

ORIGINAL PAPER

Is metabolic dysregulation associated with antidepressant response in depressed women in climacteric treated with individualized homeopathic medicines or fluoxetine? The HOMDEP-MENOP Study



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Background: Climacteric is associated with both depression and metabolic dysregulation. Scarce evidence suggests that metabolic dysregulation may predict poor response to conventional antidepressants. Response to depression treatment has not been studied in homeopathic medicine. The aim of this study was to investigate the prevalence of metabolic disorders in depressed climacteric women treated with homeopathic medicines, fluoxetine or placebo, and if these alterations have any association with response to depression treatment.

Methods: One hundred and thirty-three Mexican women (40–65 years) with depression, enrolled in the HOMDEP-MENOP study, a randomized, placebo-controlled, double-blind, double-dummy, three-arm trial with a 6 week follow-up, underwent a complete medical history and clinical examination. Metabolic parameters were assessed at baseline. Association between baseline metabolic parameters and response to depression treatment was analyzed with bivariate analysis in the three groups. Odds ratios (OR) with their 95% confidence interval (95% CI) were calculated. Metabolic parameters were considered for inclusion in the logistic regression model if they had a statistically significant relationship with response rate on bivariate analysis at $p < 0.05$ or if they were clinically relevant.

Results: Overall combined prevalence (obesity and overweight) was 86.5%; 52.3% had hypertriglyceridemia; 44.7% hypercholesterolemia; 46.7% insulin resistance; and 16% subclinical hypothyroidism. There was no statistically significant association between dyslipidemia, overweight, or insulin resistance and non-response in the homeopathy group [OR (95% CI) 1.57 (0.46–5.32), $p = 0.467$; 0.37 (0.003–1.11), $p = 0.059$; 0.67 (0.16–2.7), $p = 0.579$, respectively].

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Conclusion: Metabolic dysregulation was not significantly associated with response to depression treatment in depressed climacteric women treated with individualized homeopathic treatment (IHT), fluoxetine or placebo. Due to the high prevalence of metabolic disorders and its relationship with depression in the climacteric, further investigation should be focused on whether individualized prescriptions based on classical homeopathy for depressed climacteric women have an effect on metabolic parameters, and/or if treating the metabolic disorders at the same time could lead to higher response rates.

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Background

The climacteric stage is a period of decrease of reproductive capacity in women culminating in the menopause. The perimenopausal period refers to the interval when women's menstrual cycles become irregular due to intense hormonal fluctuations. Menopause is defined by at least 12 months of amenorrhea.¹ Hormonal changes affect the metabolic and cardiovascular parameters. The prevalence of metabolic syndrome (MS) increases as women transition from premenopause to postmenopause.² The MS refers to a combination of metabolic abnormalities that increase risk for morbidity and mortality from cardiovascular diseases.^{3–7}

Recent studies have demonstrated a significant association between menopausal transition and a higher risk for developing depression. The Study of Women's Health Across the Nation has demonstrated that among middle-aged women, depressive symptoms predicted the MS.^{8–10} Depression has been associated with increased cardiovascular risk mediated by alterations in metabolic parameters. In addition, menopausal status has been linked with both MS and depression. Studies indicate a bidirectional association between depression and MS, and support early detection and management of depression among patients with MS and vice versa.¹⁰ Recently, Mansur has described a 'metabolic-mood syndrome', a concept that may have important clinical implications. Several novel interventions have been proposed for both obesity and mood disorders.¹¹

Antidepressants are commonly prescribed medications during climacteric. In daily routine, physicians face the challenge of the inter- and even intraindividual variability in antidepressant response.¹² Scarce evidence suggests that metabolic dysregulation may predict poor response to depression treatment. Therefore, it is mandatory to focus research in their interrelation, so both aspects should be integrated in managing women at this stage. Some studies have shown metabolic and inflammatory dysregulation (elevated IL-6, low HDL cholesterol, hypertriglyceridemia, and hyperglycemia) can be found in more chronic forms of depression in antidepressant users.¹³ Understanding both

inflammatory and metabolic dysregulations as highly related processes may contribute to knowing potentially causal associations.¹⁴ Currently, sparse evidence reveals that inflammation might be associated with non-response in antidepressant users. Specifically, Lanquillon *et al.* conducted a small study with 24 depressed patients with higher blood levels of interleukin IL-6, which was associated with non-response during a 6-week treatment with amitriptyline.¹⁵ Cattaneo *et al.* found that expression of genes related to inflammation is associated with non-response to an 8-week treatment with escitalopram.¹⁶ In contrast, Manoharan *et al.* investigated the potential of serotonin (5-HT) and IL-6 to serve as functional biomarkers of fluoxetine response. Serum IL-6 and 5-HT were measured in 73 depressed patients (39 responders and 34 non-responders) at baseline and after 6 weeks of treatment and in 44 normal controls. Pre- and post-treatment levels of both biomarkers did not significantly differ between responders and non-responders.¹⁷ Although cross-sectional studies in this respect have been conducted, a longitudinal prospective study by Vogelzangs suggested that inflammatory and metabolic dysregulation worsens depression course due to reduced response to depression treatment and that alternative intervention treatments may be needed in these patients.¹³

Besides the metabolic and inflammatory dysregulations, other factors may contribute to response to depression treatment in conventional antidepressants. They appear to work via effects on one or more biogenic amine neurotransmitter systems or they may affect one or more site(s) of action. Other factors are biological variability, age, disease, internal environment, and gene expression, self-dependent changes in the internal milieu of a given individual's body due to factors such as diet, substance abuse, and medications.¹²

In homeopathy, a substance that causes the symptoms of a disease in healthy people will cure similar symptoms in sick people. Few studies have been conducted for proving if homeopathic treatment is effective for menopausal disorders and depression. Response to depression treatment has not been studied in homeopathic medicine. Most of the studies have focused on climacteric complaints only.^{18,19}

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