Managing Fibrocystic Breast Changes and Pain: Perspectives for the Clinician

Fibrocystic breast changes (FBC) occur in approximately 50% of women of child-bearing age, and some studies indicate that the lifetime prevalence of FBC may be as high as 70% to 90%.[1-3] These chang-es may include appearance of benign lumps that can be felt in the breast tissue, as well as tenderness, aches, and swelling that occur with increased severity before the menstrual cycle and begin to sub-side during menstruation.[3,4] This cyclic breast pain may be moderate to severe in approximately one-third of patients with FBC and last for more than 1 week of each monthly cycle.[5]

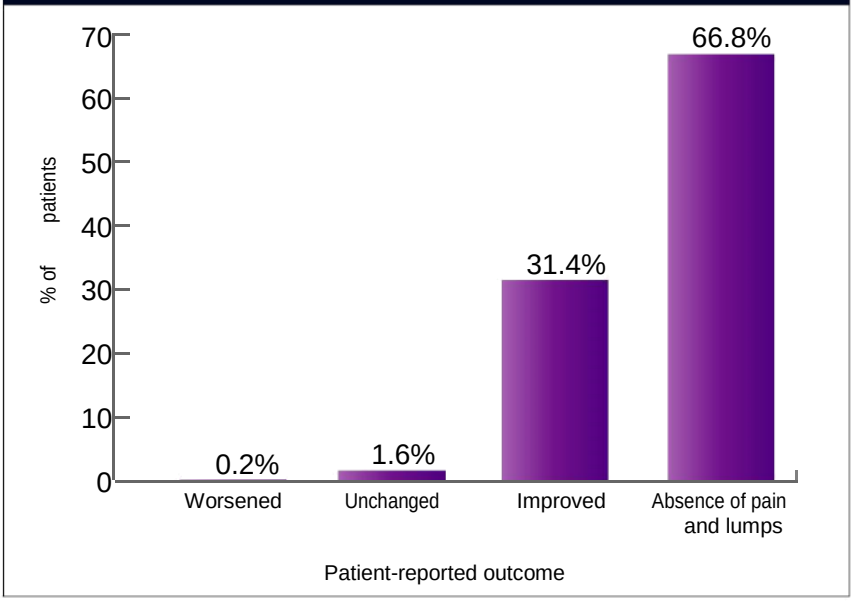
Managing Symptoms

Traditional management options for FBC may include prescription treatments such as danazol, tamoxifen, progesterone, and bromocriptine.[2] In general, these treatments are not well tolerated, and symptoms may return several months after discontinuation of treatment.[4,6] Additionally, danazol may cause suppression of ovar-ian function, bromocriptine may reduce levels of the hormone prolactin, and the antiestrogen tamoxifen is a category D pregnancy drug.[6-8]

Nonprescription pain management options include local application of heat, analgesics, diuretics, and reducing caffeine intake,[4,5] although these treatments typically do not provide sufficient relief. In one study, only 50% of patients who tried 1 or more nonprescription treatment options felt they were successful in reducing symptoms.[4]

Management of FBC is currently nonstandardized, as there are no established US guidelines for treatment of symptoms of this condition.[5] The lack of guidelines and the adverse effects of prescription medications lead many women to forgo treatment altogether. Molecular iodine, a new option for FBC that may help fill the unmet needs of these patients, has demonstrated safety and efficacy in a form unique from iodide. Unlike iodide, molecular iodine is a molecule, not a salt; as a result, it acts differently from iodide in the body and exerts different effects.[2,9,10]

FIGURE 1: SUBJECTIVE EFFECT OF MOLECULAR IODINE TREATMENT[2]
Subjective rating of fibrocystic breast changes (N = 1365), over 4 to 18-plus months of treatment



Adapted from Ghent WR, Eskin BA, Low DA, Hill LP. *Can J Surg.* 1993;36(5):453-460.

Clinical Study

Ghent and colleagues studied molecular iodine in 1365 women with FBC over 4813 woman-years of treatment (a mean of 191 days of follow-up). Approximately two-thirds (63.8%) of patients enrolled in the study were premenopausal; the remaining 36.2% of patients were postmenopausal. Over the course of the study, reductions in both objective and subjective pain scores were measured (Figure 1).[2] Additionally, in a 145-patient cross-over series leading up to the 1365-patient trial, 75% of women experienced an improvement in symptoms and reported having pain-free breasts.[2]

How Molecular Iodine Reduces Symptoms of FBC

Researchers observed that a lack of molecular iodine in the diet may increase the sensitivity of breast cells to the effects of estrogen, including swelling, fluid build up, and an increase in breast tissue cell numbers.[2] While the recommended daily allowance for iodine was sufficient to maintain normal thyroid function, it appeared to be suboptimal with regard to prevention of breast changes and pain. As a result, molecular iodine was considered

FIGURE 2: VIOLET PACKAGE WITH SUPPLEMENT FACTS[15]

Supplement Facts

Serving Size: 1 Tablet — Servings Per Container: 60

Amount Per Serving		% Daily Value
Iodine (as 84% potassium iodide, 16% potassium iodate) †	3000 mcg	2000%
Selenium (as sodium selenite)	55 mcg	79%

†Forms molecular iodine (I_2) when ingested.

as a possible therapy for FBC.[11] Regular use of molecular iodine is also thought to help reduce the sensitivity of breast cells to the proliferative effects of estrogen, resulting in normalization of breast tis-sue and improvement in the symptoms associated with FBC.[12,13] Consistent with this mechanism of action, treatment with molecular iodine in patients with FBC reduces swelling and helps reduce painful symptoms.[2,10,11]

Safety

In the 1365-patient trial previously mentioned, the most common adverse effects were initial transient increases in pain (5.7%), acne (1.1%), hair thinning (1.0%), and nausea (0.6%).[2] Hypothyroidism and hyperthyroidism were very uncommon, occurring in only 0.1% and 0.3% of patients, respectively. Although changes in thyroid hormone levels were rare, patients with thyroid disorders are advised to consult their endocrinologist before taking molecular iodine.[2,9] Additionally, molecular iodine has not been studied in pregnant patients.

About Violet™ Iodine: A Novel Option for FBC

Violet iodine is the first OTC product specifically designed to alleviate the symptoms of FBC.[14] The molecular iodine in a Violet tablet provides 3000 mcg of iodine daily, a dose that is well tolerated; it is similar to the amount consumed as part of the daily diet of women in countries throughout Asia.[11] Violet iodine also provides 55 mcg of selenium (79% of the daily value), an important nutrient that is a component of many of the enzymes in the body that process molecular iodine (Figure 2).[1,15] Because molecular iodine slowly builds up in breast tissue over time, it is important to take Violet iodine every day.[15]

Role of the Clinician

Clinicians should take a detailed his-tory about breast complaints from their reproductive-aged patients. While some therapies for FBC (eg, hormonal contraceptives) may be a part of the care provided during a particular visit, clinicians can explain the use of Violet iodine to women with FBC. Important counseling points include precautions for the use of molecular iodine in patients with a history of thyroid disease or who are pregnant. By educating patients about FBC and discussing some of the new options for long-term management of this painful condition, clinicians can help patients reduce their discomfort and achieve bet-ter clinical outcomes.

To request Violet iodine samples for your practice, please visit www.violetmd.com.

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