que la intervención puede ser efectiva para mejorar la sintomatología climatérica usando acupuntura intradermica permanente siguiendo la intervención RDM, precisa mas estudios para evaluar posibles sesgos y resultados en poblaciones mas amplias.

Palabras clave

Sofocos, climaterio, menopausia, acupuntura, Intervención RDM, Microagujas

Intervention RDM for Intra-dermal acupuncture for hot flashes during climacteric period. Pilot study.

Abstract

Objective: Climacteric symptoms are an alteration that occurs in 80% of women, with vasomotor processes being the most frequent and lasting up to 7 years, and this is suffered by half of the population.

For these symptoms there is no proven medication without adverse effects. This article presents the intervention with Intervention RDM for Intra-dermal acupuncture for the reduction of these symptoms in 6 months. A descriptive case series study is carried out. We expose 13 cases, women with a presence of high hot flashes and with a presence of them of an average of 5.2 years. It is measured through the MRS scale and it is observed that the intervention improves in 100%, being significant the improvement in the quality of life.

This study is used for designing an intervention case-control study in a doctoral thesis in URJC.

Methodology: Descriptive case series study conducted in women with vasomotor symptoms. The RDM intervention was applied for 6 months, starting with initial recruitment and training for the participants. This included a 4-week training period to master the technique, followed by monthly follow-up sessions. Progress was measured using the MRS test at baseline and on a monthly basis.

Results: The intervention began with 20 women, of whom 13 completed the study. All participants (100%) showed a percentage improvement in symptoms associated with the climacteric period, as assessed by the self-reported MRS questionnaire.

Conclusions: The study demonstrates that the intervention may be effective in alleviating climacteric symptoms through permanent intradermal acupuncture as part of the RDM approach. Further research is needed to address potential biases and to evaluate outcomes in larger populations.

Key words

Hot Flashes, climacteric, menopause, acupuncture, Intervention RDM, Microneedle

1. Introducción

The climacteric period is the stage in a woman's life that develops from the time when the ovaries have non-fertile cycles until the total elimination of problematic menopausal symptoms. This period, which ranges from 5 to 15 years, includes the three classic periods: perimenopause, menopause and postmenopause¹.

According to the National Statistics Institute of Spain there are 5.376.982 women in this vital stage in 2023.

The symptoms recorded during the climacteric period² are varied, and it has been found that there are many variables that can affect them, such as ethnicity, culture, genetics, lifestyle, etc^{3,4}, although there are no studies that show that these variables are statistically significant. Among the symptomatology that can occur are: vasomotor symptoms, vaginal atrophy, mood variability, somatic symptoms, among others. However, vasomotor symptoms are the ones that have always been directly related to this process⁵.

Thermoregulation problems in the climacteric stage seriously affect the quality of life of women. It occurs in 60-80% of women and it is currently estimated that it can last for an average of 7 years. This symptomatology is non-specific, it does not have a homogeneous pattern in all women. Although there are some risk factors that have been observed as influential: a lower level of education, suffering pre-menstrual syndrome, a high BMI, smoking, anxiety or depression, mainly⁶.

Current treatments for these problems are not a panacea, intervention on lifestyle, or decrease in obesity are not significant and HRT treatments are effective in the short term but with serious health risks⁷ (venous thromboembolism, cardiac events and urinary incontinence), according to the Clinical Practice Guide of the Ministry of Health, Consumption and Social Welfare of 2017⁸.

This complex and varied symptomatology is measured with health-related quality

of life (HRQoL) questionnaires, in this case for women's health the most widely used questionnaire^{9,10}, because it is a self-descriptive tool, is the Menopause Rating Scale (MRS) designed in 1990. This questionnaire assesses 11 items, including biopsychosocial aspects: somatic, psychological and urogenital. It is based on a likert scale from 0-4, together with emoticons that facilitate understanding and adaptation to all cultural levels¹¹.

Of the possible treatment alternatives that women have for this problem, none gives clear results without side effects¹².

One of the treatment alternatives for hot flushes problems is acupuncture, in the last review conducted by the Cochrane in 2013¹³, the articles studied are positive in the treatment, although not definitive due to the few cases studied and the impossibility of comparisons, and need more estudies.

Since 2018, an alternative called Intervention RDM for Intra-dermal acupuncture based on Nogier frequency pickup is being investigated and developed. This therapeutic technique was very effective in a first case treaty with vasomotor symptoms that impaired the quality of life of the woman studied (<https://intervencionrdm.blogspot.com/>). Therefore, a pilot study was initiated to determine the effectiveness of the intervention.

The hypothesis that the use of Intervention RDM in women in the abdominal area with a duration of 6 months resolves or improves climacteric symptomatology and especially vasomotor symptoms.

The study has been described following the guidelines of the Revised Standards for Reporting Interventions in Acupuncture Clinical Trials (STRICTA)¹⁴

The main goal is to investigate the effect of Intervention RDM in women in the abdominal area with a duration of 6 months to resolve or improves climacteric symptomatology and especially vasomotor symptoms.

2. Material and methods

- 2.1. Trial design study of case series descriptive
- 2.2. Participants and study setting: women in climacteric period with marked vasovagal symptomatology living in the Community of Madrid. excluded: women under treatment for breast cancer or Hormone Replacement Therapy (HRT) due to the impossibility of measuring the possible effects of these treatments.

The participants were chosen by unintended snowball sampling¹⁵ and all of them should sign an Informed Consent.

- 2.3. Ethical Committee of URJC approved the study.
- 2.4. Intervention. The Intervention RDM intervention consists of the application in the iliac fossa of the woman of 5 single-use semi-permanent adherent micro-needles (Image 1). These microneedles will be kept for 7 days (+/- 2) and will be renewed, maintaining the process for 6 months.

The first step the research was carried out a health survey and the first evaluation of the MRS test.

This intervention was performed by a professional nurse trained in the technique, she trained to the woman in the self-application of the intervention, when the woman was ready she made it alone and was monitored with a control test every 4 weeks with the MRS test until 6 months. The Intervention ended with a last control MRS test at year to begin.

- 2.5. Variables to be studied MRS assessment test: hot flashes, heart problems, muscle and joint problems, sleep problems, depressed mood, irritability, anxiety, tiredness, sexual problems, urinary problems, vaginal dryness.

3. Results

We enrolled 20 women who started the study, finally 13 women finished the process, (for unknown reasons), with a mean age of 51 years (42-61) and a mean time experiencing hot flashes of 5.2 years. One of the women was treated for 4 years with Hormone Replacement Therapy, presenting hot flashes again at the end of treatment two years before. 8 Women had other diseases (table 1).

All passed the MRS test controls prior to the start of the intervention and once a month during the intervention time, the results given in Table 2 show a decrease in the perception of the intensity and frequency of hot flashes by the women in 84,61% of the cases, the average decrease in the scale being 2 points. Being assessable levels in different months of almost absence of vasomotor symptoms.

In the global evaluation of the data (Table 3) it is observed that the score of the MRS test decreases in all cases 100%. In table 4 we can observe the analysis of the data where an average decrease in the global score is observed on the MRS test of 10.46 points, $\sigma=5.87$, (the dispersion range being from 1 to 23 points). Efficacy, defined as the measure of the possible total resolution of all symptoms, which would give a final test with a value of 0, has been an average of 51.43% (dispersion of 6.67%, 80%)

The partial data grouping symptoms would be:

- Somatic symptoms have decreased in 100% of the cases with a mean decrease of 4.69 points, $\sigma=2.25$, (the dispersion range being from 9 to 2 points). The efficacy has been an average of 51.52% (dispersion of 18.18% - 85.71%).
- Physiological symptoms have decreased in 87.5% of the cases with an average decrease of 2.92 points, $\sigma=4.09$, (the

Table 1. Clinic date of the cases

	NºClinic History	Age actu ally	Age onset preme nopal sal	menstruation cycle(y es/no)	Years tubal with ligatio Age hot n Menop flashe ause s Other problems
1	1	55	0	no	----- 48 7 no
2	2	50	0	no	----- 47 3 Osteoporosis
3	3	43	0	no	----- 40 3 no
4	4	42	42	yes	----- 0 0 no
5	6	53	50	no	----- 53 0.5 Constipation, Morton's neuroma
6	7	53	52	no	sleeplessness, arterial hypertension ----- 53 1
7	8	51	41	no	----- 45 6 Anxiety, Migraña
8	9	54	0	no	35 52 2 no
9	11	61	47	no	----- 48 13 no
10	12	58	49	no	Arterial hypertension, ----- 51 7 Osteoporosis
11	13	46	42	no	Endometriosis, migraines ----- 46 0.4
12	14	53	49	no	Asthma ----- 49 5
13	16	53	42	no	---- 43 11 Asthma,Osteoporosis

Average 51,69 31,85 44,23 5,27

Table 2. VARIATION OF HOT FLASHES IN THE MONTHS OF INTERVENTION.
Score: 0 absence to 4 very high intensity

	NºClinic History	outs et	1ºmon th	2º mont h	3º 4º mont mont h h	5º 6º mont mont h h	depreciatio 12º month n	EFFECTIVENESS OVER THE TOTAL POSSIBLE
1	1	4	3	2	2 2	2 2	13 points	75
2	2	4	4	3	2 2	2 2	12 points	50
3	3	4	4	1	1 1	2 0	13 points	75
4	4	4	4	2	0 1	1 1	13 points	75
5	6	3	2	2	3 2	2 2	21 points	33,34
6	7	3	3	3	2 1	2 1	12 points	66,67
7	8	4	1	0	2 0	1 4	13 points	75
8	9	3	2	2	1 1	2 1	12 points	66,67
9	11	3	1	0	1 2	0 0	03 points	100
10	12	4	4	4	0 4	4 4	40 points	0
11	13	3	3	1	1 2	3 1	12 points	66,67
12	14	4	4	4	3 2	3 3	22 points	50
13	16	2	2	1	2 2	2 2	20 points	0
average 2 points								56,41

Table 3. RESULTS OF THE COMPLETE MRS TEST DURING THE WHOLE INTERVENTION

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outset																											
1	1	55	12	04	12	28	6	4	3	135	42115	3	1943	0	7	4	3	0	8	3	1	1	5				
2	2	50	15	11	10	36	10	8	8	265	24116	2	101862	8	16	4	2	4	10	6	1	14	6	0	10	16	
3	3	43	8	6	2	16	3	1	1	53	1152	0	1363	2	11	5	1	1	7	5	1	1	7	3	0	2	5
4	4	42	5	0	0	5	0	0	0	02	0020	0	0010	0	1	1	0	0	1	1	0	2	1	0	0	1	
5	6	53	12	7	6	25	9	4	1	1410	77241088248	7	5227462265	3	14	6	6	4	16	6	5	3	14	7	6	1	14
6	7	52	9	7	25	10	10	11	318	77241088248	8	5227462265	7	18	7	5	7	19	7	7	8	22	5	1	9	15	
7	8	51	10	8	5	23	1	2	0	32	3052	1	0303	0	3	1	3	0	4	7	12	0	19	7	7	0	14
8	9	54	6	5	2	13	6	5	0	114	4194	2	06410	0	14	5	4	0	9	4	4	0	8	3	3	0	6
9	1161	7	4	4	15	1	0	0	10	0221	0	2322	2	6	1	0	1	2	1	1	3	1	0	2	3		
10	1258	12	6	7	25	12	7	6	258	66209	3	61882	9	19	9	3	6	18	10	4	7	21	8	3	7	18	
11	13	46	9	7	6	22	4	4	125	52127	6	51886	6	20	8	5	7	20	4	5	8	17	4	2	4	10	
12	1453	11	2	12	25	10	6	6	2212	107297	1	61454	3	12	8	4	4	16	8	9	2	19	9	7	0	16	
13	1653	6	1	8	15	6	2	8	165	28155	3	81642	8	14	3	1	8	12	5	3	8	16	4	2	8	14	

TABLE 4. DATA EVALUATION

	HC	AGE	DEPRECIATION*	EFFICACY**	DECREASE IN SOMATIC SYMPTOMS	EFFICACY ON SOMATIC SYMPTOMS	DECREASES IN PHYSIOLOGICAL SYMPTOMS	EFFICACY ON PHYSIOLOGICAL SYMPTOMS	DECREASE IN URO-GENITAL SYMPTOMS	EFFECTIVENESS IN URO-GENITAL SYMPTOMS
1	55	23	82,14%	9	75,00%	3	75,00%	11	91,67%	
2	50	20	55,56%	9	60,00%	11	100,00%	0	0,00%	
3	43	11	68,75%	5	62,50%	6	100,00%	0	0,00%	
4	42	4	80,00%	4	80,00%	0	0,00%	0	0,00%	
6	53	11	44,00%	5	41,67%	1	14,29%	5	83,33%	
7	52	10	40,00%	4	44,44%	8	88,89%	-2	-28,57%	
8	51	9	39,13%	3	30,00%	1	12,50%	5	100,00%	
9	54	7	53,85%	3	50,00%	2	40,00%	2	100,00%	
11	61	12	80,00%	6	85,71%	4	100,00%	2	50,00%	
12	58	7	28,00%	4	33,33%	3	50,00%	0	0,00%	
13	46	12	54,55%	5	55,56%	5	71,43%	2	33,33%	
14	53	9	36,00%	2	18,18%	-5	-250,00%	12	100,00%	
16	53	1	6,67%	2	33,33%	-1	-100,00%	0	0,00%	
AVERAGE		10,46	51,43%	4,69	51,52%	2,92	23,24%	2,85	40,75%	
STANDARD DEVIATION		5,87		2,25		4,09		4,34		

*DECREASE IN THE TOTAL BEGINNING AND ENDING VALUES IN THE MRS TEST

**PERCENTAGE OF EFFICACY OVER THE TOTAL POSSIBLE POINTS TO DESCENT FROM THE INITIAL SCORE WITH RESPECT TO THE FINAL SCORE OF THE SYMPTOMS

dispersion range being from 11 to -5 points). The efficacy has been an average of 23.24% (dispersion of 100% - 250%).

- The urogenital symptoms have decreased in 87.5% of the cases with a mean decrease of 2.85 points, $\sigma=4.39$, (the dispersion range being from 12 to -2 points). The efficacy has been an average of 40.75% (dispersion of 18.18%, 85.71%).
- The negative points in these cases indicate that symptoms have appeared that were not present at the beginning of the intervention.

In relation to the appearance of side effects, a case of discomfort related to the point of insertion of the microneedle, which moved due to profuse sweating, has been described. There have been no other side effects to the intervention. Other comments parallel to the control of climacteric symptoms have indicated a decrease or even disappearance of joint pain.

4. Discussion

In view of the results, the intervention is positive, since it has given clinical improvement in 100% of the cases. The intensity of the improvement is highly variable, although it is important in the reduction of vasovagal symptoms, hot flashes are reduced in frequency and intensity, although they are not completely eliminated, like other studies, it's not clear if the advantage is only for the intervention¹⁶. Acupuncture has good results in climacteric symptoms^{12,17}, this, can be, a new tip for to use easy.

In women who had not been regulated after an average of 5 years of suffering from hot flashes, this improvement significantly increases their quality of life, the way to properly address it is still very unknown¹⁸. It's necessary to look after new treatment to help a woman during the climacteric symptoms, no one knows are perfect¹⁹.

This study presents the bias²⁰ of a positive view of a new treatment, although these women who participated had tried

other treatments without obtaining these results.,

The RDM²¹ intervention favors the stimulation of the endocrine and hormonal systems by being located on the area in which, according to R. Nogier²², it modifies them by capturing light waves. The microneedles on the lower abdominal area, modifies the formation of chemical neuromediators, and favors the passage of bioelectric waves with different frequencies, normalizing the internal ionic charges, favoring fluctuating hormonal disorders that produce hot flashes.

Two cases increase de symptoms, we don't have a more variables to explain this, and it's necessary studies with more patients and variables . This study provides an effective treatment regimen for climacteric hot flashes. However, this study still has some limitations. Firstly, this research is a prospective study with limited sample size and single source. Therefore, it is necessary to carry out lots number of prospective research to confirm the conclusion. Secondly, the research on the mechanism of hot flashes still needs deep research.

5. Conclusion

The study is the first step to propose the Intervention RDM as an new treatment for calm de hot flashes in climacteric periods. To verify the effectiveness of the intervention, a study supported by a doctoral thesis and a double-blind clinical study methodology is planned to corroborate these results with more women and more variables studied.

6. Conflict of interest

We declare no conflicting financial or non-financial interests

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