Randomized, double blind placebo-controlled trial: effects of Myo-inositol on ovarian function and metabolic factors in women with PCOS

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Abstract. – Oligomenorrhea and polycystic ovaries in women are one of the most important causes of the high incidence of ovulation failure. This is linked, perhaps, to insulin resistance and related metabolic features. A small number of reports show that myo-inositol improves ovarian function, but in these trials the quality of evidence supporting ovulation is suboptimal. Furthermore, few of them have been placebo-controlled. The aim of our study was to use a double-blind, placebo-controlled approach with detailed assessment of ovarian activity (two blood samples per week) to assess the validity of this therapeutic approach in this group of women. Of the 92 patients randomized, 47 received 400 mcg folic acid as placebo, and 45 received myo-inositol plus folic acid (4 g myo-inositol plus 400 mcg folic acid). The ovulation frequency assessed by the ratio of luteal phase weeks to observa-tion weeks was significantly ($P < 0.01$) higher in the treated group (25%) compared with the placebo (15%), and the time to first ovulation was significantly ($P < 0.05$) shorter [24.5 d; 95% confidence interval (CI), 18, 31; compared with 40.5 d; 95% CI, 27, 54]. The number of patients failing to ovulate during the placebo-treatment period was higher ($P < 0.05$) in the placebo group, and the majority of ovulations were characterized by normal progesterone concentrations in both groups. The effect of myo-inositol on follicular maturation was rapid, because the E2 circulating concentration increased over the first week of treatment only in the myo-inositol group. A significant increase in circulating high-density lipoprotein was observed only in the myo-inositol-treated group. Metabolic risk factor benefits of myo-inositol treatment were not observed in the morbidly obese subgroup of patients (body mass index > 37). After 14-wk myo-inositol or placebo therapy, no change in fasting glucose concentrations, fasting insulin, or insulin responses to glucose challenge was recorded. There was an inverse relationship between body mass and treatment efficacy. In fact a significant weight loss (and leptin reduction) ($P < 0.01$) was recorded in the myo-inositol group, whereas the placebo group actually increased weight ($P < 0.05$).

These data support a beneficial effect of myo-inositol in women with oligomenorrhea and polycystic ovaries in improving ovarian function.

Key Words:

Myo-inositol, PCOS, Ovarian function.

Introduction

Polycystic ovary syndrome (PCOS) is shared by many women like a common premenopausal disorder, characterized by hyperandrogenism and chronic anovulation[1,2]. Its etiology remains unsolved in spite of the fact that there have been no specific population-based studies, but probably only a 5-10% prevalence of this kind of disorder in women of reproductive age is a reasonable moderate value. This early is based to get the upper hand of any studies prevalency on polycystic ovaries which detected that a 20% of self-selected normal women had polycystic ovary morphology on ovarian ultrasound[3]. The most of them had a slight endocrine abnormality[3]. The lower amount is based on the reported 3% prevalence rate of secondary amenorrhea for 3 or more months[4]: an available datum shows that the 75% of women with secondary amenorrhea will fulfill diagnostic criteria for PCOS[5]. PCOS women can

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