

## 60007-100

Subcutaneous testosterone-anastrozole implant therapy in breast cancer survivors.

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**Author(s):**

R. L. Glaser; Department of Surgery, Wright State University, Dayton, OH

**Background:** Breast cancer survivors commonly experience severe symptoms of hormone deficiency that can adversely affect their health and quality of life. Beneficial effects of subcutaneous testosterone therapy include relief of hot flashes, heart discomfort, insomnia, depression, irritability, anxiety, fatigue, memory loss, sexual problems, incontinence, vaginal dryness, and joint and muscular pain. In addition, testosterone protects against bone loss, stimulates bone marrow and enhances immune function. Evidence supports that testosterone is breast protective. However, aromatization of testosterone to estradiol may have adverse effects on breast cancer proliferation. Unpublished data (Glaser) had previously demonstrated that 12 mg of anastrozole, delivered subcutaneously with up to 1,200 mg of testosterone, effectively prevented the conversion of testosterone to estradiol in men with elevated estradiol levels. **Methods:** To evaluate the efficacy of subcutaneous anastrozole in maintaining therapeutic testosterone levels without elevating estradiol in breast cancer survivors, two 3.1 x 6.1 mm implants containing a total of 120 mg testosterone and 8 mg of anastrozole were implanted in the upper gluteal area of 55 patients. Serum levels of testosterone and estradiol were measured 2 weeks following pellet insertion. **Results:** Testosterone-anastrozole therapy was effective in treating symptoms of androgen (hormone) deficiency. In all but 5 of 75 anastrozole/testosterone subcutaneous pellet insertions, serum estradiol levels measured < 30 pg/ml with therapeutic testosterone levels (mean: 281, range: 120-518 ng/dl). A single post-menopausal patient had an estradiol level > 40 pg/ml. A subsequent level measured < 30 pg/ml. There have been no adverse drug events from subcutaneous testosterone-anastrozole therapy in over 110 insertions. No breast cancer survivor treated with testosterone implants has been diagnosed with recurrent disease in up to 3 years of therapy. There has been no progression of disease in 2 patients with metastasis. **Conclusions:** The combination of testosterone with anastrozole, delivered subcutaneously, provides therapeutic levels of testosterone without elevating estradiol levels.

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