

Fibrocystic Breast Disease

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Breast nodules are a frequently presented gynecologic complaint. These nodules have two chief causes: benign breast disease and cancer. However, benign breast disease is the most common cause of nodules and can stem from cyst formation, obstructed ducts, inflammation, or infection. Although benign breast nodules have several causes and manifest themselves differently, for purposes of this discussion, all fibrous nodules or lumps will be referred to as fibrocystic breast disease (FBD).

According to the National Cancer Institute/National Institutes of Health (2001a,b), fibrocystic breast disease (FBD) is a common condition that affects many women at some time in their lives. FBD is most common between the ages of 30 and 50 (AMA 1989), but younger women as well as menopausal women taking hormone replacement therapy (HRT) may also experience FBD (Imaginis 2000). More recently, some physicians have preferred to call FBD, fibrocystic breast "condition" or "change" (FBC).

The symptoms of FBD can vary significantly. Some women experience severe breast tenderness and pain with multiple lumps in both breasts. Other women have only mild tenderness with no detectable lumps. In some women the symptoms are relatively constant, while in others the symptoms come and go either monthly or over several months. According to the National Cancer Institute (2001a), the chances of developing FBD are greater in women who have never had children, women who have irregular menstrual cycles, or women who have a family history of FBD or breast cancer.

FBD is a condition generally characterized by lumps that move freely in the breast tissue and vary in texture and size (Lark 1996). However, because the clinical signs of breast cancer are not easily distinguished from benign breast conditions, all breast lumps should be examined by a physician and not be assumed to be benign. Only a physician can determine the nature of breast lumps or changes (National Cancer Institute 2001a).

Because FBD is a benign condition, it usually does not lead to breast cancer (American Cancer Society 1991, 1997; National Cancer Institute 2001b). Fortunately, only about 5% of FBD cases involve the type of changes that would be considered a risk factor for developing breast cancer. However, benign conditions may eventually result in calcifications (Anon. 1998). Calcifications are quite small--sometimes as small as a grain of salt--and cannot be detected during a routine exam; however, calcifications may be detected by routine mammography. Since calcifications may be associated with some types of pre-malignant lesions, it is important to follow your physician's recommendations concerning the frequency of mammography (AMA 1989).

NORMAL BREAST TISSUE

- Breast Nodules
- Benign Nodules

The breast is composed of 15-20 lobes of milk-secreting glands that are embedded in fatty tissue. Ducts link the lobes of these glands and have an outlet through the nipple. The area between the lobules and ducts is filled with fatty tissue. Breast tissue itself contains no muscles; however, there are small, very fine ligaments throughout the breast that attach to the skin and determine the shape of the breast. There are no muscles in the breast itself, although pectoral muscles lie just under each breast and over the ribs (AMA 1989).

The breasts undergo changes each month when a female begins to have menstrual periods. Hormones that are implicated in

development of breast mammary glands and prolactin, the milk release hormone secreted by the pituitary gland (Lark 1996). An increase in prolactin may also be responsible for some FBC changes because higher levels of prolactin seem to be connected with a higher occurrence of FBC. (Prolactin levels of over 100 ng/mL may be a causative factor). Often the painful symptoms of FBC will decrease once menstruation begins. In some women, however, the repeated cycles of hormonal stimulation result in chronic inflammation and development of fibrous tissue. When fibrous tissue makes it more difficult for the fluid in breast cysts to escape and be normally absorbed by a woman's body, the cysts become denser, which can cause pain and pressure on surrounding tissues (Lark 1996). This fibrous tissue is similar to the type of tissue in ligaments and scars and feels firm, thick, rubbery, and ridge-like. It may also feel like small or large beads scattered throughout the breast.

In addition to estrogen, progesterone, and prolactin, all naturally occurring female hormones, many other natural hormones (hypothalamic, other pituitary hormones, thyroid, parathyroid, adrenal, pineal, pancreas, ovarian, and duodenal hormones) can also contribute to FBC (Ayers 1983; AMA 1989). Environmental estrogens, called xenoestrogens, may also contribute to human hormone levels. Xenoestrogens come from phytoestrogens (produced by plants), dietary estrogens from meat and dairy products, and many other chemicals such as pesticides, fertilizers, alkylphenols (used in detergents), and plastics (food packaging) (Nimrod et al. 1996). Additionally, as women approach menopause, they have an additional, complicated decision to make concerning the use of synthetic hormone replacement therapy (HRT) (Lundstrom et al. 2001; Mayo Clinic 2001; Women's Health Initiative Investigators 2002).

Breast Nodules

As stated earlier, because breast tissue is naturally a glandular type of tissue, almost all women develop nodules or lumps in their breasts at some time or another. Lumps, also called "dominant lumps," feel different from surrounding tissue (AMA 1989). Some may be quite large, while others are small and even diffuse over time (Lark 1996). Fibrous tissue in the breast may even be mistaken for a lump. Breast nodules or lumps are the result of several medical causes, including cysts, fibroadenomas, areolar gland abscesses, breast abscesses, intraductal papillomas, mammary duct ectasia, mastitis, Paget's disease, and cancer (Anon. 2000).

Benign Nodules

- Cysts
- Sclerosing Adenosis
- Intraductal Papillomas

Cysts

Cysts are the most common cause of nodules or breast lumps. Cysts are usually smooth, round, fluid-filled, and slightly elastic. Although the fluid that comes from a cyst is often discolored, the color of the fluid is of little cause for concern unless it is bloody. Cysts occur as an isolated lump, in clusters, or widespread with well-defined lumps of various sizes. Cystic lumps are mobile and do not attach themselves to underlying breast tissue; therefore, cysts do not produce tissue deviation or dimpling. Mobility is one major characteristic that differentiates cysts from malignant nodules. However, cysts are sometimes accompanied by thickened adjacent tissue that is palpable and not so mobile. Breast cysts may also produce a discharge from the nipple that varies from clear and watery to sticky (AMA 1989).

Cysts frequently occur in the upper outer quadrant and the underside of the breast. Symptoms range from a feeling of fullness or heaviness to a dull ache, extreme sensitivity, or a burning sensation. For some women, these symptoms may be severe, making exercising or sleeping on their stomachs painful.

Cysts also often increase in size and tenderness in response to the monthly menstrual cycle because breast tissue undergoes changes related to the normal rise and fall of hormone levels (Lark 1996). After menstruation, the changes and symptoms sometimes abate. Physicians recommend that the best time for breast examination is about 7-10 days after the start of menstruation when breast tissue is more likely to be at its most normal state. Sometimes, after menopause, FBC symptoms completely disappear or become less noticeable (without HRT) (Imaginis 2000).

The occurrence of multiple cysts in one or both breasts is also common in FBC (also called fibroadenosis or chronic cystic mastitis) (Anon. 2000). If a mass is determined to be a cyst, the next step is to determine if it is a simple cyst (one compartment) or a complex cyst (more than one compartment within the cyst). Simple cysts are very unlikely to be malignant.

Sclerosing Adenosis

A benign condition with excessive tissue growth in the lobules of the breast is sclerosing adenosis (National Cancer Institute

2001b). The condition frequently causes breast pain. Sclerosing adenosis may produce lumps and appears on a mammogram as a calcification (a small deposit of calcium) in breast tissue.

Intraductal Papillomas

Small, wart-like, benign growths that project into the breast ducts near the nipple are intraductal papillomas (National Cancer Institute 2001b). They usually occur singly, but can also appear as multiple lesions. The smaller nodules are difficult to palpate. The primary sign of intraductal papilloma is nipple discharge, either clear or bloody. Breast pain and tenderness may occur.

NODULES WITH POTENTIAL FOR CANCER

- Complex Cysts
- Fibroadenomas
- Paget's Disease
- Phyllodes Tumor

Complex Cysts

Complex cysts have more than one compartment within the cyst. Ultrasonography is valuable in differentiating simple cysts from complex cysts or solid masses (Bassett et al. 1991). Complex cysts are somewhat more likely to be cancerous, so doctors will often order further tests, beginning with fine needle aspiration and perhaps a biopsy, to be certain the cyst is not cancerous or pre-cancerous.

Fibroadenomas

Fibroadenomas (sometimes called adenofibromas) are smooth, firm, benign tumors that are extremely mobile, feel slippery, and move around easily in the breast. They consist of structural (fibro) and glandular (adenoma) tissue (Anon. 2000, National Cancer Institute 2001b). Fibroadenomas feel round with well-defined margins and vary from pinhead in size to very large. They grow rapidly and usually occur near the nipple or on the outside of the upper quadrant. Fibroadenomas occur most often in women in their 20s and 30s and occur twice as often in African-American women as in other American women (National Cancer Institute 2001b). When aspirated, if there is no fluid in the lump, it is most likely a fibroadenoma. Fibroadenomas do not cause pain or tenderness. A "complex" fibroadenoma contains abnormal growths or exhibits abnormal cell changes. Although fibroadenomas themselves do not become cancerous (National Cancer Institute 2001b), they can act as markers for the disease. Women with a family history of breast cancer who also develop complex fibroadenomas might be at a higher risk for developing cancer than other women. Fibroadenomas are not difficult to remove and rarely recur.

Paget's Disease

A slow-growing intraductal carcinoma that begins as a scaling, eczema-like lesion on the nipple is called Paget's disease (Anon. 2000). The nipple becomes red and irritated and the lesion extends along the skin and into the ducts. The lesion can progress to a mass located deep in the breast.

Phyllodes Tumor

Phyllodes tumor is a breast tumor that might be malignant (Mazy et al. 1999). Phyllodes tumor is a rare type of breast tumor, similar to a fibroadenoma, but it is composed of an overgrowth of fibrous connective breast tissue that can become quite large. If malignancy is discovered (rare) through biopsy, the tumor and a margin of normal breast tissue are removed surgically.

FACTORS AFFECTING INCREASED RISK OF BREAST CANCER

When a woman finds a breast nodule, the first concern is that it might be cancerous. Most of the time, breast nodules are not cancerous (benign). According to Hurley et al. (1997), there are three basic, agreed-upon classifications of benign breast disease: nonproliferative, proliferative without atypia, and atypical hyperplasia. However, there can be an association with benign changes in the breast in young women and an increased risk of breast cancer with age, particularly later in life. Therefore, pathologists sometimes add comments to the pathology report indicating whether or not benign changes are relevant to an increased risk of cancer. One study followed 644 women with breast nodules between 1976 and 1982. The researchers found a relationship between subsequent cancer in women with multiple cysts and in 15 of the women whose cysts had been aspirated. The authors concluded that women with multiple breast cysts that have been aspirated have an increased risk of breast cancer. These women should perform more breast self-examinations and have follow-ups accordingly (Bundred et al. 1991).

Benign breast conditions are more often found in premenopausal women (Ernster 1981; Bodian 1993a). Breast cancer occurs more often in postmenopausal women (75% of cases) (NBCC 1999). Estimating the risk for future breast cancer from a benign condition is difficult: the extent of mammography screening differs in the population and often, significant time passes between diagnosis of benign disease in a younger woman and the increased risk for breast cancer development in older women. Because benign breast disease is difficult to distinguish from malignant disease, diagnostic biopsy is required for a definitive diagnosis (NBCC 1999).

Women with biopsy-confirmed benign disease do appear to have an overall modest increase in risk for subsequent development of breast cancer, particularly for more hyperplastic or epithelial (the covering or lining) proliferative forms. However, the evidence regarding the risk of breast cancer for nonproliferative conditions is conflicting. Some research found that the risk of breast cancer for women with nonproliferative disease is about double that of women without benign disease (Bodian et al. 1993b), while others find that lesions with no proliferative changes were not associated with an increased risk (Oza et al. 1993; Henderson et al. 1996; NBCC 1999). According to Hurley et al. (1997) atypical hyperplasia is a risk factor, but it is not with certainty followed by breast cancer; risk applies to both breasts, with greater risk on the affected side. There is no means to predict which women will go on to develop breast cancer and the effectiveness of current screening and management methods is unknown. Further complicating a physician's ability to predict a woman's risk for breast cancer is that most women do not have a history of biopsy for a benign lesion. Additionally, at the time of this writing there is no generally agreed upon classification of mammography patterns of breast tissue that is a predictive measure of which conditions are indicative of increased risk (Bodian et al. 1993c; NBCC 1999).

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Fibrocystic Breast Disease

HORMONE REPLACEMENT AND BREAST CANCER

■ Signs of Breast Cancer

In the July 17, 2002 edition of the *Journal of the American Medical Association*, after decades of accumulated observational evidence, the Women's Health Initiative Investigators group raised concerns about the balance of risks and benefits for hormone use in healthy postmenopausal women. The concerns resulted from a randomized controlled primary prevention trial. The trial recruited 16,608 postmenopausal women (50-79 years of age) with an intact uterus at age 40 to United States clinical centers from 1993-1998. The study was designed to last 8.5 years. Participants in the study received placebo (8102 subjects) or conjugated equine estrogen (0.625 mg daily) plus medroxyprogesterone acetate (2.5 mg daily) in a single tablet (8506 subjects), commonly known as Prempro. The study monitored coronary heart disease, invasive breast cancer, stroke, pulmonary embolism, endometrial cancer, colorectal cancer, hip fracture, and death due to other causes.

After 5.2 years, the data and safety monitoring board recommended stopping the trial because one statistic (for invasive breast cancer) had exceeded the stopping boundary for an adverse effect and the global index statistic supported risks exceeding benefits. Although the absolute risk was still low, investigators stopped the estrogen plus progestin part of the study. They concluded: "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy postmenopausal U.S. women." Women in the other groups in the study (women taking estrogen alone, on a low-fat diet, taking calcium and vitamin D supplements, and women in the observation-only group) were advised to continue with their assigned treatment regime. However, prescribing the combination of estrogen and progestin was not recommended for long-term use or for prevention of chronic diseases (Women's Health Initiative Investigators 2002). Theories abound about why there appear to be complications with combination HRT, with one being that the progestin part of the therapy may have an antagonistic action on the estrogen part. Other co-factors include obesity, diabetes, and influence of family health history.

Another much smaller study in 2001 (158 women: 58 using HRT with Prempro (conjugated equine estrogen, 0.625 mg, plus medroxyprogesterone acetate, 5 mg); 51 using low-dose oral estrogen alone (estriol), 2 mg daily; and 55 using transdermal estrogen via a patch with estradiol, 50 mcg each 24 hours) evaluated the impact of different HRT regimens on mammographic breast density. Independent radiologists were unaware of the HRT and analyzed coded mammography films. The research indicated that an increase in mammographic density was more common in women taking continuous combined HRT (40%) than in those using oral low-dose estrogen (6%) or transdermal (2%) treatment (Lundstrom et al. 2001). The researchers reported that increased density was already apparent at the first visit after beginning HRT. During long-term follow-up, there was very little change in mammographic status, leading Lundstrom et al. (2001) to conclude that there was an "urgent need to clarify the biological nature and significance of a change in mammographic density during treatment and, in particular, its relation to symptoms and breast cancer risk."

Scientists, environmentalists, physicians, and governmental agencies have all produced reports in support of their particular stance on hormones: are they safe or not and should they be used or not? Therefore, in light of continuing concerns about the safety of using HRT, particularly HRT containing estrogen plus a progestin component, decisions concerning hormone use and modulation are personal ones related to each woman's particular risk factors and her reasons to consider using HRT. It is more important than ever to consult your physician for guidance concerning the decision to use any hormone therapy (also see the Female Hormone Modulation Therapy protocol).

Signs of Breast Cancer

Nodules that are hard, poorly delineated, and fixed to the skin or to underlying tissue are suggestive of breast cancer. Cancerous nodules can cause dimpling, nipple deviation, or nipple retraction. They usually occur singly and often are not painful. There may be nipple discharge that is clear or bloody. Bloody discharge is more suggestive of breast cancer. Ulceration may occur in later stages (Anon. 2000). (Further discussion of breast cancer is beyond the scope of this protocol. See the Breast Cancer protocol for a discussion of additional information.)

OTHER CAUSES OF BREAST NODULES

- Mammary Duct Ectasia
- Pseudolumps
- Fat Necrosis
- Breast Pain

Mastitis or postpartum mastitis is an infection in women who are breastfeeding in which a milk duct becomes blocked, causing milk

to pool, permitting a bacterial infection, and resulting in inflammation (AMA 1989). The breast appears red and feels warm and may also be tender. Mastitis can be accompanied by chills, fever, and cracking of the nipple.

Mammary Duct Ectasia

Mammary duct ectasia causes ducts beneath the nipple to become clogged and inflamed, particularly in women nearing menopause or in postmenopausal women (National Cancer Institute 2001b). The condition can be itchy and tender, with transient pain, and it may produce a thick, sticky multicolored discharge. The skin over the nodule may even be a blue-green color. Nearby lymph nodes can also be inflamed.

Pseudolumps

Pseudolumps are normal lumpy areas of breast tissue. This type of lumpiness will often disappear or vary with cyclic hormonal levels. Pseudolumps also result from silicone injections to enlarge the breasts or as a consequence of breast surgery or radiation therapy.

Fat Necrosis

Fat necrosis produces painless, round, firm lumps that form from damaged and disintegrating fatty tissue (National Cancer Institute 2001b). Fat necrosis is more likely to occur in obese women with large breasts. It may also develop in response to a bruise or blow to the breast. Sometimes the skin around these lumps looks red or bruised.

Breast Pain

Mastalgia refers to breast pain that is severe enough to cause a woman to seek medical treatment. Mastalgia can occur at rest or during movement, intermittently, cyclically, or constantly and can be sharp or dull and radiate to the back, arms, or neck. Pain can be aggravated by palpation (such as during physical examination). However, mastalgia is an unreliable indicator of a serious condition such as cancer (Anon. 2000). Although many women experience uncomfortable tenderness and swelling, pain characterized as severe occurs only about 15% of the time.

Breast pain not related to the menstrual cycle is called non-cyclical breast pain. Non-cyclical breast pain is rare and much more difficult to treat. Non-cyclical breast pain can be caused by old trauma to the breast (such as a blow to the breast, a biopsy, or surgery), infection, or some other condition completely unrelated to the breast (Anon. 2000). Arthritis is a possible cause of breast pain. Arthritis pain is usually felt in the breastbone, at the center of the chest. Women with arthritic breast pain also may experience increased discomfort when they breathe deeply.

An early study showed that there were significant abnormalities in pituitary function (via prolactin mechanisms) seen in severe cyclical mastalgia and nodular breast disease, but not in women with noncyclical mastalgia (Kumar et al. 1984).

DIAGNOSING FIBROCYSTIC BREAST DISEASE

A healthcare provider who is experienced in diagnosing breast conditions should examine any new breast mass or lump. Additionally, if there is any skin irritation, dimpling, nipple pain or retraction, redness or scaling of the nipple or breast skin, or nipple discharge other than breast milk in lactating women, see a physician for an evaluation. Breast conditions usually can be diagnosed by an examination by a physician. It is not unusual for a physician to recommend a mammogram, ultrasound, or biopsy procedure to assist or confirm the diagnosis (National Cancer Institute 2000b).

A mammogram, the most frequently used diagnostic tool for breast lumps, is a type of x-ray examination. If the mammogram suggests that abnormal tissue is benign, follow the physician's recommendations and recheck the lump (in perhaps 4 to 6 months) (National Cancer Institute 2000b). If the mammogram is inconclusive or if it indicates the need for further examination, your physician may recommend a computer-aided diagnosis procedure using ultrasound. This additional diagnostic procedure is designed to improve identification of a potentially malignant lesion.

Ultrasound uses high-frequency waves to outline a part of the body and is useful to further evaluate possible abnormalities found during mammograms or physical examinations. Besides aspiration, ultrasound is the only way to determine if the lump is a fluid-filled cyst. Fluid-filled cysts have a distinctive appearance on an ultrasound screen.

Fine-needle aspiration biopsy (FNAB) is used if the physician is almost certain that the lump is a cyst. Aspiration is also used to extract a material from a lump for further analysis (National Cancer Institute 2001b). A very thin needle is inserted into the breast tissue as the doctor palpates the lump. The procedure is essentially painless because nerves are located primarily in the skin, not in the breast tissue itself. Ultrasound is used to guide the needle when a lump is difficult to palpate or is very small. FNAB has

decreased the need for surgical biopsy.

Core-needle biopsy uses a needle larger than the type employed with FNAB. The procedure is performed in a physician's office with local anesthesia of the breast area to be biopsied. Core-needle biopsy removes a small cylinder of tissue for examination.

Stereotactic biopsy is a newer approach that relies on a three-dimensional x-ray to guide the needle biopsy of non-palpable mass (National Cancer Institute 2001b). The breast is x-rayed from two different angles and a computer plots the position of the suspicious area. Once the area is precisely identified, the radiologist uses a needle to biopsy the lesion.

Surgical biopsy may also be necessary to remove all or part of a lump for examination (National Cancer Institute 2001b). This procedure is done either in a physician's office or in an outpatient hospital facility under intravenous sedation or local anesthesia.

There are newer methods, such as vacuum-assisted biopsy, which remove even more tissue, but so far there is no universal agreement about when these procedures should be used, even though current studies show consistent reliable results (Fine 2001; Maganini et al. 2001; Ohsumi et al. 2001; Jackman et al. 2002; Perlet et al. 2002).

TREATING FIBROCYSTIC BREAST DISEASE

- Intraductal Papilloma
- Mastitis
- Mammary Duct Ectasia

Although some physicians consider FBD to be more correctly termed a condition, its symptoms cause significant pain and discomfort for many women. Women who have FBD may find relief from any of several conventional and natural treatments. Some procedures (FNAB) for the conventional treatment of FBD can often be performed in a physician's office. Other procedures (such as a biopsy) are usually performed in an ambulatory or hospital surgical facility.

Breast cysts are relatively simple to treat. Simple breast cysts are aspirated by a physician with a needle and syringe (National Cancer Institute 2001b). A biopsy is often not necessary. Fluid aspirated from a cyst is rarely tested unless it is bloody or the woman is older than 55 years of age. Gross breast cysts that are benign disappear after aspiration. (However, a cancerous lump remains even after fluid is withdrawn.) Following imaging by mammography and ultrasonography, complex cysts require laboratory investigation usually beginning with fine needle aspiration and perhaps biopsy.

Intraductal Papilloma

In intraductal papilloma, the diseased ducts can be removed surgically if discharge becomes bothersome (National Cancer Institute 2001a; 2001b). The appearance of the breast is usually unchanged.

Mastitis

Mastitis or postpartum mastitis is an infection that is treated with antibiotics (Anon. 1998). Pus-filled abscesses may need to be drained or removed. Lactating women with mastitis should use a breast pump to prevent additional pooling of breast milk and discard the milk. Breast milk should not be used until the infection has responded to antibiotic treatment.

Mammary Duct Ectasia

Mammary duct ectasia is treated with antibiotics, warm compresses, and sometimes surgery (National Cancer Institute 2001b).

HORMONE AND DRUG THERAPY

- Oral Contraceptives
- Hormone Replacement Therapy (HRT)
- Tamoxifen
- Danazol
- Bromocriptine
- Lisuride
- DHEA

The anterior pituitary gland secretes follicle-stimulating hormone (FSH) which in turn causes follicle cells in the ovaries to secrete estrogens. The anterior pituitary also secretes luteinizing hormone (LH) which causes the corpus luteum to secrete progesterone and a small amount of estrogens, including estradiol (E2). LH and FSH work together to bring about ovulation and menstruation. The corpus luteum produces progesterone for about 11 days (the luteal phase) after ovulation. About 3 days later, when levels of estrogen and progesterone are at their lowest, menstruation begins.

In an early study comparing women with normal breast tissue to women with benign breast disease, there was a significant imbalance of progesterone over estradiol during the luteal phase in women with benign breast disease (Sitruk-Ware et al. 1979). When the women were grouped according to the type of breast lesion, there was elevated or normal estradiol in women with adenosis tumors and increased nodularity of both breasts. Plasma progesterone was also consistently lower in all groups as compared to the normal women. The authors concluded: "From these results it may be postulated that an imbalance in the secretion of E2 and progesterone by the corpus luteum is a constant finding in women with benign breast disease" (Sitruk-Ware et al. 1979).

Oral Contraceptives

Sometimes physicians treat breast pain and swelling associated with FBD by prescribing oral contraceptives which tend to stabilize (or level out) hormone levels. Results of studies indicate that oral contraceptives have positive benefits by decreasing the symptoms of FBD, particularly in younger women (Mishell 1993; Rohan et al. 1999; Scott 1993).

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Fibrocystic Breast Disease

Hormone Replacement Therapy (HRT)

HRT, often recommended to post-menopausal women, may actually increase the symptoms of FBD depending on the hormone combination used. As with any type of hormone administration, however, the results and effects differed widely among women studied. When on HRT, it is important to monitor any changes in breast tissue and to evaluate these changes with your physician as they relate to the positive benefits (cardiovascular, bone density) versus the risks (increased density of breast nodules) of continuing HRT (Lundstrom et al. 2001; Ozdemir et al. 1999). (See the protocol on Female Hormone Modulation Therapy.)

In a 1997 study, doctors treated women with painful FBD by giving them estroprogestins (estrogen-progesterone compounds) for 3 months. They found that 60% of the women reported reduced or improved symptoms (Leonardi 1997). However, like HRT, estrogen replacement therapy (ERT) has also been linked to higher rates of FBD among postmenopausal women; in fact, they are twice as likely to develop FBD as women who have not used estrogen replacement (Pastides et al. 1987). Women on ERT also experience more fibroadenomas. The risk seems to increase the longer the therapy is employed.

Powerful drugs with hormonal effects are also available and are prescribed with caution when pain from FBD is severe. However, physicians are hesitant to use them because of potential side effects and interactions with other drugs or conditions (such as tamoxifen and danazol).

Tamoxifen

A medicine that blocks the effects of the estrogen hormone in the body, Tamoxifen, is primarily used to treat breast cancer that is estrogen receptor positive (Chatterji 2001/2002). It has also been used in some women who do not have breast cancer, but who are at high risk to develop it. Tamoxifen has been used to relieve significant breast pain associated with FBD. An early double-blind controlled study was done with tamoxifen in 60 patients who had severe mastalgia lasting more than 6 months. The patients were treated with a placebo or 20 mg of tamoxifen for 3 months. There was relief of pain in 71% of the patients receiving tamoxifen, demonstrating that tamoxifen was valuable in the treatment of severe cyclical and non-cyclical mastalgia and that treatment can be achieved with few side effects (Fentiman et al. 1986). How tamoxifen works and its long-term effects are not precisely known. However, the use of tamoxifen requires careful monitoring by a physician to assess side effects, blood levels, and so forth.

Indole-3-carbinol (I3C) is a phytonutrient with similar properties to tamoxifen: I3C partially inactivates estrogen (Bradlow et al. 1994); fights free radicals (Arnao et al. 1996); and interferes with tumor cell production (Bradlow et al. 1999a). See the detailed description below on I3C and how it may be used as an adjunct or an alternative to tamoxifen.

Danazol

Danazol is a synthetic steroid that is prescribed for pain and infertility caused by endometriosis and for the pain and tenderness of FBD. When prescribed for FBD, danazol may produce partial or complete disappearance of nodules and relief from pain and tenderness (Greenblatt et al. 1982; Mansel et al. 1982; Lopez et al. 1996). However, danazol has undesirable side effects such as allergic reactions (particularly for persons who are allergic to preservatives or anabolic steroids) and drug interactions. For example, danazol may increase the anticoagulant effect of warfarin, a drug frequently prescribed as a blood-thinning agent, increase blood sugar levels in diabetes mellitus, and increase the occurrence of migraine headaches (Meeks et al. 1992). Additionally, this synthetic testosterone derivative may cause women to develop male sexual characteristics such as facial hair (Peress et al. 1982). Danazol is not recommended for pregnant women or women who are breast feeding because of undesirable effects on the infant. However, danazol does help alleviate breast pain. As early as 1985, a study found that the drug eased pain in 70% of women with cyclical pain and in 31% of women with noncyclical pain (Pye et al. 1985). Symptoms often recur after treatment with danazol is stopped.

Bromocriptine

Another drug, bromocriptine, also helped 20% of women with non-cyclical pain and 47% of women with cyclical pain (Pye et al. 1985). Bromocriptine is a drug that affects the pituitary gland (blocks the release of the hormone prolactin) and is prescribed for menstrual problems and to stop milk production in some women. It is also used to treat other conditions such as infertility, Parkinson's disease, and acromegaly (overproduction of growth hormone). Bromocriptine has side effects, including significant nausea, allergic reactions, and interactions with drugs taken for other conditions (hypertension, mental illness, and liver conditions).

Lisuride

Lisuride (used in Parkinson's disease), a drug with endocrine effects similar to those of bromocriptine, reduced FBD symptoms in 63% of the women studied. Estrogen levels in those patients were reduced and progesterone levels were increased (Lopez-Rosales et al. 1991).

DHEA

Dehydroepiandrosterone (DHEA) is a steroid hormone chemically related to testosterone and estrogen. It is made by the adrenal glands from cholesterol. DHEA levels in the human body peak in the mid-20s and steadily decline beginning about the mid-30s (Leowattana 2001). Researchers have studied the actions of DHEA for over 20 years and have found that it may have beneficial implications in many areas, such as improving immunity; reducing menopausal symptoms; preventing cancer, heart disease, Alzheimer's disease, and chronic inflammation; improving longevity; and aiding weight loss (Kimura et al. 1998; Kurzman et al. 1998; Murialdo et al. 2000; Leowattana 2001; Corsini et al. 2002; Polleri et al. 2002; Simpson 2002; Takayanagi 2002; Yang et al. 2002). DHEA should only be taken under the supervision of a physician who can monitor blood levels of steroids and cholesterol and existing health conditions (Nestler et al. 1988; Barrett-Connor et al. 1995; Yen et al. 1995). DHEA is contraindicated in both men and women who have hormone-related cancer. (See the DHEA Replacement Therapy Protocol. Life Extension recommends specific dosing and blood testing schedules for all persons desiring to take DHEA safely.)

NUTRITIONAL RECOMMENDATIONS

- Dietary Fat
- Fatty Acids
- Conjugated Linoleic Acid
- Omega-3 and Omega-6 Fatty Acids
- Evening Primrose Oil
- Borage and Flax Seed Oils
- Fruits, Vegetables, and Dietary Fiber
- Indole-3-Carbinol
- Soy
- Simple and Complex Carbohydrates
- Vitamins
- Detoxifying Herbs
- Supplements and Herbs for Pain and Inflammation
- Caffeine

There are a number of natural treatments that may help women with FBD. These therapies may be employed alone or in combination with conventional treatments.

Nutritionists make several general recommendations concerning FBD and diet:

- Reduce fat to less than 20% of your diet, particularly saturated fats (animal products).
- Include more foods that are high in fiber. (Fiber is important in aiding bowel transit time.)
- Limit eggs, chicken, and dairy products.
- Include soy protein products (tofu).
- Reduce caffeine intake or consider avoiding coffee, tea, soft drinks, and chocolate (caffeine and methylxanthine) altogether.
- Reduce or eliminate sugar, white flour, and refined foods.
- Take vitamins (beta-carotene, vitamin C, vitamin E, vitamin B-complex, vitamin B6).
- Take minerals (selenium, zinc, copper, calcium, magnesium, iodine).
- Consume omega-3 fatty acids from cold-water fish, fish oil supplements, or Perilla-seed oil supplements.

In addition, some form of daily exercise (walking, bicycle riding, yoga, weight training) and not smoking are strongly recommended.

As with any nutritional issue, studies concerning dietary recommendations seem to often be contradictory. Therefore, many choices concerning a type of diet to follow or foods to be included or avoided will be personal ones based on each individual's particular circumstance and experience. Consult with your physician with any concerns before making nutritional changes to control or treat FBD.

Dietary Fat

Beginning as early as 1980, numerous studies have examined the relationship between FBD and dietary fat. Obesity tends to increase estrogens, free fatty acids, and triglycerides (Leijd 1980; Clarke 1981; Bates et al. 1982; Siiteri et al. 1987; Blum et al. 1988; Zumoff 1988; Kaplan 1989; Hunt et al. 1995; Singh et al. 1995; Vanhala et al. 1998; Inukai et al. 1999; Despres et al. 2000;

Hudgins et al. 2000). The typical Western diet provides about 40% of its calories from fat. However, nutritionists recommend that a healthy diet should include 30% of calories from fat with only 10% of these calories coming from saturated fat. Some researchers suggest that additional lowering of dietary fat levels (to 15%) may help stabilize hormonal imbalances that can lead to FBD (Mishra et al. 1994). In an early two-part study reported by Rose et al. (1987), investigators put 16 women on a diet with fat comprising 20% of total calories. After 3 months, the investigators found significant reductions in circulating estrogens, while levels of serum progesterone remained stable.

In another early study, researchers studied women who had had severe cyclical FBD for at least 5 years (Boyd et al. 1988). These women were advised to limit their dietary fat to 15% of calories consumed, while increasing complex carbohydrate consumption. After 6 months, the women reported significant reduction in the severity of premenstrual breast tenderness and swelling (Boyd et al. 1988). In a follow-up study in 1997, 817 women were randomly assigned to two groups (an intervention group to reduce intake of dietary fat and increase carbohydrates and a control group) and followed for two years. In all subjects, baseline mammography images were taken and compared with images that were taken two years later. After two years, there was a reduction in breast mass, leading the authors to conclude that "a low-fat high-carbohydrate diet reduced the area of mammographic density, a radiographic feature of the breast that is a risk factor for breast cancer." The authors suggested that longer follow-up of a larger number of subjects is required to determine if these effects are associated with changes in the risk for breast cancer (Boyd et al. 1997).

A study conducted at Harvard University followed more than 300,000 women (Huang et al. 1999). Their data suggested that "greater waist circumference increases risk of breast cancer, especially among women who are otherwise at lower risk because of never having used estrogen replacement hormones."

Conversely, mounting evidence also suggests that some dietary fat is desirable and provides protection for the breast (Kaizer 1989; Franceschi et al. 1996; Maillard et al. 2002). Women experienced better breast health if their diet included moderate levels of fat. However, women desiring to add some dietary fat should not do so by merely increasing their consumption of meat, dairy products, and products with vegetable oils that contain saturated fat (palm and coconut oil). Better sources of dietary fat are from unsaturated fats such as fish; olive, peanut, and sunflower oils; olives; and avocados.

Beneficial Fatty Acids

Beneficial or essential fatty acids (EFAs) are vital nutrients for good health just like other vitamins and minerals. EFAs are polyunsaturated fats ("good" fats) and contribute to healthy functioning of cell membranes, the skin, the immune system, and the cardiovascular system. Although fatty acids are essential for overall health, our body does not manufacture them. We need to obtain them through our diet.

Conjugated Linoleic Acid

Conjugated linoleic acid (or CLA) is a source of natural dietary fat. CLA is an essential fatty acid occurring in dairy and other products such as whole milk, cheese, and red meats from ruminant animals. CLA is considered to be "a healthy fat" because it is polyunsaturated (liquid at room temperature). Because the CLA content in dairy products is directly related to the fat content, CLA levels are greatest in higher fat (rather than lower fat) products. Good dietary sources of CLA are homogenized milk, butter, plain yogurt, cheese, and ground beef. Interestingly, the CLA content of milk and other dairy products is highest in pasture- or range-fed cows (McBean/National Dairy Council 1999). Skim milk does not contain CLA (Roloff 1997). As stated earlier, CLA is found in dairy products; however, it occurs at relatively low levels in these dietary sources. Therefore, we probably cannot get adequate CLA from food alone. (Life Extension suggests 3000-4000 mg of a 76% CLA supplement be taken daily.)

Studies in animals have documented a number of potential health benefits of CLA: an anti-carcinogenic effect, lowered total and LDL cholesterol, a reduction of body fat, increased rate of bone formation, and improved glucose utilization (McBean/National Dairy Council 1999). Although FBD is often a benign condition, there are important tumor-modulating, anti-cancer, and anti-inflammatory effects associated with CLA that are beneficial and perhaps preventative. In studies conducted using laboratory rats, CLA was found to confer lifelong protection against mammary cancer and to also reduce the density of mammary glands.

Banni et al. (1999) continued earlier research suggesting that CLA fed during mammary gland development resulted in diminished mammary epithelial branching, which might possibly result in reduced mammary cancer risk. Data showed a "graded and parallel reduction of terminal end bud density and mammary tumor yield produced by 0.5 and 1% CLA. No further decrease in either parameter was observed when CLA in the diet was raised to 1.5-2%." Banni et al. (1999) concluded: "optimal CLA nutrition during pubescence could conceivably control the population of cancer-sensitive target sites in the mammary gland." Ip et al. (1999a,b) also conducted studies in laboratory rats to investigate the role of CLA in inhibiting mammary carcinogenesis. They found that CLA "can act directly to inhibit growth and induce apoptosis of normal mammary epithelial cell organoids and may thus prevent breast cancer by its ability to reduce mammary epithelial density" (Ip et al. 1999a). (Apoptosis is the normal, healthy programmed death of cells.) CLA is therefore recommended because of its anti-tumor effects (three to four capsules of CLA-76% supplement daily for healthy people).

Omega-3 and Omega-6 Fatty Acids

The omega-3 and omega-6 fatty acids are important members of the EFA family. Omega-3 and omega-6 are scientific names derived from the chemical composition of their fatty acid molecules. Each one contains different fatty acids. Although the names are scientifically useful, most people just need to know that both of them are essential fatty acids and the body needs both of them in balance.

Omega-6 fatty acids are generally available in adequate amounts from the grains and vegetable oils that are commonly present in the processed foods in our diet unless lifestyle (consumption of alcohol, excessive sugar, and saturated fats) or health conditions are a factor. Dried beans, including inexpensive northern beans and soybeans, are an excellent source of omega-6 fatty acids. Omega-6 fatty acids are also found in linoleic acid from safflower, sunflower, corn, and soybean oils.

Greater effort is often required to ensure that adequate omega-3 EFAs are available from our daily diet. Omega-3 fatty acids are abundant in fish oils from mackerel, salmon, halibut, and herring. Soybeans, flaxseed, and green leafy vegetables also contain omega-3 fatty acids.

Women with severe mastalgia and FBD appear to have abnormal fatty-acid levels that may lead to endocrinologic hypersensitivity (imbalance of proper hormonal ratios and the resultant affect on other systems) (Ayers 1983; Mansel et al. 1990c). FBD seems to be associated with exaggerated estrogen-progesterone ratios and increased levels of prolactin (Kumar et al. 1985; BeLieu 1994). Thus, increasing omega-6 fatty acids may reduce FBD symptoms (Mansel et al. 1990a). The correct balance of omega-6 and omega-3 fatty acids will also help to inhibit the inflammatory cascade that may precede the onset of fibrous tissue.

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Fibrocystic Breast Disease

Evening Primrose Oil

Several European studies support using evening primrose oil to treat breast pain and cysts (Pye et al. 1985; Gateley 1990; Mansel et al. 1990b; Gateley et al. 1991; McFayden et al. 1992; Cheung 1999; Norlock 2002). Evening primrose oil is a good source of beneficial gamma-linolenic acid and linoleic acid. In a 1990 survey, as many as 13% of surgeons and 30% of breast surgeons in Great Britain recommended evening primrose oil, particularly for cyclic mastalgia (Pain et al. 1990; BeLieu 1994). Evening primrose oil significantly improved the fatty-acid profiles of women with FBD (Gateley et al. 1992) and improved pain symptoms.

Borage and Flax Seed Oils

These two oils modulate inflammatory prostaglandins (Mancuso et al. 1997; Belch et al. 2000), often giving considerable relief to FBD symptoms. It may take 4-6 weeks before there is noticeable improvement. Nonetheless, treatment should be continued for 4-8 months.

Fruits, Vegetables, and Dietary Fiber

A diet that emphasizes fruits and vegetables also includes benefits for women with FBD. Natural, beneficial chemicals present in fruits and vegetables assist enzymes in the body to detoxify potentially harmful compounds (called carcinogens) (BCERF 1998). In fact, women who maintain a vegetarian diet are actually able to excrete two to three times more estrogen than omnivorous women. This could be part of the explanation for why vegetarian women have a lower incidence of breast cancer (Goldin 1981, 1982).

In addition, some of the chemical components of fruits and vegetables benefit the function of (switch on) the parasympathetic nervous system, thus minimizing development of tumors and cysts. Increasing fiber consumption appears to be a component in reducing the symptoms of FBD in some women. Fiber assists elimination of waste from the system, decreasing levels of circulating estrogens (BCERF 1998). Obtain plenty of fiber from your diet. Good sources of dietary fiber are legumes (kidney and pinto beans, peas, and lentils), vegetables (Brussels sprouts, broccoli, and carrots), raw fruits (apples, oranges, and bananas), and grains (particularly bran and oats) (Anderson et al. 1988; Van Horn 1997). Additional fiber may be obtained from dietary supplements in the form of powders or capsules. (Life Extension recommends Fiber Food Caps, Fiber Food Powder, and Apple Pectin Powder.)

Indole-3-Carbinol

Indole-3-carbinol (I3C) is a naturally occurring dietary compound (a phytochemical) that is found in some fruits and the cruciferous vegetables such as broccoli, cauliflower, brussels sprouts, cabbage, turnips, kohlrabi, bok choy, and radishes. Phytochemicals are also natural anti-cancer compounds. Indole-3-carbinol appears to work in several ways: partially inactivating estrogen (Michnovicz 1997; Bradlow et al. 1994; Wong et al. 1997); fighting free radicals (Arnao et al. 1996); and directly interfering with tumor cell reproduction (Bradlow et al. 1999a). Indole-3-carbinol triggers the release of enzymes that help break down estrogen precursors into a harmless form rather than the form that is linked to breast cancer (Michnovicz et al. 1997; Bradlow et al. 1999b; Meng et al. 2000; Terry et al. 2001). Cabbage and broccoli also contain sulforaphane, another phytonutrient that has been shown to stimulate the release of enzymes that attach to cancer-causing substances and transport them from the body (Mowatt 1998).

The National Cancer Institute and the U.S. Department of Agriculture have said that by eating five servings of vegetables and fruit a day, a person can cut the risk of cancer by more than 50%. Most people do not come close to meeting this guideline, particularly the recommendation for vegetables, because they do not like cruciferous vegetables, the vegetables are not readily available, or they cannot eat the quantity required each day to meet recommended dietary guidelines for phytonutrients. Sometimes raw vegetables are not easy for the system to digest. Storage and processing by the supplier or overcooking in the home contributes to loss of phytonutrients. Often, only half the phytonutrients in any serving of raw vegetables ultimately becomes available for absorption--the other half is quickly eliminated from the body. Concentrated vegetables (particularly those with the water content removed and which are ground to the consistency of powdered sugar) are more digestible. In this form, it is estimated that 90 to 100% of phytonutrients, and all of their cancer-fighting properties, become available for absorption into the body (Mowatt 1998). (Indole-3-carbinol is available from Life Extension in capsule form.)

Studies in animals indicate that I3C is safe at recommended doses (NIEHS 2000). Trials in humans have also found no significant side effects (Wong et al. 1997). A study by Cover et al. (1999) found that the naturally occurring chemical I3C found in vegetables of the Brassica genus, is "a promising anticancer agent that we have shown previously to induce a G1 cycle arrest of human breast cancer cell lines, independent of estrogen receptor signaling." According to Cover et al. (1999), a combination of I3C and anti-estrogen tamoxifen cooperated to inhibit growth of the estrogen-dependent human MCF-7 breast cancer cell line more effectively than either agent used alone. They suggested that "I3C works through a mechanism distinct from tamoxifen." Cover et al. (1999) concluded that "these results demonstrate that I3C and tamoxifen work through different signal pathways to suppress the growth of human breast cancer cells and may represent a potential combinatorial therapy for estrogen-responsive breast cancer."

Caution: Some recommend that pregnant women should not take indole-3-carbinol. Research is continuing on indole-3-carbinol and at this time there are no well-known drug interactions. Do not attempt to treat breast nodules with indole-3-carbinol without first consulting with your physician.

Note: *The Life Extension Foundation suggests indole-3-carbinol to persons seeking an alternative to tamoxifen. See the protocol on Breast Cancer for more information.*

Soy

Soy has been the subject of research for overall breast health. Some studies indicate that soy foods containing phytoestrogens (natural estrogens from plants) may offer some protective benefit. Researchers also believe that soy may play a role in balancing hormone levels in premenopausal women and perhaps in relieving premenstrual syndrome and menopausal symptoms (Imaginis 2001). Good dietary sources of soy are canned soybeans, tofu, soy protein bars, and tempeh. Life Extension suggests a supplement called Natural Estrogen (containing phytoestrogens from soy extract and other phyto extracts).

Researchers speculate that some of the anti-tumor activity of soy compounds may result from production of enzymes that attack free radicals (Molteni et al. 1995). However, as with other nutrients, agreement is impossible and many authorities are reluctant to give soy universal endorsement. Others suggest that soy can modulate hormonal activity and even act as an antioxidant. If using soy, carefully monitor your breasts to assess the response of breast tissue to soy products.

Caution: Soy extract or soy products should not be used by persons with estrogen-receptor-positive cancer.

Simple and Complex Carbohydrates

Carbohydrates, whether simple or complex, might be an even greater concern in FBD than fat. Italian researchers found that heavy consumption of starchy foods, including pasta and white bread, increased breast cancer risk (Franceschi et al. 1996; Augustin et al. 2001). Carbohydrates are of two types: simple and complex. Both types are composed of sugar units. Simple carbohydrates are composed of one or two sugar units. Simple carbohydrates are found in fruit and vegetable juices, candy, soft drinks, and foods with added sugar. The problem with simple carbohydrates is that they induce an insulin spike upon ingestion. Insulin can promote cancer cell division which is why consumption of starchy foods might increase cancer risk. Complex carbohydrates are made from many sugar units that would structurally look like beads in a bracelet. Foods such as whole grain products, fruits, vegetables, and legumes (dried beans and peas) are good sources of complex carbohydrates that do not induce a sharp insulin spike because they release sugar more slowly into the bloodstream. Both simple and complex carbohydrates are converted to blood sugar by the body to use as energy or fat storage. However, complex carbohydrates are a much better nutritional value because they include vitamins, minerals, and fiber (Quagliani 1997).

Vitamins

- Vitamin E
- Folic Acid
- Vitamin A
- Vitamin C

Vitamin E

Since 1965, using vitamin E has been recommended by some researchers for treatment of FBD (Abrams 1965). However, researchers are not unified concerning the use of vitamin E to successfully treat or manage FBD and evidence has been inconclusive. Vitamin E in the form of alpha tocopherol has corrected abnormal estrogen-progesterone ratios in some patients with mammary dysplasia (London et al. 1981). Results of that study, however, were not replicated in 1985 (London et al. 1985). Another study of 105 women with FBD found that 600 mg of vitamin E for 3 months had no effect on symptoms (Meyer et al. 1990).

Vitamin E should be taken in doses of 600-800 IU daily. However, women with hypertension should start with about 400 IU. If you take a blood-thinning medication, consult your physician before taking vitamin E and monitor your usage carefully since vitamin E is known to enhance blood thinning. Vitamin E containing both alpha and gamma tocopherols may produce the most desirable results. It may be necessary to use vitamin E for several months before noticeable improvement is realized.

Folic Acid

Many physicians also recommend taking folic acid along with vitamin E. In some women, combining the two seems to have a more beneficial effect than either one taken alone. Folic acid is abundant in green, leafy vegetables, but is often deficient in the standard

American diet. Women of child-bearing age are particularly encouraged to include folic acid in their diet. (Life Extension recommends at least 800 mcg of folic acid along with at least 300 mcg of vitamin B12 daily.)

Vitamin A

Studies have shown that vitamin A has been able to inhibit the growth of breast cancer cells (Fontana et al. 1992; Wu et al. 1997; Yang et al. 1999; Widschwendter et al. 2001). Therefore, there is some justification for women with FBD to take vitamin A. In one of only a few studies (Band et al. 1984), 12 women with FBD were given 150,000 IUs of vitamin A daily for 3 months. Nine of the women reported marked pain reduction.

However, large doses of vitamin A can also be toxic. Therefore, beta-carotene may be a more practical treatment. In one study, 25 women who had moderate to severe pain before their menstrual periods were given daily supplements of beta-carotene and retinol. After 6 months, most of the women reported marked reduction in breast pain with no side effects (Santamaria et al. 1989). A diet high in yellow and orange fruits and vegetables will raise beta-carotene levels. You may also wish to use a beta-carotene supplement.

Vitamin C

The immune system requires vitamin C for proper function, tissue repair, diuretic action, anti-inflammatory responses, and adrenal hormone balance. Try 2.5-6 grams daily. If using buffered ascorbate, take it with magnesium or potassium.

Detoxifying Herbs

The liver supports many mechanisms including providing a detoxifying and filtering system for all body wastes as well as binding and eliminating extra hormones (including estrogen clearance). If the liver does not adequately perform its detoxifying and binding functions, estrogen stores may increase. As noted earlier, increased fiber in the diet improves removal of toxins and waste from the system. Nutrients that support the liver include choline, S-adenosyl-methionine (SAME), green tea, and N-acetyl-cysteine. If you have FBD, consider using these supplements daily. Detoxifying your system by aiding cleansing of the liver may also improve symptoms of FBD.

Herbs that support detoxification include echinacea (*Echinacea purpurea*) and goldenseal (*Hydrastis canadensis*). These herbs should be started about a week before menstruation begins, used for 7-10 days, and then discontinued for 4-7 days. Goldenseal should be followed by a probiotic that contains acidophilus and Bifido bacteria to replace good bacteria in the gut. Life Flora provides beneficial intestinal bacteria (flora) to recolonize the gastrointestinal (GI) tract when normal GI bacteria have been destroyed by disease, digestive conditions, poor absorption of nutrients, infections, and toxins. (Life Flora contains *Bifidobacterium longum* and *bifidum*, *Lactobacillus acidophilus*, *Streptococcus faecium*, and *Lactobacillus casei*.)

Supplements and Herbs to Relieve Cyclical Pain and Reduce Inflammation

- Dandelion and Milk Thistle
- Saw Palmetto
- Violet Leaf
- Castor Oil Packs
- Chasteberry

Dandelion (Taraxacum Officinale) and Milk Thistle (Silibinin Marianum)

Dandelion and milk thistle will help to detoxify your system (Maliakal et al. 2001; Saller et al. 2001; Cho et al. 2002; Hagymasi et al. 2002; Kosina et al. 2002). Dandelion has also been used to treat painful breasts and relieve impacted milk glands. Drink up to two cups of dandelion tea daily (or take a 500-mg capsule two to three times daily). In large doses, dandelion can provoke hypoglycemia in some people. High potency silibinin extract from milk thistle may also be taken at a dosage of about 500 mg daily.

Saw Palmetto

Saw palmetto (*Serenoa repens*) is used to treat prostate problems, but its anti-estrogenic characteristics also make it useful as a treatment for hormonal disturbances. Saw palmetto should be standardized to contain 85-95% fatty acids and sterols. (One capsule containing saw palmetto extract at a dosage of 320 mg daily is recommended.)

Violet Leaf

Poultices made from violet leaf may be used for pain and inflammation. Two or more cups made of 500 mL daily may bring dramatic relief for cyclical swelling and tenderness.

Castor Oil Packs

Warm castor oil packs may help dissolve lumps and relieve pain. Sometimes lumps will shrink after only a few applications. Warm castor oil packs over the liver not only invigorate, but also reduce inflammation. Some herbalists recommend alternating castor oil packs with ginger packs.

Chasteberry

Chasteberry (*Vitex agnus-castus*) has been used to relieve FBD. Chasteberry may decrease prolactin, leading to increased progesterone production during the menstrual cycle, and it seems to result in a shift in the estrogen-progesterone balance, regulating hormones and inhibiting release of FSH and LH. This results in less estrogen to stimulate breast tissue. Eat the equivalent of 20-40 mg of fresh chasteberry berries daily or take 175-225 mg daily of a preparation that is standardized to contain 0.5% agnuside.

Caution: Avoid chasteberry if you take oral contraceptives or are pregnant.

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Fibrocystic Breast Disease

Caffeine and Breast Conditions

Some women find that reducing or even eliminating caffeine intake by avoiding coffee, tea, chocolate, and soft drinks significantly decreases breast discomfort (Russell 1989). However, the topic is controversial because studies linking caffeine and FBD have had inconsistent results or have been inconclusive (Allen et al. 1985, 1987; Horner et al. 2000; Imaginis 2000).

An early study by Minton et al. (1981) was widely publicized because it claimed that abstaining totally from caffeine lessened symptoms and resolved FBD completely. According to Minton, abstinence from consuming methylxanthine (a chemical present in foods and beverages that contain caffeine) decreased the need for major breast surgery and breast biopsies because of benign disease (Minton 1979, 1981, 1989). A 2002 study of the literature on causes of breast pain found that some investigations did find an association between caffeine intake and FBD and breast pain (Norlock 2002). However, other studies over the past 20 years have examined the relationship of caffeine to breast conditions and have reported inconclusive or even the opposite conclusions (Boyle et al. 1984; La Vecchia et al. 1985; Rosenberg et al. 1985; Horner et al. 2000). One study of more than 2000 women reported by Rosenberg et al. (1985) concluded that coffee consumption was not associated with an increase of breast cancer among women with a history of FBD. Another study, reported by La Vecchia et al. (1985), even found "slight" evidence that the more coffee a woman consumed, the less likely she was to have breast cancer.

Even though the evidence of a direct link between caffeine and FBD is inconclusive, many clinicians do recommend a low caffeine intake in women with FBD. Some women report significant relief from FBD symptoms after eliminating caffeine from their diets. If you suspect caffeine might have a role in your FBD symptoms, eliminate sources of caffeine (chocolate, coffee, tea, soft drinks) from your diet for 3 months to see if your symptoms improve.

As noted above, methylxanthine is a chemical present in foods and beverages that contain caffeine. Methylxanthines increase circulating catecholamines (chemicals which are present in responses to stress). There is some evidence that women with FBD have an increased sensitivity to catecholamines. However, as with caffeine, the studies are inconclusive. Both the National Cancer Institute and the American Medical Association's Council on Scientific Affairs state that there is no association between methylxanthine intake and FBD at this time (AMA 1984; Schairer et al. 1986).

OTHER CONSIDERATIONS

- Thyroid Deficiency
- Pancreatic Enzymes

Thyroid Deficiency

According to some alternative-care practitioners, a malfunctioning thyroid gland may be a precursor to many disorders in females. With hypothyroidism, hormones such as LH, FSH, and prolactin may be overly stimulated. Researchers have linked breast abnormalities, including FBD, to repeated hormonal arousal (Lark 1996). An early study of 19 women with breast pain (mastodynia) and nodularity caused by FBD reported that almost half (47%) the women had total relief after daily treatment with 0.1 mg of levothyroxine (Synthroid). Three patients had elevated serum prolactin levels. Their prolactin levels became normal and they experienced dramatic pain relief after treatment with levothyroxine (Estes 1981).

A review of three clinical studies using sodium iodide, protein-bound iodide, and molecular iodine showed clinical improvements in FBD of 70%, 40%, and 72%, respectively (Ghent et al. 1993). The review concluded that molecular iodine was non-thyrotropic (did not alter) and was the most beneficial. Thus, some suggest that treating thyroid problems might reduce the risk or incidence of FBD and improve the symptoms (Ghent et al. 1993).

Another study looked at thyroid hormones and FBD. The data suggested that free T3 had an important role in the physiology of FBD (Martinez et al. 1995). To further examine this theory, a study looked at the levels of triiodothyroxine (T3), thyroxine (T4), thyroid stimulating hormone (TSH), and prolactin (Prl) in FBD (Zych et al. 1996). The authors found that the T4 levels were significantly lower in women with FBD than in controls. They concluded that there seemed to be a connection between FBD and thyroid function (Zych et al. 1996).

Taking daily iodine will help support a healthy thyroid. Kelp may also be beneficial. However, be certain that the seaweed is harvested from clean water. A simple, convenient source of iodine is table salt containing iodine.

Pancreatic Enzymes

According to researchers from Germany, pancreatic enzymes may reduce tumors and cysts, inflammation, and soreness. In a study of 96 patients, cyst size was reduced significantly after women took an enzyme preparation for 6 weeks. Additionally, the women reported significant improvement and less pain. A preparation containing lipase, protease, and amylase was recommended at a dosage of 103 strength (Ditmar et al. 1993)

SUMMARY

More than 50% of all women experience symptoms of FBD at some time in their lives. In some women, the symptoms improve after a menstrual cycle. Symptoms may also cease or improve after menopause. It is not unusual for FBD to continue in postmenopausal women who use hormone replacement therapy (HRT). There is no conclusive evidence that FBD is associated with an increased risk of breast cancer.

Practice monthly breast self-examination. If a new or an unusual change is detected, contact your health care practitioner promptly for an evaluation. Have a yearly breast examination from your health care practitioner. Also have a mammogram yearly or as recommended by your physician.

Dietary Recommendations

Take preventive measures to lessen your chances of developing or intensifying FBD. Eat whole foods, emphasizing fruits and vegetables, and support your immune and hormonal systems with supplements. While there is little evidence that caffeine causes FBD, some women report that FBD improves after eliminating caffeine from their diets.

Supplements

Consider Indole-3-Carbinol: 1 capsule twice daily for those weighing under 120 pounds; 1 capsule 3 times daily for those weighing 120-180 pounds; and 1 capsule 4 times daily for those over 180 pounds.

If you have FBD, try natural therapies (diet and nutritional supplements) for three months and monitor your symptoms. If you choose conventional medical therapy, consult your physician for advice about the options for treating FBD. Proceed to hormonal or drug treatments only with the advice of a physician or if you still experience no relief (see the protocol on Breast Cancer).

Caution: Some believe that pregnant women should avoid indole-3-carbinol.)

1. Consider Natural Estrogen (a soy-based phytoestrogen), one caplet morning and evening taken cyclically: 3 weeks on and 1 week off, beginning on day 5 of the menstrual cycle for premenopausal women and every day for postmenopausal women.
2. Consider Pro Fem, natural progesterone cream from soy, applied according to label instructions.
3. DHEA should be considered in women over the age of 40. The usual dose ranges from 15-50 mg. Refer to the DHEA Replacement Therapy protocol for specific directions.
4. CLA 76% may be taken for anti-cancer, anti-inflammatory effects: three to four 1000-mg capsules daily for healthy people.
5. A balanced formula of the essential omega-3 and omega-6 fatty acids is available in Super GLA/DHA; 6 softgels daily are recommended.
6. Take Fiber Food Caps (6 capsules with each meal), Fiber Food Powder (1 tsp with each meal), or Apple Pectin Powder (1 tsp before meals).
7. **Note:** Do not take fiber supplements with oil-based products such as CLA.
8. Consider taking Life Flora. Six 300-mg capsules taken daily with NutraFlora (1/2 to 1 tsp daily) are suggested for initial GI tract loading. One to four capsules of Life Flora are suggested for maintenance of healthy GI tract bacteria. Life Flora is most effectively used when taken between meals in divided doses, either dissolved in the mouth or taken with water.
9. Take folic acid (800 mcg) + B12 (300 mcg), 1 capsule daily for healthy people. Folic acid is especially important for women of child-bearing age.
10. Vitamin A (beta-carotene), 1 or 2 capsules (25,000-50,000 IU) daily, may inhibit the growth of breast cancer cells.
11. Vitamin C is required for all tissue repair; 2.5-6 grams daily are suggested (includes dietary and supplemental sources). (Vitamin C Caps from Life Extension contain 1000 mg per capsule.)
12. Gamma E Tocopherol/Tocotrienols is a balanced vitamin E supplement that acts as an antioxidant and may also help balance hormone levels; 1 capsule daily is suggested.
13. Support the pancreas with pancreatic enzymes. Pancreatin (4X enzymes), 1-3 (500-mg) capsules taken on an empty stomach between meals, is suggested.
14. Echinacea is a detoxifying herb. For healthy people, take 1-2 capsules daily for 10-14 days, then 4-7 days off. Smaller doses, such as in Life Extension Herbal Mix, may be taken continuously.
15. Goldenseal may be taken as a substitute for Echinacea: 1-3 capsules daily for healthy people in divided doses for 1-2 weeks. Smaller doses, such as in Life Extension Herbal Mix, may be taken continuously.
16. Saw palmetto may relieve cyclical pain and reduce inflammation; 160-320 mg daily, standardized to contain 85-95% fatty acids and sterols, is suggested. (Super Saw Palmetto softgel from Life Extension contains 320 mg per capsule.)
17. Consider the herb chasteberry for anti-inflammatory properties: 20-40 mg of fresh berries or 175-225 mg daily.
Caution: Women taking oral contraceptives or pregnant women should not take chasteberry.)
18. Drink up to 2 cups of dandelion tea daily (or take a 500-mg capsule 2-3 times daily).

19. Apply warm castor oil packs.
20. Apply violet leaf poultices: 2 or more cups made from 500 mL.
21. Support a healthy thyroid by taking 200-250 mcg of iodine daily. Kelp, 1500-2000 mg in divided doses, may also be beneficial.

FOR MORE INFORMATION

For more information about research studies, contact the American Cancer Society, (800) 227-2345.

PRODUCT AVAILABILITY

Indole-3-Carbinol, Natural Estrogen, Pro Fem, Super Soy Extract Powder, DHEA, Fiber Food Caps, Fiber Food Powder, Life Flora, NutraFlora, CLA 76%, Folic Acid + B12, Vitamin A, Vitamin C Caps, Super GLA/DHA, Gamma E Tocopherol/Tocotrienols, Pancreatin (4X enzymes), Echinacea, Goldenseal, Super Saw Palmetto, and green tea extract, may be ordered by calling (800) 544-4440 or by ordering online.



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