ORIGINAL RESEARCH—WOMEN'S SEXUAL DYSFUNCTIONS

Assessment and Management of Women's Sexual Dysfunctions: Problematic Desire and Arousal

Rosemary Basson, MD,* Lori A. Brotto, PhD,† Ellen Laan, PhD,‡ Geoffrey Redmond, MD,§,¶ and Wulf H. Utian, MB.BCH, PhD**,††

*UBC Department of Psychiatry, B.C. Centre for Sexual Medicine, Vancouver, BC, Canada; †UBC Department of Gynecology, Vancouver, BC, Canada; ‡Universiteit van Amsterdam, Amsterdam, the Netherlands; §Hormone Center of New York, New York, NY; ¶Center for Health Research, Inc, New York, NY; **The North American Menopause Society; ††Reproductive Biology, Case Western Reserve University, Cleveland, OH, USA

Corresponding Author: Rosemary Basson, MD, Clinical Professor, UBC Department of Psychiatry, B.C. Centre for Sexual Medicine, Echelon 5, 855 West 12th Avenue, Vancouver, BC, V5Z 1M9, Canada. Tel: (604) 875-8254; Fax: (604) 875-8249; E-mail: sexmed@interchange.ubc.ca

ABSTRACT

Introduction. Women frequently report low sexual desire or interest. An associated lack of subjective arousal during sexual activity is clinically highly apparent but has not been the focus of traditional sexual inquiry, definitions of dysfunction, or management. The frequent poor correlation of women's subjective sexual arousal and observable increases in genital congestion in response to sexual stimulation has not been reflected in assessment, diagnosis, or management.

Aim. To provide recommendations/guidelines for the assessment and management of women's sexual dysfunctions focusing on low desire, low interest, and lack of arousal.

Methods. An international consultation, in collaboration with major sexual medicine associations, assembled over 200 multidisciplinary experts from 60 countries into 17 committees. One subcommittee of five members focused on women's sexual desire and arousal, developing over a 2-year period various recommendations.

Main Outcome Measure. Expert opinion was based on grading of evidence-based scientific literature, widespread internal committee discussion, public presentation, and debate.

Results. Women's sexual response in health can be reconceptualized as a circular model of overlapping phases of variable order influenced by psychological, societal, and biological factors. Subsequent revisions to definitions of arousal and desire disorder are given. Recommendations regarding assessment and management focus on factors reducing arousability and satisfaction. These include women's mental health and feelings for their partner, generally and at the time of sexual activity. Recommendations reflect the poor correlation of subjective arousal and increases in genital vasocongestion.

Conclusion. Further outcome research of management based on new conceptualization of sexual response and revised definitions of dysfunction is needed. The basis of the variable correlation between genital vasocongestion and subjective arousal needs clarification as do the biological underpinnings of sexual response and their changes with age and life cycle.

Key Words. Female Sexual Dysfunction; Diagnosis and Treatment of Women's Sexual Dysfunction; Desire Disorder; Arousal Disorder; Women's Sex Response Cycle

Introduction

Lack of desire to engage in sex is frequently reported by women [1–3]. Until recently, the associated lack of subjective arousal/excitement has been overlooked in epidemiological surveys. Reconceptualization of women's sexual response has produced a framework to clarify women's complaints of low desire and subjective arousal (excitement), and led to revised definitions of desire and arousal disorders.

Characteristics of Women's Sexual Response

The linear model of human sex response of Masters, Johnson, [4] and Kaplan [5] depicts relatively discreet phases of sexual responding of invariant order—desire, arousal (with a marked genital focus), orgasm, and resolution. However, women commonly, especially in longer-term relationships, initiate and/or agree to sex for a variety of reasons [6]—sexual desire is infrequently cited [6–8]. Reasons include increasing emotional closeness with the partner, increasing the women's own sense of well-being, to feel more attractive, more attracted to the partner, to conceive, and only sometimes to satisfy her own sense of sexual desire/sexual need [9]. Motivated for one or many reasons, the woman attends to sexual stimuli, guides her partner, or provides them herself.

Potentially, subjective arousal results from sexual stimulation—provided the context of that stimulation is deemed appropriate. Aside from women with known damage to the autonomic nerves subserving the active neurogenic dilatation of vulval structures and vaginal submucosal plexus, e.g., after non-nerve sparing radical hysterectomy [10], the reflexive increase in genital vasocongestion occurs within seconds of exposure to an erotic stimulus [11]—with highly variable correlation with subjective arousal [11–14]. Many factors modulate the mind's processing of the sexual information, potentially reducing any subjective arousal. Biological factors include fatigue, depression, sexually negative effects of medications, reduced sex hormone activity, and less often as a presenting feature, hyperprolactinemia or hypothyroidism. Psychological factors include distractions of daily living, fear of a negative outcome (e.g., dyspareunia or partner dysfunction), lack of safety from unwanted pregnancy, sexually transmitted disease, again being proven infertile, past negative sexual experiences, inexperience, or feelings of shame or embarrassment [15,16].

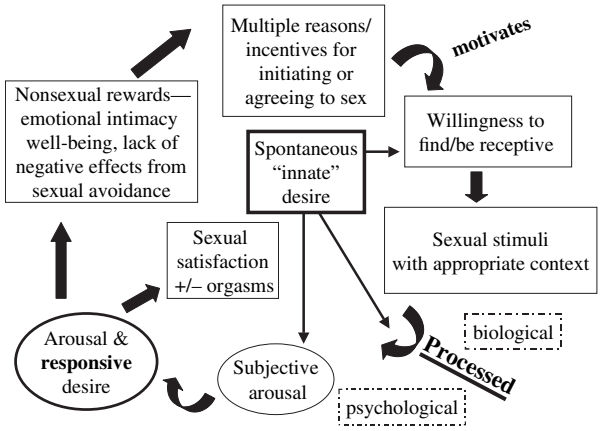

Figure 1 Women's circular sexual response cycle of overlapping phases of variable order.

Even when initially absent, desire is triggered during the experience once the woman has become subjectively aroused/sexually excited (Figure 1) [16–18]. Desire and arousal then coincide and compound one another. Sexual satisfaction is now desired and may involve one or many orgasms. An emotionally and physically positive outcome allows her to reach her original goal, e.g., feeling closer to her partner, thereby increasing subsequent sexual motivation.

Initial apparent spontaneous sexual desire, now known to have broad spectrum of frequency across women [2], may augment the cycle as shown in Figure 1.

Thus, women's sex response consists of overlapping phases of variable order [17]. Sexual desire may not be present initially. The woman assesses her subjective arousal by how sexually exciting she finds the stimulus [11] and by concurrent emotions and cognitions generated by the arousal [19]. This modulation of her subjective arousal appears to be more consistent than the variable modulation by feedback from the genital vasocongestion. Sexual satisfaction may occur without orgasms. Alternatively, orgasms may be experienced before the maximum arousal, and further orgasms may occur at peak arousal and during its very gradual resolution. Thus, for women, orgasm and arousal are not particularly distinct entities. As cited in a previous publication in this journal [20], several studies with varying degrees of scientific rigor support this reconceptualization of women's sexual response.

Characteristics of Women's Sexual Dysfunction at Variance with the American Psychiatric Association's Diagnostic and Statistical Manual Definitions of Dysfunction (DSM-IV-TR)

Just as the phases of women's sexual response overlap, so typically do women's sexual difficulties [21–23]. Regarding the specific dysfunctions, first, loss of subjective arousal is frequently associated with severe distress but is not mentioned in the DSM-IV-TR definition of female sexual arousal disorder [24]. Second, the DSM-IV-TR definition of hypoactive sexual desire disorder focuses on desire at the outset of the experience and in between the experiences, an absence of which is now known to be common in sexually healthy women [6–8]. It also focuses on sexual thinking—the infrequency of which has been well documented in sexually healthy women [25] and in large nationally representative studies of women [2]. The DSM-IV-TR definition focuses on sexual fantasies, but women frequently use fantasies deliberately to stay focused on the sexual stimulation, rather than fantasies being a marker of desire [26].

Recommended Definitions of Women's Sexual Dysfunction

The recommendations by an international committee organized by the American Foundation of Urological Disease and working over a 2-year period to propose revisions of the current DSM-IV-TR definitions have been published [27], and testing their validity is a focus of current clinical research. The definition of women's sexual desire/interest disorder is

> Absent or diminished feelings of sexual interest or desire, absent sexual thoughts or fantasies and a lack of responsive desire. Motivations (here defined as reasons/incentives) for attempting to become sexually aroused are scarce or absent. The lack of interest is considered to be beyond a normative lessening with life cycle and relationship duration [27].

Given the variable correlation between genital vasocongestion and subjective sexual arousal in women with and without sexual dysfunction, revised definitions now focus on the subjective experience. Women may report an absence of subjective arousal from any type of sexual stimulus. When there is also lack of awareness of genital vasocongestion, the dysfunction is one of combined genital and subjective sexual arousal disorder:

> Absence of or markedly diminished feelings of sexual arousal (sexual excitement and sexual pleasure) from any type of sexual stimulation as well as complaints of absent or impaired genital sexual arousal (vulval swelling, lubrication) [27].

When, despite lack of subjective arousal from any type of stimulus, the woman does note lubrication and/or genital swelling, then the dysfunction is one of subjective sexual arousal disorder:

> Absence of or markedly diminished feelings of sexual arousal (sexual excitement and sexual pleasure) from any type of sexual stimulation. Vaginal lubrication or other signs of physical response still occur [27].

A smaller subgroup of women remain able to be subjectively aroused from a variety of nongenital stimuli, but they report loss of sexual excitement from genital stimulation and an acquired loss of any awareness of genital congestion. Typically, at least for a period of time, they retain sexual interest and motivation given their arousability from nongenital stimuli. Their dysfunction is termed genital arousal disorder:

> Absent or impaired genital sexual arousal. Self-report may include minimal vulval swelling or vaginal lubrication from any type of sexual stimulation and reduced sexual sensations from caressing genitalia. Subjective sexual excitement still occurs from nongenital sexual stimuli [27].

Despite the subtyping, there is a broad range of etiology for any one subtype. Because of the highly contextual nature of women's sexuality, especially the well-documented correlation of sexual health with both mental health [21,28] and feelings for the partner [18,28,29]—both generally and at the time of sexual interaction—contextual descriptors are recommended to be used within the diagnostic framework [27]. Descriptors also include potentially relevant medical factors [30–32]. However, despite the presence of medical factors, mood and psychological contributors may more strongly correlate with sexual dysfunction. This has been shown to be true for women with diabetes [30] and women with gynecological disease [33]. When the dysfunction seems to be largely related to contextual factors, evidence of something psychologically or biologically amiss within the woman being absent, it could well be stated that the "dysfunction" is logical and adaptive [28]. Nevertheless, possibly it is highly distressing to her. The following three types of descriptors were recommended [27]:

- predisposing factors in the woman's past affecting her psychosexual development, e.g., past abuse;

- precipitating and perpetuating factors in the current context—e.g., interpersonal, environmental, sexual, social; and
- past and present medical/surgical entities.

Clarifying the degree of distress—mild, moderate, or marked [27]—is also recommended. In the absence of distress, a disruption of sexual response or lack of interest may have epidemiological but not clinical importance.

Prevalence of Desire and Arousal Disorders

There is uncertainty regarding the prevalence of women's sexual desire/interest disorder, given the previous acceptance that lack of initial/spontaneous desire and desire in between sexual experiences, as well as paucity of sexual thoughts and fantasies, was necessarily reflective of disorder. The prevalence of self-reported sexual difficulties ("disabilities"), as opposed to clinician's careful diagnosis, appears high in communities where women are free to acknowledge their own sexual needs and sexual pleasure [2,3]. Using the criteria of experiencing spontaneous sexual desire only occasionally, rarely, or never, research shows that the percentage of women affirming they have "low sexual desire" could be as high as 80%—only 22% of 1,335 women in a Scandinavian community study experienced sexual desire more than occasionally [3]. This percentage would drop from 80% to 14% in the same cohort of women if the criteria used for diagnosing low sexual desire is, "experiencing sexual desire only rarely or never." Some authors report both on sexual interest and sexual desire. In the above study, women with reduced sexual interest represented 33% of the sample and almost half of them perceived it to be a problem associated with sexual dissatisfaction. Other nationally representative surveys suggest that from 8% to 33% of women self-report or are assessed to have, via questionnaire and/or interview, low sexual interest or desire [1,2,22,34–37]. Exactly how women interpret the words "sexual interest" and "desire" is often unclear and is currently the focus of ongoing qualitative study. Overall, age seems to have a fairly minimal effect, with two large studies showing increasing prevalence of low desire after the early 50s, and one showing a marked, and one a mild decrease with age. A modest increase with age but less associated distress characterizes other studies [28,37]. All of this is complicated by the known normal lessening of desire with relationship duration [38] and increase with the onset of a new relationship [18].

Assessment of Women's Sexual Dysfunction

A biopsychosocial assessment is advocated [39]. Optimally, the two partners are interviewed together and then individually [40]. Their descriptions of current sexual difficulties, the context—specifically at the time of sexual exchange—and the context of the relationship, work and living arrangements, and cultural influences are obtained. How the difficulties have evolved and the remaining details of each partner's sexual response are clarified. It is often necessary to interview each partner separately to clarify their sexual response when alone, past sexual relationships, along with their past developmental history, which may have influenced their psychosexual development. Nonsexual themes from childhood will play out in adult sexual lives, e.g., a woman may have coped with childhood losses by defending herself from being so close/intimate with another person, so as to be able to cope with future losses. The defense was appropriate and allowed her to survive but is now problematic as an adult. Each partner's medical history is noted, as well as personality traits and psychiatric comorbidities.

A physical exam may be necessary, possibly simply for good medical care. However, when the specific focus is on sexual dysfunction, an exam may or may not be necessary. It must be remembered that such an examination is intrusive and may elicit emotions linked to past coercive/abusive and/or painful sexual experiences. The procedure needs to be explained and the woman's understanding and consent confirmed. She may or may not prefer a partner or a nurse to be present. Clearly, if dyspareunia is also present, a careful exam is mandatory. In other situations it may be helpful, although it should be noted that the exam is of the genitalia in a nonaroused state and is therefore of limited value. For women with genital arousal disorder, estrogen deficiency or more rarely conditions such as connective tissue disorder can be identified. For many women with combined sexual arousal disorder, likely there will be no abnormal findings. (We know that nothing arouses these women subjectively—be it written, visual, physical nongenital, or genital stimulation—and the evidence to date is that their physical genital response is healthy.) The exam can nevertheless be reassuring. It is also possible that a woman with combined arousal disorder goes on to become estrogen deficient, and physical vulval atrophy compounds a long-standing problem of disconnection from genital events that were formerly healthy. Wherever

there is a question of neurological disease affecting the pelvic nerves, a detailed neurological genital exam is necessary, clarifying light touch, pressure, pain, temperature sensation, anal and vaginal tone, voluntary tightening of the anus and vagina, as well as bulbocavernosal reflexes. Genital examination is also necessary for women with histories of pelvic trauma or disease potentially affecting genital health.

A complete physical exam is necessary for the women with symptoms other than those sexual, e.g., undue fatigue, irregular menses. For women with chronic medical conditions, a general exam is necessary to address mobility requirements for sexual activity and also cardiac and respiratory status given the physical demands of orgasm and intercourse. The presence of stomas, catheters, urinary diversions, or parts of the body that give rise to chronic pain influencing sexual enjoyment can also be identified.

Laboratory Investigations

Investigations are guided by relevant symptoms or findings in the general medical assessment, but specifically for sexual symptoms, the following may be necessary:

- microscopy, culture, and sensitivity of vaginal discharge when dyspareunia is also present and considered to be potentially due to infection;
- sensitive and accurate assays for androgen activity to be in keeping with a clinical diagnosis of androgen insufficiency; and
- psychophysiological investigation to identify the common inattention to apparently healthy genital response. Note that the role of psychophysiological testing in the clinical arena is unclear.

Establishing the Diagnosis

Comorbidity of sexual dysfunction in women is common [21–23]. Clarify for each dysfunction:

- lifelong or acquired;
- situational or generalized;
- contextual factors past, current, medical; and
- degree of distress—mild, moderate, or marked.

Formulation of Sexual Problems

Construction of women's sex response cycle, noting the problematic areas, is highly recommended. Figure 2 shows breaks in a woman's cycle subsequent to altered sexual interaction (perfunctory intercourse), reduced emotional intimacy associated with infertility testing, and unsuccessful assisted reproductive techniques.

Management of Women's Sexual Desire/Interest and Arousal Disorders

Management will involve a biopsychosocial approach, addressing the various breaks in her sex response cycle (Figures 1 and 2).

Management of Psychological Components

Referral for improvement of the emotional intimacy in the relationship may be needed. Information about women's normal need for specific sexual stimuli in sexual contexts may be necessary, along with psychoeducation of women's sexual response. Psychological factors reducing a woman's arousability may be addressed, e.g., encouraging the use of fantasy to avoid distractions. However, brief psychotherapy may be needed for low self-image, mood instability—these being very common in women presenting with low desire complaints even when diagnostic criteria for a mood disorder are not met [21]. Past coercive and/or abusive sexual experiences may well require psychotherapy.

Outcome of Psychological Treatments

Psychological therapy remains the mainstay of management of women's sexual interest and desire disorders usually comorbid with lack of subjective arousal. There are various elements of psychological therapy, including cognitive behavioral ther-

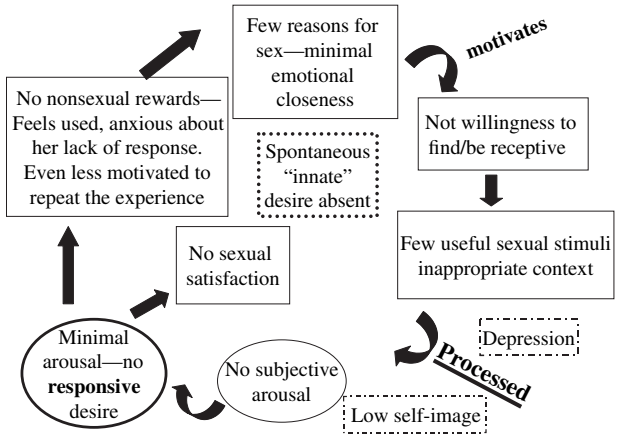

Figure 2 Women's sexual response cycle with various breaks subsequent to stressors of infertility testing and procedures. Adapted from Basson R. Obstet Gynecol 2001; 98:350–3. Permission granted from publisher Lippincott Williams & Wilkins.

apy (CBT), which involves attention to cognitive restructuring of various sexual distortions and sexual myths. This places a heavy emphasis on work within the sessions and at home involving behavioral changes. There are few outcome studies, and the focus has been on low desire, with minimal attention to low subjective arousal. CBT has resulted in some 75% of women significantly improving with 65% remaining improved at 1-year follow-up [41]. Sensate focus techniques originate from the work of Masters and Johnson and consist of exchanging physical touch moving from nonsexual to sexual touching, and resemble systemic desensitization—common to behavioral therapies in that anxiety reduction is incorporated throughout the process. Again, outcome studies are few but suggest improvement in some 50% of couples following treatments, but poor maintenance of improvement over 6 years [42]. Sex therapy can address women's distractions during sexual stimulation and promote more varied and more prolonged stimulation and encourage the couple to guide each other as to their required sexual stimulation. Safety, privacy, optimal timing of sexual interaction can be addressed. The few follow-up studies that exist suggest that sex therapy improves self-reported desire more effectively than relaxation training alone [43,44]. Psychotherapy is frequently recommended, but outcome data are minimal.

There are no published trials of psychological intervention for arousal disorders. These are urgently needed as it is clear the majority of arousal disorders in women do not mirror those in men—where vasoactive medication has been successful.

Management of Biological Components

Biological factors reducing arousability must be addressed—most notably mental health issues. Recent advances in some biological areas are of note.

Depression-Associated Arousal and Desire Disorders and Antidepressant Association Dysfunction

Impaired sexual desire has been found in the majority of patients with depressed mood since the 1960s [45,46], with studies suggesting half of samples of women with major depression experienced desire and arousal problems [47]. How frequently treating the depression usefully restores arousal and desire has not been vigorously studied. There is more research into the sexual effects of antidepressants themselves—specifically those that are highly serotonergic, typically reducing desire and arousability in the majority. Despite anecdotal reports and case series, there is extremely limited evidence of benefit from any "antidote" or additional antidepressant that is more dopaminergic, noradrenergic, and/or only selectively serotonergic [48]. However, a recent Cochran Review noted that bupropion was of interest, given that one of two Level 1 studies showed benefit [49]. Attention to other factors detected in her sex response cycle (Figure 1) is recommended, as the antidepressant may well have to be maintained for psychiatric reasons, despite it being a factor in a woman's sexual dysfunction.

Loss of Androgen Production

The long-suspected role of androgen in women's sexual function has been difficult to establish [50]. One reason is that androgen activity in women is not accurately reflected by hormonal serum levels—either by the various assays for testosterone itself or by the adrenal and ovarian precursors. The latter may be metabolized into either androgen or estrogen. The phenomenon of intracrinology allows testosterone to be produced within various cells of the body (some 50% of the total production in younger women and close to 100% of testosterone production in women after surgical menopause), from precursors. Very little of this testosterone produced within the cells spills back into the blood stream [51]. Adrenal precursors of testosterone substantially decrease during the 40s to early 60s, markedly reducing intracellular production of testosterone. Measurement of testosterone metabolites via various glucuronides is possible but not clinically available, nor yet are ranges established in women with and without dysfunction [51].

Thus, any diagnosis of androgen insufficiency relies on careful clarification of the clinical syndrome and careful differential diagnosis. The syndrome consists of an acquired loss of sexual arousability from formerly effective sexual stimuli. These now fail to elicit subjective arousal or trigger any sexual desire to continue the experience. Also, any former innate sexual desire is lost, genital sensitivity may be much reduced, orgasms absent or markedly delayed and minimally intense. The context is one of reduced androgen production, e.g., after bilateral oophorectomy, premature menopause from chemotherapy, some cases of premature menopause where androgen as well as estrogen production ceases, pituitary and adrenal disease, and aging.

All randomized controlled trials of testosterone supplementation—three of which recently have involved attempts to attain testosterone levels close to the upper limit of the normal premenopausal range [52–54]—have all been conducted in estrogenized women. Women post natural menopause have a high T : E ratio, and prescribing testosterone alone would be highly nonphysiological. Prescribing oral estrogen to postmenopausal women creates a very low T : E ratio because of the increase in sex hormone binding globulin (SHBG) and lowering of free testosterone. There are recently reported studies giving 300 μg of transdermal testosterone in addition to estrogen to naturally, as well as surgically, menopausal women [55,56]. The criteria used to prove benefit and their relationship to real life are also subjects of ongoing debate. These recently released results indicate statistically significant improvement in desire items on the instrument used (the profile of female sexual function) as well as increased numbers of "sexually satisfying sexual episodes." The population studied may or may not represent clinical practice whereby androgen insufficiency is considered when women report it is impossible to now experience any sexually satisfying episodes.

Testosterone Assays. In addition to the important consideration of intracrinology and a questionable relevance of any testosterone assay, the assays themselves are problematic. This is relevant, given that testosterone levels are used to monitor testosterone therapy. Equilibrium dialysis is considered the gold standard for free testosterone measurement but is expensive and rarely available. Recommended is a calculated free testosterone based on the total T and SHBG and albumin. However, total T is also problematic at the low levels found in women. Liquid chromatography with mass spectrometry is recommended.

Loss of Estrogen Production

Systemic estrogen administration post menopause can restore well-being, improve sleep quality, and restore sexual sensitivity of skin, all of which may improve desire and arousability. There is minimal outcome study to support these clinical observations. The role of systemic estrogen therapy in improving sexual desire and arousability remains unclear. The observed benefit from androgen administration may result from increased estrogen availability to the estrogen receptor, testosterone being converted within brain cells to estradiol, and/or testosterone administration lowering SHBG. However, in light of the Women's Health Initiative (WHI) study based on asymptomatic women receiving oral conjugated estrogens and medroxyprogesterone, beginning on average 10 years post menopause, guidelines are that systemic estrogen should be given for the shortest time consistent with treatment goals. Studies whereby estrogen in various formulations is initiated at menopause for women with sexual symptoms are urgently needed.

Genital arousal disorder may be in part due to estrogen deficiency, and topical (or systemic) estrogen is recommended. The management of genital arousal disorder in estrogen-replete women is unclear. Only some of this subgroup have observable decrease in the genital vasocongestion in response to sexual stimulation [57], and these particular women may benefit from vasoactive medications, including phosphodiesterase inhibitors [57]. The pathophysiology underlying other similar clinical presentations, unaccompanied by observable decrease in congestion to erotic stimulation, is unclear. Research into the role of testosterone for these women's symptoms is needed.

Selective Estrogen Receptor Modulators

Selective estrogen receptor modulators (SERMs) are chemically diverse substances without the steroid structure of estrogen but containing a tertiary structure that allows binding to α and β estrogen receptors. The exact mechanisms of the tissue-selective, mixed agonist/antagonist action of SERMs are unclear. These molecules potentially could retain estrogen's benefit and avoid most of the adverse effects. Unfortunately, there are no reported sexual benefits from the two SERMs available, namely, raloxifene and tamoxifen. Specifically, estrogen deficiency-associated vulvar and vaginal changes do not reverse, nor do vasomotor symptoms and disturbances of mood and sleep. Other SERMs under development are being tested for benefit on vulval and vaginal response [58], as well as desire and arousability.

Nonhormonal Pharmacological Approach to Arousal and Desire Disorders

Tibolone. A synthetic steroid with tissue-selective estrogenic, progestogenic, and androgenic actions, Tibolone has been shown to relieve sexual symptoms from vaginal atrophy [59] and may be of use with women diagnosed with genital arousal disorder. However, the women studied were not identified as having sexual dysfunction. A few studies have reported significant improvement in sexual

desire/interest, but again, women were not recruited for sexual desire problems. Various prospective randomized trials have compared tibolone with placebo or with various formulations of estrogen and progestin therapy [60,61]. Unfortunately, the recent million women study on breast cancer and hormone therapy did report a significant increase of breast cancer for women currently using tibolone, as well as those using various estrogen and progesterone combinations [62].

Bupropion. Women diagnosed with DSM-IV-TR hypoactive sexual desire disorder were randomized to receive either bupropion or placebo, and the women on active drug improved in sexual arousability and response but not in "desire" as in sexual thinking, fantasizing, and initial desire/interest for sex [63]. There is ongoing research regarding drugs that are noradrenergic and/or dopaminergic, which may usefully improve women's sexual arousability and desire. Similarly, there is ongoing investigation of selective serotonergic agonist/antagonist medications.

Conclusion

Understanding the contextual nature of women's sexual desire and arousal, the importance of subjective arousal and the strong association of desire and arousability with women's mental health and their feelings for their partners has moved the focus away from "spontaneous desire" and "vaginal lubrication." In keeping with the more circular model of overlapping phases of sexual response in variable order, revised definitions of desire/interest and arousal disorders have been proposed. Management is holistic—addressing the present context including the interpersonal relationship and types of sexual stimulation, as well as psychological factors possibly stemming from past nonsexual experience, as well as biological issues. The latter require scientific study including their modulation by stress, mood, and positive and negative emotions.

Summary of Committee. For the complete report please refer to *Sexual Medicine: Sexual Dysfunctions in Men and Women*, edited by T.F. Lue, R. Basson, R. Rosen, F. Giuliano, S. Khoury, F. Montorsi, Health Publications, Paris 2004.

Conflict of Interest: None.

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