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Metformin as a new option in the medical management of breast fibroadenoma; a randomized clinical trial

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Abstract

Background: Fibroadenoma (FA) is the most common benign solid breast mass in women, with no definite method of management. Because fibroadenoma is dependent on female sex hormones and comprises hypertrophic changes at cellular levels, we investigated the effects of metformin (MF), a safe hypoglycemic agent with anti-estrogenic and anti-proliferative properties, in the management of fibroadenoma.

Methods: In this randomized clinical trial study, eligible women with fibroadenomas were assigned randomly to the metformin (1000 mg daily for six months) or the placebo group. Breast physical and ultrasound exam was performed before and after the intervention, and the changes in the size of fibroadenomas were compared in the two groups.

Results: Overall, 83 patients in the treatment, and 92 in the placebo group completed the study. A statistically significant difference in changing size between the two groups was observed only in the smallest mass. In the largest FAs, the rate of size reduction was higher in the treatment group (60.2 % vs. 43.5 %); while a higher rate of enlargement was observed in the placebo group (38 % vs. 20.5 %). In the smallest FAs, the rate of the masses that got smaller or remained stable was about 90 % in the treatment group and 50 % in the placebo group. We categorized size changes of FAs into < 20 % enlargement and \geq 20 % enlargement. The odds ratio (OR) for an enlargement less than 20% was 1.48 (95 % CI = 1.10–1.99) in the treatment group in comparison with the placebo group; the odds for an enlargement less than 20% was higher in women with multiples fibroadenomas (OR = 4.67, 95 % CI: 1.34–16.28). In our study, no serious adverse effect was recorded, and the medicine was well-tolerated by all users.

Conclusions: This is the first study that evaluates the effect of MF on the management of fibroadenoma, and the results suggest a favorable effect. Larger studies using higher doses of MF and including a separate design for patients with single or multiple FAs are suggested in order to confirm this effect.

Trial registration: This trial (IRCT20100706004329N7) was retrospectively registered on 2018-10-07.

Keywords: Fibroadenoma, Fibrocystic Breast Disease, Breast Ultrasonography, Metformin, Therapy

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Declarations

Ethics approval and consent to participate

The Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran approved the study (Approval ID: IR.TUMS.VCR.1397.357). All participants read and signed a written informed consent before entering the study.

Consent for publication

Not applicable.

Competing interests

The authors have no conflict of interest to declare.

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