Efficacy and Safety of Metformin Compared to Watchful Observation in Breast Fibroadenoma— A Randomized, Controlled, Assessor-Blinded Study from India

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Abstract

Background: Fibroadenoma is benign solid breast mass, most commonly seen in pre-menopausal women between 14 and 35 years of age. The exact underlying cause is not known presence of estrogen receptor (ER) and progesterone receotor (PR) on breast tissues suggests a hormonal pathophysiology. Metformin has been demonstrated to have anti-proliferative and ant-estrogenic effects; therefore, it was assessed for clinical effectiveness in breast fibroadenoma.

Aims and Objectives: Aim of this study was to assess efficacy and safety of metformin in comparison with watchful observation among patients of breast fibroadenoma. Primary objective was to assess effect of metformin as compared to watchful observation in reducing size of breast lumps whereas secondary objectives were to assess effect of metformin as compared to watchful observation in reducing number of breast lumps, safety and intolerability and glycemic status and BMI.

Materials and Methods: Key inclusion criteria were women aged between 18 and 50 years and having breast fibroadenoma of size<5cm. Primary outcome was change from baseline in size of largest and smallest masses and secondary outcomes were change from baseline in number of masses, regression rate and change from baseline in BMI, RBS and HbA1c at 12 and 24 weeks. Study involved 12-week intervention and 24-week follow-up periods.

Results: 168 patients were randomly allocated to metformin group (1000 mg twice daily) and watchful observation group. The change from baseline in size of largest and smallest masses, in number of masses and regression rate were significantly higher in metformin group than in watchful observation group at both 12 and 24 weeks. Metformin caused significant reduction in RBS and HbA1c but did not cause hypoglycemia. Most women tolerated metformin well.

Conclusion: Metformin caused significant reduction in size as well as number of breast masses. Therefore, it can be an initial treatment for women with breast fibroadenoma of size<5cm.

Index Terms

Breast fibroadenoma, Efficacy, Metformin, Safety