

**A COMPARATIVE STUDY OF SEXUAL DYSFUNCTION
IN REMITTED PATIENTS TAKING ANTIPSYCHOTICS
VERSUS ANTIDEPRESSANTS**

*Dissertation submitted for partial fulfillment of the
rules and regulations*

**DOCTOR OF MEDICINE
BRANCH – XVIII (PSYCHIATRY)**

Reg. No. : 201728008



**THE TAMILNADU
DR.M. G. R MEDICAL UNIVERSITY
CHENNAI, TAMILNADU**

MAY 2020

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This is to certify that this dissertation entitled “**A COMPARATIVE STUDY OF SEXUAL DYSFUNCTION IN REMITTED PATIENTS TAKING ANTIPSYCHOTICS VERSUS ANTIDEPRESSANTS**” submitted by **Dr. SUBASHREE K** to The Tamilnadu Dr. M.G.R. Medical University, Chennai is in partial fulfillment of the requirement for the award of M.D. [PSYCHIATRY] and is a bonafide research work carried out by him under direct supervision and guidance. This work has not previously formed the basis for the award of any degree or diploma.

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This is to certify that this dissertation entitled **“A COMPARATIVE STUDY OF SEXUAL DYSFUNCTION IN REMITTED PATIENTS TAKING ANTIPSYCHOTICS VERSUS ANTIDEPRESSANTS”** is a bonafide record work done by **Dr. SUBASHREE K** under my direct supervision and guidance, submitted to The Tamilnadu Dr. M.G.R. Medical University regulation for **M.D Branch XVIII – Psychiatry.**

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DECLARATION

I, **Dr. SUBASHREE K**, solemnly declare that dissertation entitled **“A COMPARATIVE STUDY OF SEXUAL DYSFUNCTION IN REMITTED PATIENTS TAKING ANTIPSYCHOTICS VERSUS ANTIDEPRESSANTS”** is a bonafide work done by me at the Institute of Mental Health under the guidance and supervision of **Dr. P. POORNACHANDRIKA D.C.H., M.D.**, Professor of Psychiatry. It was not submitted by me or any other for any award, degree, diploma to any other university board either in India or abroad.

This dissertation is submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulations for the award **M.D. Degree Branch – XVIII (Psychiatry)** to be held in May 2020.

Place:

Date:

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ACKNOWLEDGEMENT

I sincerely thank **The Dean**, Rajiv Gandhi government general hospital and Madras Medical College, Chennai for permitting me to do this study.

I sincerely thank **Prof. Dr. P. Poornachandrika D.C.H., M.D.**, Head of the Department & Professor of Psychiatry, Institute of Mental Health, Madras Medical College, Chennai who has been a source of inspiration and for her immense guidance and help throughout the study.

I am very grateful to my co-guide Asst. Professor **Dr. D. Devi**, M.D., for her valuable support and guidance for the study.

I would like to express my sincere thanks to **all my associate and assistant professors**, Department of Psychiatry, Institute of Mental Health, Madras Medical College, who has guided me in literature search, developing protocol and helped in completing this dissertation.

I would like to place on record, my gratitude to Mr. Ashok Bhoorasamy, **statistician** for helping me in statistical analysis. I thank all **my juniors and seniors** for helping me during tough times and I thank all those **patients** who participated in the study, without whom this study would have been only a dream.

**INSTITUTIONAL ETHICS COMMITTEE
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Dear Dr.K.Subashree,

The Institutional Ethics Committee has considered your request and approved your study titled **"A COMPARATIVE STUDY OF SEXUAL, DYSFUNCTION IN REMITTED PATIENTS TAKING ANTIPSYCHOTICS VERSUS ANTIDEPRESSANTS" - NO.21112017**

The following members of Ethics Committee were present in the meeting hold on **07.11.2017** conducted at Madras Medical College, Chennai 3

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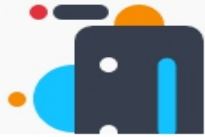
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ABBREVIATIONS

GnRH	Gonadotrophin Releasing Hormone
FSH	Follicle Stimulating Hormone
LH	Luteinising Hormone
VIP	Vasoactive Intestinal Peptide
NO	Nitric Oxide
PERT	Post Ejaculatory Refractory Time
SQoL	Sexual Quality of Life
DHEAS	Dehydroepiandrosterone Sulphate
SSRI	Selective Serotonin Re-uptake Inhibitor
ICD	International Classification of Diseases
DSM	Diagnostic and Statistical Manual of Mental Disorders
HSDD	Hypoactive Sexual Desire Disorder
NE	Norepinephrine
DA	Dopamine
5-HT	5- Hydroxy tryptamine
Ach	Acetyl choline

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INTRODUCTION

‘Human sexuality’ is described as individual’s own sexual interest and attraction to others, also accounts for one’s capacity to have erotic experiences and responses, based on their sexual orientation. The concept of sexuality has evolved over the years. It is also studied under a variety of disciplines. The term “normalcy” in sex varies between individuals of same gender and across culture. The description of sexual response cycle to both male and female are different. The understanding about sexual scripting and courtship behaviour throws further light on human sexuality. Now-a-days sexual functioning is not seen as only a part of procreation. This changing view towards sex has brought its growth under variety of disciplines. Sexual dysfunction is always as a ‘taboo’, from the era of Hippocrates to till date. Seeking help for such dysfunction, has brought a view on it to be curable and not to be stigmatised. The stigma associated with this, has made many myths deep rooted in society. In relevance to psychiatry, one such myth is all psychiatric drugs completely impair one’s sexual functioning. But on the contrary, some don’t have such effects or have minimal effects.

SCOPE OF THE STUDY

The study focusses on the comparison of various factors associated with sexual dysfunction due to the use of antipsychotics and antidepressants in patients who are in the remission phase of their illness. So, this study paves way for bringing out the need to use a drug with a low propensity of causing sexual side effects. Thereby, offers a better quality of sexual life. Also, choosing a drug with a low propensity to cause sexual side effects, will therefore improve drug adherence and

compliance, as one of the major reasons for drug discontinuation is sexual side effects.

PLAN OF THE STUDY

- Review of literature
- Methodology
- Results
- Interpretation of current study
- Discussion
- Final conclusion of the study

REVIEW OF LITERATURE

DEFINITIONS:

SEXUALITY⁽¹⁾

Sexuality is a central aspect of being human throughout life and encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy, and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles and relationship. While sexuality can include all of these dimensions, not all of them are always experienced or expressed. Sexuality is influenced by interaction of biological, psychological, social, economic, political, cultural, ethical, legal, historical, religious and spiritual factors.

SEXUAL HEALTH⁽¹⁾

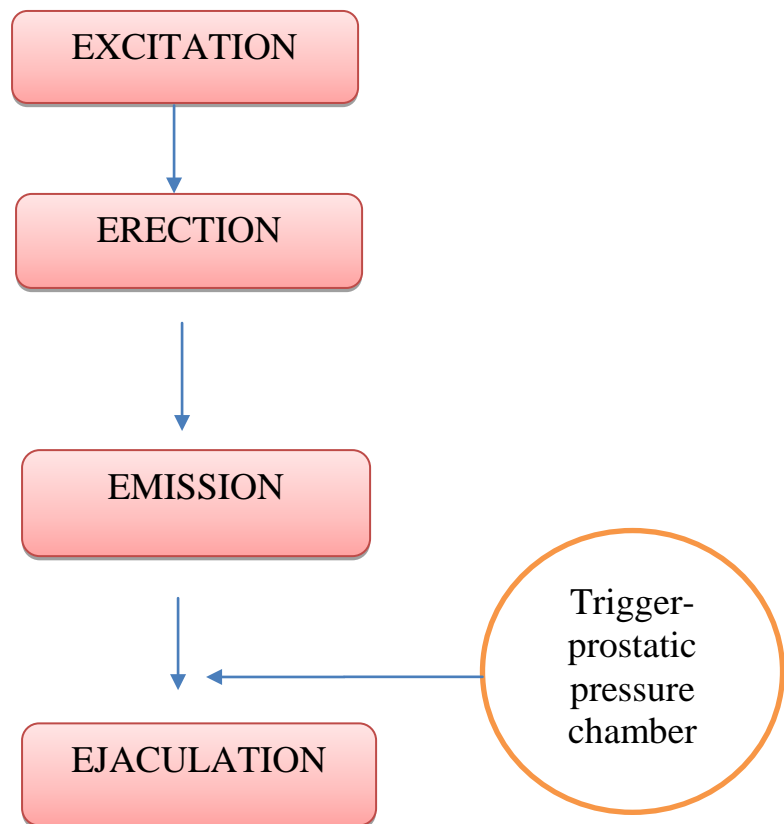
Sexual health is defined as a state of physical, emotional, social well-being in relation to sexuality, it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled (WHO 2006a)

MALE REPRODUCTIVE SYSTEM

The male genital consists of both internal and external reproductive (sexual) organs. External organs consist of penis and urethra. Internal organs consist of testis, the ductal system (epididymis, vas deferens), and glandular system (seminal vesicles and prostate)². The gonadotropin

releasing hormone (GnRH) secreted by hypothalamus regulates the release and secretion of follicle stimulating hormone (FSH) and luteinising hormone (LH) from anterior pituitary³. Feedback regulatory mechanisms takes the role of establishing a physiological homeostasis and hence normal functioning of reproductive system⁴. Spermatozoa made within the testicles, which mature in epididymis (sperm reservoir) travels through the vas deferens, where it is added by ejaculate (seminal fluid) and prostatic fluid^{2,3}. An alkaline secretion from bulbourethral glands (Cowper's glands) called pre-ejaculate is also added which facilitates high sexual arousal and lubrication for sperm passage².

NORMAL SEXUAL AROUSAL IN MALE⁵



Sexual excitation occurs through psychogenic or somatogenic stimuli. Multiple site co-activation happens in brain among which

predominant sites being ventral tegmental area, amygdala and hypothalamus in male sexual arousal.¹⁰

Erection is defined as the conversion of flaccid urinary penis to a rigid sexual penis. The act of erection is facilitated by erectile chambers consisting of pair of corpora cavernosa and corpora spongiosum. During sexual arousal, release of vasoactive intestinal peptide (VIP) and nitric oxide (NO) occurs. Nitric oxide activates cyclic guanosine monophosphate, which causes muscle relaxation. Vasoactive intestinal peptide, a vasodilator and a smooth muscle relaxant, together with nitric oxide causes engorgement of blood vessels promoting rigidity of penis finally causing erection.

The emission phase is under the control of hypogastric nerve, through sympathetic spinal reflex, T10-L2. This phase is supported by contractions of the smooth muscles of male genital tract and accompanied peristaltic movements of ducts, thereby facilitating initiation of ejaculation.

The concept of prostatic pressure chamber is vital for ejaculation reflex, which was described by Marberger⁵. Semen entering prostatic urethra, followed by closure of bladder neck and addition of prostatic secretions leads to further distension and increased chamber pressure. The coordinated process is mediated by both sympathetic (hypogastric nerve) and parasympathetic (pudendal nerve) nervous system. This pressure in the chamber now activates rhythmic contractions of pelvic smooth muscles, setting up an ejaculatory pressure, causing ejaculation to occur. The internal prostatic sphincter closes preventing retrograde ejaculation, whereas external sphincter relaxes promoting antegrade ejaculation.

ORGASM

Orgasm and ejaculation are two related process, but different physiologically⁶. Studies state larger the ejaculate volume greater is the orgasmic pleasure⁷. Quality of orgasm depends of orgasmic pleasure which in turn depends upon ejaculate volume⁹. Orgasm is the sudden discharge of accumulated sexual excitement during sexual response cycle, resulting in rhythmic muscular contractions in pelvic region characterised by sexual pleasure⁸. Orgasm is associated with release of prolactin and oxytocin. Lower levels of androgen are associated with weaker orgasms as in old age and hypogonadism⁹.

FEMALE REPRODUCTIVE SYSTEM

The human female reproductive system is divided into external and internal components¹¹. Internal reproductive organs comprise of uterus, fallopian tubes, ovary, cervix and vagina. External reproductive organs comprise of clitoris, pudendal cleft, labia majora and minora, vulva, mons pubis and Bartholin glands.

The labia majora and minora contains erectile tissue that surrounds vaginal introitus. The outer labia usually meet and covers the introitus but in some females the inner labia protrude even when they sexually unaroused (protrusion when they are sexually aroused is a common or a normal phenomenon). Sexual arousal creates a vaso-congestion leading to engorgement and becomes sensitive to touch and friction.

The role of peri-urethral glans which extends from just below clitoris, enclosing the triangular area of mucous membrane around the urethra and extending up-to vagina is important in erotic stimulation this structure is homologous with male glans. The quality of erotic stimulation

depends on the mobility, density of innervation and sensitivity of erotic site, which in turn facilitates orgasm.

The clitoris, penile homologue in women, again comprises of erectile tissue lying in medial sagittal plane which bifurcates internally into paired crura and externally capped with glans¹². During sexual arousal, blood flow to clitoris increases as a result of action from nitric oxide (NO) and vasoactive intestinal peptide (VIP). This again responsible for stimulation by touch or friction¹².

The role of vagina in sexual activity is that vaginal lubrication prevents anterior and posterior walls from adhesion and also facilitates painless intercourse¹³. Sexual arousal causes increased blood supply to vaginal walls as a result of release of vasoactive intestinal peptide (VIP)¹⁴. After orgasm, blood flow reaches baseline and fluid is reabsorbed back. Baseline blood flow is maintained by vasoconstrictive tone mediated by noradrenergic system, where capillaries open and close randomly according to needs and demands in the surrounding tissue^{13,14}.

The G spot (now known as female prostate), Halban's fascia (pubocervical fascia, fibroelastic mesenchyme, close to second part of anterior vaginal wall and rich in vascularity) and urethra are considered to be erotic structures, stimulation of which promotes arousal and orgasm^{14,15}. So, any pressure on anterior vaginal wall will indirectly stimulate these erotic structures, facilitating progress through sexual response phases¹⁴.

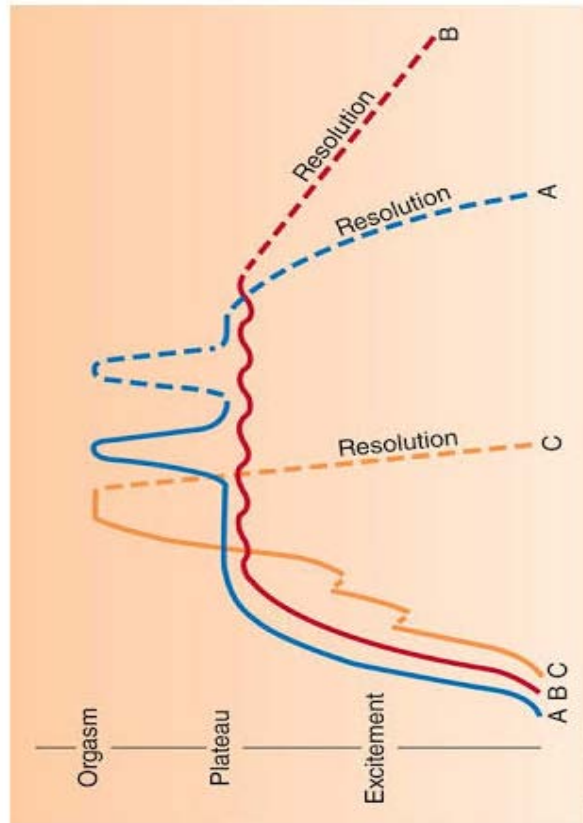
Any stimulation of erotic structures promotes orgasm, an ecstatic pleasure accompanied usually by muscle contractions both subjectively and physiologically.

FEMALE SEXUAL RESPONSE CYCLE¹⁶

The first stage is the desire for sex, characterised by sexual urges, fantasies and wishes. This phase initiates the sexual response cycle. The second stage, sexual excitement phase characterised by subjective feeling of sexual pleasure associated with subjective perception of physiological changes in the body. Vaginal lubrication in female occurs during this phase. Heightening of excitement is the stage of plateau, which is attained by continuous stimulation. This phase of plateauing sets up a sexual tension, which paves way for orgasm. The stage of plateau can either be regarded as a separate phase or as a part of end stage of excitement. Orgasm is defined as the peak stage of sexual pleasure, with rhythmic contractions of genital musculature, following which the resolution phase sets in. The resolution phase is the final phase, during which there is a sense of relaxation and well-being is felt subjectively. In females, refractory period is absent which provides the reason for multiple orgasms in females.

A major difference between male and female is that a female can be multi-orgasmic because they do not have a PERT (post-ejaculation refractory time) after orgasm¹⁷. The evidences on human PERT is limited¹⁸. It is defined as the period during which further erections or ejaculations are inhibited. The dopaminergic and adrenergic pathways are thought to shorten PERT, whereas serotonergic pathways lengthen it¹⁸.

Female Sexual Response



Adapted from: T.S Sathyanarayana Rao and Anil Kumar M. Nagaraj, Indian journal of psychiatry. 2015 July; 57(suppl2); female sexuality

SEXUAL REFLEXES¹⁹

Sexual response is a reflex. A reflex is an involuntary response to a stimulus. The reflex arc is a neural pathway consists of receptor, afferent arm, integrating centre, efferent arm and effector organ. So, sexual response is better explained by reflex arc. The arc consists of special senses of the body which perceive sexual stimuli from both genital and non-genital areas or even imagination of sexual fantasies, integrating in brain and spinal cord, thereby producing an efferent response, which has both emotional or psychological component (pleasure), systemic non-genital responses (heart rate and respiratory rate increase), or genital changes (erection, ejaculation, orgasm). So, a single sexual stimulus can result in various responses each acting as a different reflex arc, hence sexual response is rightly called as series of reflexes.

SEXUAL ACTIVITY AND AGING:

A fulfilling sexual life is important for greater relationship satisfaction, love, commitment and relationship stability across life span²⁰. The subjectively perceived quality of sexual aspects of life known as sexual quality of life (SQoL)²¹. The sociocultural influences masks many facts underlying sexuality and aging, thereby its impact on sexual quality of life²². Aging is characterised by physiological, behavioural, psychosocial and pathological changes interwoven among them, all of which can affect sexual functioning.

As age advances, there is a positive relationship between age and quality of other domains of life²³. But negative relationship between age and SQoL has been established through cross sectional studies²⁴. These effects are more pronounced in women than in men²⁵.

On an average roughly studies state that 10-year increase in age is associated with 5 % decline in SQoL, with this decline more rapid for older adults than for younger ones^{21,24}.

Over increasing years, women show less interest in both coital(sexual) and non coital(non - sexual) activities, when compared with men of same age, which is more significant above 50 years. The reason portrayed for declining sexual activity is the increase in “interest – activity gap”²⁶. Also, both sexes reported increased time needed for arousal.

The following table shows the factors for decline in sexual functioning and impact of gender over increasing years²⁶.

Factors affecting sexual desire	Male (%)	Female (%)
Age	30	43.3
Deteriorating health	56.7	13.3
Loss of job	3.3	0
Financial crisis	3.3	10
Loss of partner	3.3	20
Loss of other family member, close friend	0	10
None	3.3	3.3
Total	100	100

($P=0.008$)

STRESS AND SEXUAL FUNCTIONING

Stress is known to have its impact on sexual functioning. “Hassles” also known as daily stressors accumulate over time resulting in chronic stress in cumulative manner²⁷. Stress leads to conflicts in marital life, which in turn decreases libido and sexual satisfaction²⁸. Effects of stress on sexual functioning is always individualised, because it takes into account individual’s coping and dyadic coping²⁹.

Bondenmann classifies stress into externa stress (financial stress, work place stress, neighbourhood stress at living place) and internal stress (negative communication patterns, health problems).

Dyadic coping paves way for better sexual well-being. Dyadic coping is defined as process in which one partner’s subjective communication of stress is evaluated and then the other partner responds with supportive coping³⁰. Dyadic coping promotes sense of “we-ness” and promotes stress reduction, thereby improving sexual well-being³¹.

Chronic stress leads to elevated levels of catecholamines and sympathetic response, as well as suppress sex hormones^{32,33}. Chronic stress is generally defined as major life events, the effect of which lasts over a period of time or accumulation of small stressors over a long

period³⁴. Chronic stress raises individuals allostatic load. Higher cortisol levels inhibit hypothalamic pituitary gonadal axis interfering with release of sex hormones. Cortisol: DHEAS ratio predicts sexual functioning³⁵. Increase in DHEAS improves sexual activity, but if cortisol raises it suppress DHEAS thereby has negative effect on sexual functioning³⁶. Chronic stress leads to increased sympathetic activity. For example, increased sympathetic activity raises blood pressure which inhibits blood flow to genitals thereby inhibiting arousal³⁷. Also, with chronic stress there will not be an acute spike of sympathetic activity, as the baseline is set a higher limit³⁸. This also leads to impairment of sexual functioning.

PSYCHOPHARMACOLOGY OF SEX

NEUROTRANSMITTERS AND THREE PHASES OF HUMAN SEXUAL RESPONSE CYCLE³⁹

LIBIDO:

Libido is the first stage of human sexual response cycle. This stage is linked to desire. This stage is mediated by mesolimbic pathway. Dopamine and sex hormones (testosterone and oestrogen) promotes libido. Prolactin inhibits this stage

AROUSAL:

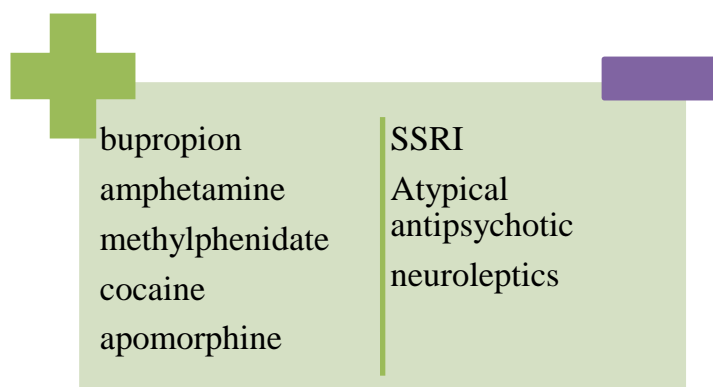
This stage is marked by changes in external genitalia like erection in men, lubrication and swelling in women. Nitric oxide and acetylcholine are the key neurotransmitters promoting this pathway.

ORGASM:

The final stage of sexual response cycle, which is accompanied by ejaculation. Norepinephrine promotes this stage and serotonin inhibits this stage.

EFFECTS OF DRUGS ON HUMAN SEXUAL RESPONSE CYCLE⁴⁰:

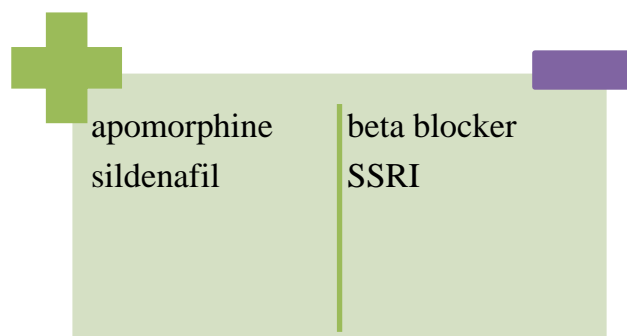
LIBIDO:



AROUSAL:



ORGASM:



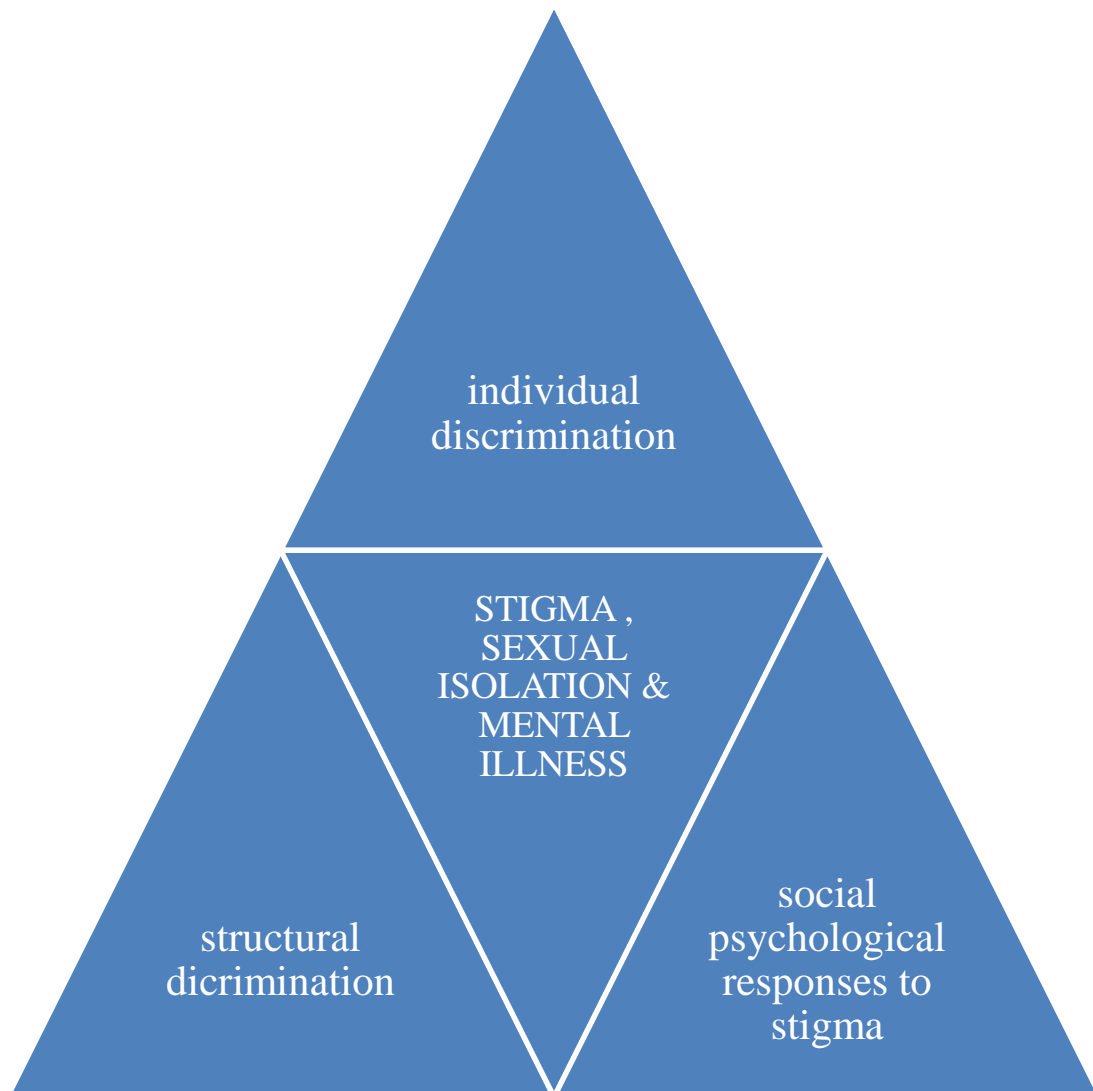
SEXUAL DYSFUNCTION AND MENTAL ILLNESS:

Sexual dysfunction is prevalent and related to both the psychopathology and the pharmacotherapy⁴¹. People with mental illness have difficulties in finding and maintaining intimate partner relationships. Sexual isolation of people with serious mental illness is also added by outcome of discrimination and coping strategies associated with the stigma of mental illness⁴². The following bulletin describes the causes of sexual inactivity in people with mental illness⁴².

SEXUAL INACTIVITY IN PMI

- POOR ACCESS TO SEXUAL PARTNERS
- PSYCHOSOCIAL DIFFICULTIES FORMING SEXUAL PARTNERS
- FEARING DISEASE RELAPSE OR PREGNANCY
- EXPERIENCING SEXUAL DYSFUNCTION
- MORAL & QUALITY OF RELATIONSHIP CONCERNS
- FEELING DEVALUED AND BEING WITHDRAWN
- SEXUALLY RESTRICTIVE TREATMENT CULTURES & SETTINGS
- EVERYDAY DIFFICULTIES WITH MENTAL ILLNESS ALSO POSES IMPACT ON SEXUAL FUNCTIONING

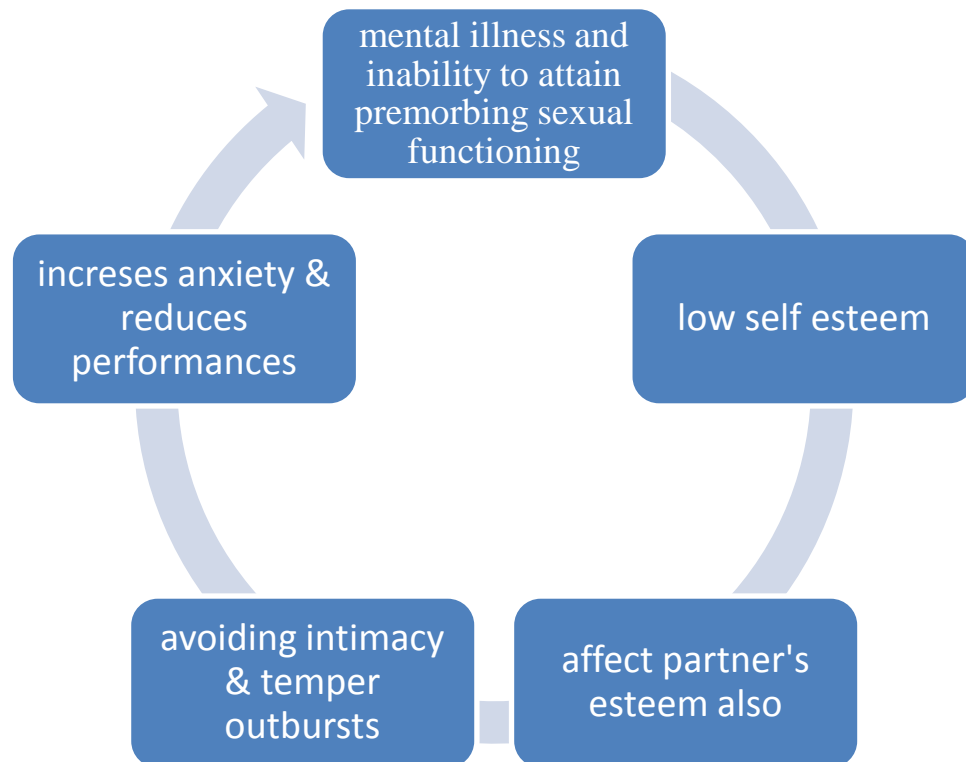
**AN INTER-RELATION BETWEEN STIGMA, SEXUAL
ISOLATION & MENTAL ILLNESS ^{43,44,45,46}:**



The stigma process can influence on the lives of the stigmatized at three levels. First, individual discrimination may occur as result of overt rejection in people with mental illness in almost all activities in everyday life. Second, the structural discrimination which includes role of psychiatric illness and treatment. The organization and everyday patterns of social institutions also facilitate structural discrimination and limit the opportunities of stigmatized people. Third, the stigma process through “social-psychological processes” operating through the stigmatized

person through the loss of self-esteem, self-efficacy and personal mastery.

ILLNESS PER SE AND SEXUAL DYSFUNCTION^{42,47,48}

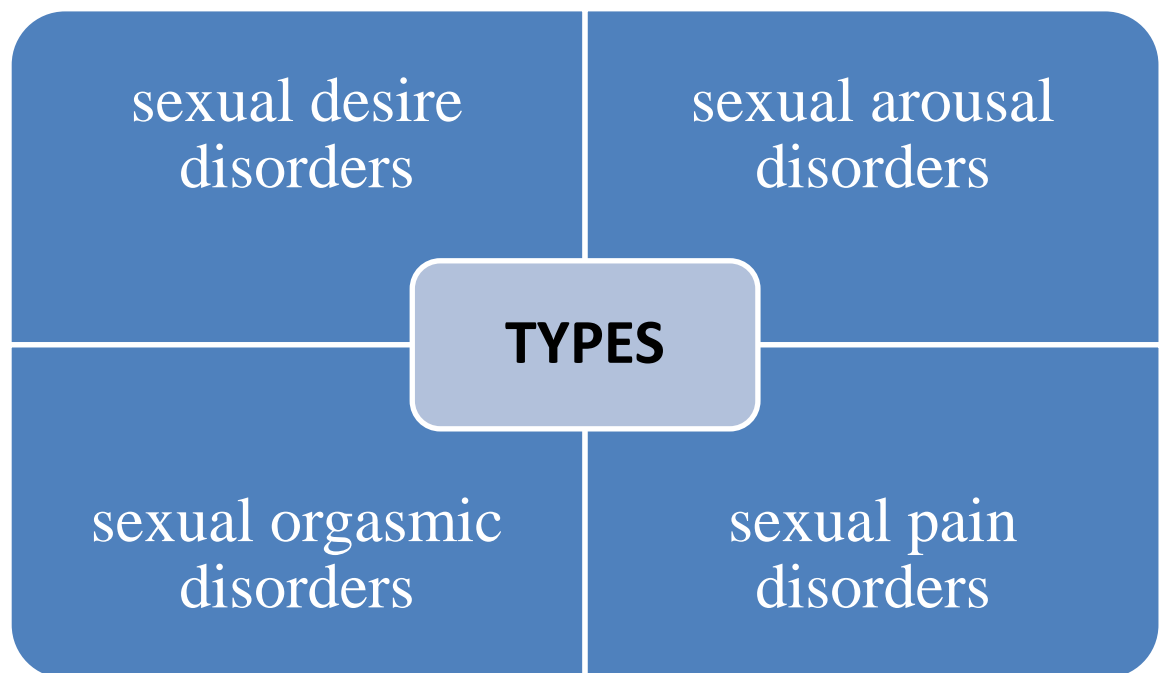


As a part of mental illness, sexual dysfunction does occur with varying severity. Initially the patient identifies that sexual functioning is affected either qualitatively or quantitatively or both. This lowers self-esteem of patient, which in turn affects the esteem of partner or spouse. So, patient tries to exhibit avoidance behaviour like avoiding intimacy and throw temper outbursts whenever the spouse tries to engage in sexual activity. As a result, when the patient tries to engage further in sexual activity despite overcoming his avoidance behaviour, he encounters with performance anxiety which again impairs his sexual functioning. The patient despite having symptomatic recovery he feels ill of attaining his premorbid sexual functioning. This becomes a vicious cycle.

SEXUAL DYSFUNCTION

International classification of diseases and health related problems (ICD 10) defines sexual dysfunction as “a person’s inability to participate in a sexual relationship as he or she would wish.” So, it can either be inability to experience or respond to sexual stimulation physiologically or psychologically or on the other hand can be experience of pain during sexual act. Before diagnosing a case of sexual dysfunction, cultural factors and aging needs to be considered.

CLASSIFICATION OF SEXUAL DYSFUNCTION



Each of the dysfunction can be lifelong or acquired, generalised or situational, with varying severity. And to add on all these is not better accountable by any other medical or psychiatric disorders or effect of medication.

FEMALE SEXUAL DYSFUNCTION DISORDERS

SEXUAL DESIRE DISORDERS

HYPOACTIVE SEXUAL DESIRE DISORDER

Hypoactive sexual desire disorder – defined as a lack of or significantly reduced interest in sexual activity, sexual thoughts or fantasies (includes memories of past sexual experiences), initiation of sexual activity⁴⁹. Hypoactive sexual desire disorder is defined in DSM IV-TR as persistent or recurrent deficit (or absent) sexual fantasies and desire for sexual activity that causes marked distress or interpersonal difficulty⁵⁰. While taking sex history and making clinical judgement of sexual dysfunction, cultural factors and age needs to be considered. The clue to pick out HSDD inability to engage in sexual fantasies following a trigger or cue, which normally happens in a sexually healthy women⁵¹. Consideration of dysfunction of desire phase is important as it precedes arousal and orgasm in a sequential manner, so interruption of it may have an impact in individual's sexual cycle⁵².

Also, “desire discrepancy” in which partner A has low desire than partner B will not be sufficient enough to make a diagnosis of hypoactive desire.

SEXUAL AVERSION DISORDER

Often used synonymous with the above-mentioned disorder, but it is distinguished by persistent or recurrent aversion to, and avoidance of, all (or almost all) genital sexual contact with a sexual partner, causing distress or interpersonal difficulty⁵³. Clinical clue revealing this disorder is characterised by presence of extreme anxiety and/ or disgust at the

anticipation of or attempt to have sexual activity or intimacy. This disorder often goes underdiagnosed or misdiagnosed.

SEXUAL AROUSAL DISORDER

Female sexual arousal disorder, according to DSM-4 TR is defined as “persistent inability to attain or to maintain until completion of sexual activity an adequate genital lubrication-swelling response of sexual excitement, that causes marked distress or interpersonal difficulty”. This criterion focusses on genital response of reflexive vaginal lubrication, psychological sense of sexual excitement or sexually awakened, physiological sense of breast and nipple sensations.

The following details the different types of female sexual arousal disorder^{53,54}.

subjective sexual arousal disorder	genital sexual arousal disorder	combined genital and subjective sexual arousal disorder
<ul style="list-style-type: none"> • reduced or absence of sexual arousal • lack or absence of sexual excitement and sexual pleasure from sexual stimulation 	<ul style="list-style-type: none"> • impaired genital arousal only • common in autonomic nerve damage or estrogen deficit women • subjective excitement prevails usually 	<ul style="list-style-type: none"> • most common presentation • features of both • co-exists with lack of interest

FEMALE SEXUAL AROUSAL / INTEREST DISORDER

This disorder is defined as lack of, significantly reduced sexual interest or arousal as manifested by three out of six mentioned criteria, with minimum duration of approximately 6 months, causing significant distress to the individual. The six criteria take into account sexual

activity, sexual/ erotic thoughts or fantasies, unreceptiveness to partners attempt to initiate sexual activity, sexual excitement/pleasure, sexual interest/arousal, genital/non-genital sensations during sexual activity.

AN UNDERSTANDING OF DIFFERENCE AND UNIFICATION OF ENTITIES:

The major difference between DSM-4 TR description of female sexual arousal disorder and DSM-5 description of female sexual arousal/ interest disorder brings to light that DSM-4 TR criteria focusses on deficits associated only in arousal phase (phase 2) of sexual cycle, whereas in DSM-5 it takes into account desire, arousal, excitement/ pleasure during sexual activity along with genital and non-genital sensations. Hence in DSM-5, female hypoactive desire disorder and female arousal disorder are merged together as female sexual arousal/ interest disorder.

FEMALE ORGASMIC DISORDER

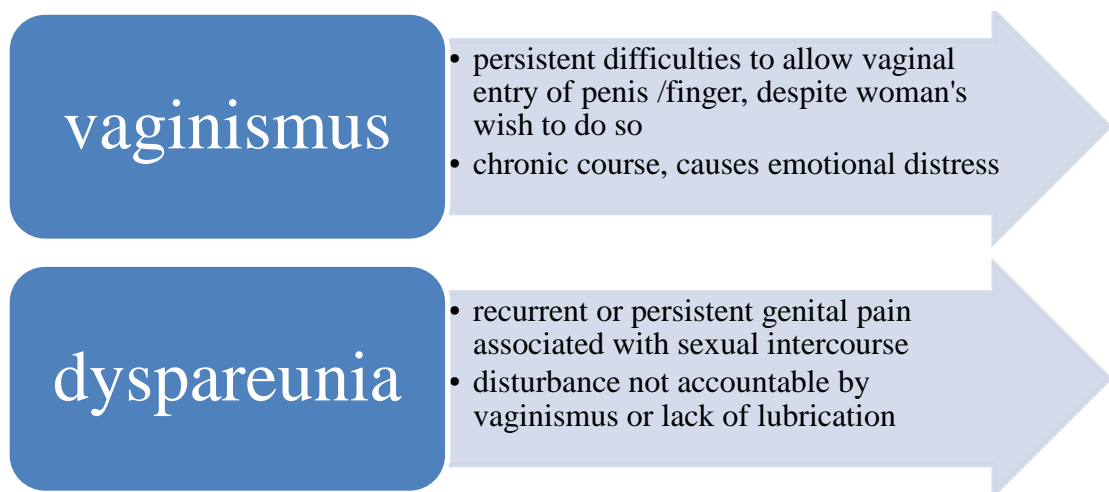
The description of female orgasmic disorder is carried over from DSM-4 TR to DSM-5 with no much changes. According to DSM-4 TR, this disorder is characterised by persistent or recurrent delay in, or absence of, orgasm following a normal sexual excitement phase. According to DSM-5, presence of either of the symptoms (marked delay or infrequent / absence of orgasms, markedly reduced orgasmic sensation), experienced on almost all or all occasions of sexual activity, being it situational or generalised. The common supporting criteria includes impairment being present for six months, causing distress to the individual, not explained by any other non-sexual mental disorder or severe relationship distress (E.g.: violence).

CRITISCSMS:

Having in mind the definition of orgasm itself vague with varied characterisations, this accountability, stability and clinical judgement of the disorder remains a debate. Some concepts emphasize 'Consciousness' not necessary as a part of orgasm to happen, it can occur even with sleep⁵⁵. The stigma associated with reporting of deficit orgasm in culture-oriented country like India, is again questionable. On the other end of the spectrum, where women experience multiple spontaneous orgasm without or with minimal stimulus is not considered as a disorder (in contrast to any variation from normal range is always considered as disorder) or given special entity⁵⁵.

SEXUAL PAIN DISORDERS

DSM-4 TR classifies sexual pain disorders into 2 types^{56,57}



GENETIC PELVIC PAIN/ PENETRATIVE DISORDER

DSM 5 defines this disorder as persistent difficulties with one or more of the following features- vaginal penetration during intercourse, marked vulvovaginal or pelvic pain (superficial or deep pain, qualitative characterisation like burning, cutting etc.,) during intercourse or

penetration attempts, marked fear or anxiety about pain in anticipation, tensing or tightening of pelvic floor muscles (contrary to normal guarding or tensing during intercourse which allows penetration) during attempted vaginal penetration. Its mandatory to rule out any pelvic floor dysfunction through detailed assessment by a specialist gynaecologist or pelvic floor therapist.

CURRENT STATUS:

The current status of sexual pain disorders is collapsed together under a single entity- genetic pelvic pain/ penetrative disorder. Vaginismus and dyspareunia focusses on pain associated with sexual activity. As often there is a grey area, difficult to differentiate between pain associated with penetration alone and from pain associated with other sexual activity, and for most of the time they co-exist or overlap, it seems to be on the nail when both are collapsed together to avoid diagnostic and treatment related issues.

MALE SEXUAL DYSFUNCTION DISORDERS

MALE HYPOACTIVE SEXUAL DESIRE DISORDER

Male hypoactive sexual desire disorder (302.71; F52.0) is defined as persistently or recurrent deficit (or absent) sexual/ erotic thoughts or fantasies and desire for sexual activity. As said previously, clinical judgement takes into account cultural and age-related factors. Usually clinical picture presents with not initiating sexual activity or minimally receptive to partner's attempt to initiate. At times, masturbation can be present even in presence of low sexual desire.

Short term changes in desire for sex, need not be diagnosed under this disorder. Normative age-related sexual decline needs to be considered.

MALE ERECTILE DYSFUNCTION

DSM-5 defines this disorder as, presence of one out of three (marked difficulty in obtaining erection during sexual activity, marked difficulty in maintaining erection until the completion of sexual activity, marked decrease in erectile rigidity), as experienced by all or almost all occasions of sexual activity, which can be generalised or situational, with varying severity⁵⁸.

History reveals repeated failure to obtain or maintain erection during partnered sexual activities. Men with erectile dysfunction often presents with low self-esteem, decreased sense of masculinity, depressed affect, fear or avoidance of future sexual encounters. This also paves way for low desire and low sexual satisfaction. Following an acute stressor resulting in mood change can cause low desire or erectile difficulties, which cannot be counted under this disorder. Psychogenic aspect of erectile dysfunction also needs to be kept in mind.

DIAGNOSTIC DIFFERENCES:

During initial presentation often, men verbalise of having low desire only (as they presume, erectile difficulties is an outcome of reduced interest), so its mandatory to confirm there has never been erectile difficulties previously before making a diagnosis of hypoactive desire disorder. The scenario can be vice versa where low desire can result in impairment in all phases. Careful sex history differentiates both the diagnosis.

PREMATURE EJACULATION

A premature or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately 1 minute following vaginal penetration and before the individual wishes it. The core feature is ejaculatory latency after vaginal penetration is short.

The addition of cut-off time as 60 seconds is included in DSM-5, which was not mentioned in DSM-4 TR. The diagnosis of premature ejaculation can be applied to individuals engaged in non-vaginal sexual activities, but time cut-off has not been established

MALE ORGASMIC DISORDER

DSM-4 TR defines male orgasmic disorder as persistent or recurrent delay in, or absence of, orgasm following a normal sexual excitement phase during sexual activity taking into account person's age.

DELAYED EJACULATION

DSM-5 defines delayed ejaculation as either of the following (either marked delay in ejaculation or marked infrequency/ absence in ejaculation) must be experienced on almost all or all occasions of partnered sexual activity, and without individual desiring delay. The concept of "delay" has no defined cut-off as described for premature ejaculation, where the current description of delay is subjective, where individual (men) feels it to be unacceptably long or as reported by 'most' of their sexual partners. This has an impact on orgasm or sexual satisfaction.

DSM-5 STATUS:

DSM- 5 discarded former male orgasmic disorder and now included the disorder of delayed ejaculation.

CHANGES IN DSM-5⁵⁹**FEMALE SEXUAL DYSFUNCTION:**

DSM IV- TR DIAGNOSES	DSM – 5 DIAGNOSES
Female hypoactive desire disorder	Female sexual interest/ arousal disorder
Female arousal disorder	
Female orgasmic disorder	Unchanged
Dyspareunia	Genito-pelvic pain/ penetration disorder
Vaginismus	

MALE SEXUAL DYSFUNCTION:

DSM IV-TR DIAGNOSES	DSM-5 DIAGNOSES
Male erectile disorder	Erectile disorder
Hypoactive sexual desire disorder	Male hypoactive sexual desire disorder
Premature (early) ejaculation	Unchanged
Male orgasmic disorder	Delayed ejaculation
Male dyspareunia	Not listed
Male sexual pain	

OTHER DYSFUNCTIONS:

DSM -IV TR DIAGNOSES	DSM-5 DIAGNOSES
Sexual aversion disorder	Deleted
Sexual dysfunction due to general medical condition	
Substance/ medication induced sexual dysfunction	unchanged
Sexual dysfunction not otherwise specified	Other specified and unspecified sexual dysfunction

SUBSTANCE / MEDICATION – INDUCED SEXUAL DYSFUNCTION

Substance/ medication- induced sexual dysfunction is defined as a clinically significant disturbance in sexual function is predominant in the clinical picture, along with the evidence from history, physical examination or laboratory findings of symptoms developed during or soon after substance intoxication or withdrawal or even after exposure of substance and substance involved is capable of producing such dysfunction. Also, the disturbance is not better explained by a sexual dysfunction that is not substance / medication induced. This disturbance causes clinically significant distress in individual but this does not occur during delirium.

If disturbance arises prior to the onset of substance or medication use, it favours towards independent sexual dysfunction disorders, which might have aggravated following substance or medication use. Also, the

sexual dysfunction remains despite substance or medication discontinuation for about a month and also recurrent or previous episodes of non-substance/ medication-related episodes, is in favour of independent sexual dysfunction disorders.

This dysfunction also varies in severity. Medications that can induce sexual dysfunction include antidepressants, antipsychotics and hormonal contraceptives. DSM-5 states antidepressants induced dysfunction to be 30% clinically significant. Both atypical and typical antipsychotics are found to cause significant sexual side effects, with prolactin sparing drugs have less sexual side effects. On a comparison range, antipsychotics affect initial stages of sexual cycle (desire, arousal) whereas antidepressants affect latter stages (ejaculation, orgasm).

On an average prevalence of sexual dysfunction or sexual side effects following medication use varies between 25%-80%. Among medications the variation remains unclear. Antidepressant induced side effects may be as early as 8 days after medication use is initiated. No definite latency period of antipsychotic induced sexual side effects has been established. Gender differences and functional consequences may overlap the clinical picture.

SELECTIVE SEROTONIN REUPTAKE INHIBITORS AND SEXUAL DYSFUNCTION

An assumption that people with mental illness were asexual and lacked any sexual desire led to lack of awareness, discussion and underreporting of drug induced sexual dysfunction⁶¹. Lack of awareness is because it's under-emphasized in package inserts in drug packs and verbal information given to patients by doctors⁶².

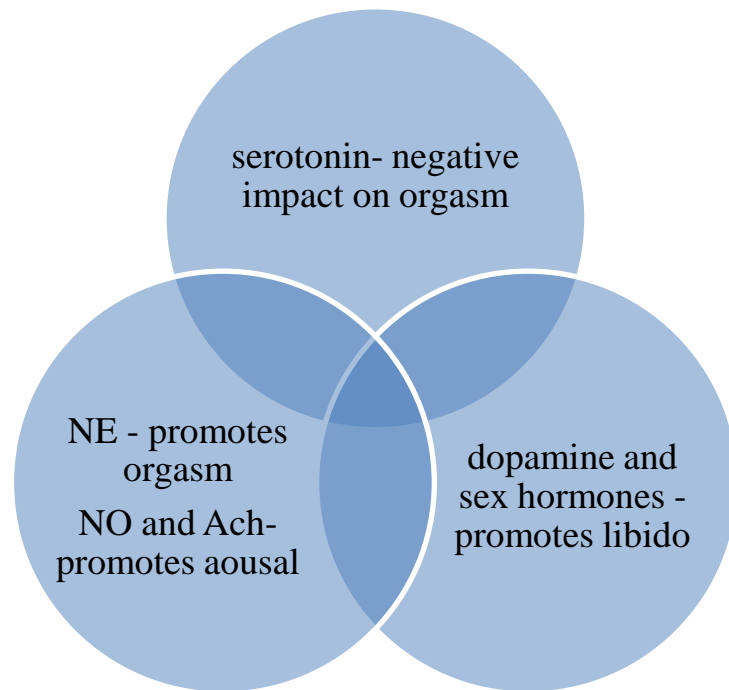
SSRI may have negative effect on all stages of sexual functioning⁶³. Studies quote after SSRI use women complain more sexual dysfunction than men⁶⁴. Sexual side effects are common with SSRI but they vary in intensity and presentation, which are attributable due to variation in individual factors^{64,65}.

Decrease in dosage of drug may cause reversal of both sexual dysfunction and symptoms⁶⁶. But such symptoms negatively affect drug compliance⁶⁷. A thought of allowing dose reduction, waiting for tolerance to occur, considering possibility of 2-4day drug holiday or to switch medication are possible general management strategies of clinicians⁶⁸.

NEUROTRANSMITTER AND IMPACT SEXUAL FUNCTIONING:

Although SSRI are relatively selective for serotonin, they also affect another neurotransmitter systems also⁷⁰. The following table gives an overview of SSRI affecting other neurotransmitters.

SSRI	NEUROTRANSMITTERS
Escitalopram	5-HT
Citalopram	5-HT
Sertraline	5-HT, NE, DA
Fluoxetine	5-HT, NE, DA
Fluvoxamine	5-HT
Paroxetine	5-HT, Ach, NE

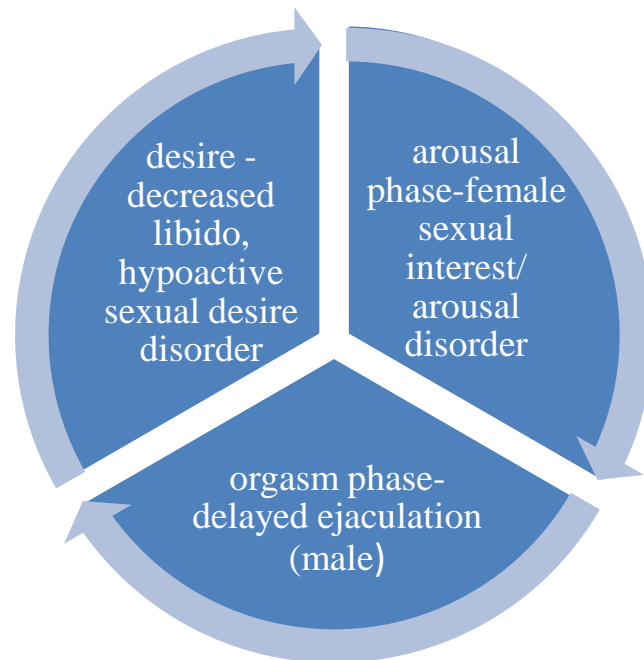


This figure depicts a sexual response involves multiple neurotransmitters and SSRI also has impact on various neurotransmitters.

The interlinked or inter-regulatory feedback mechanisms linked to a single neurotransmitter (e.g.: serotonin) alters various neurotransmitters (e.g. nor-epinephrine, dopamine, etc.). For example, a SSRI like sertraline, which has serotonin reuptake blocking property thereby increases serotonin in synapse which has a negative impact on orgasm phase of sexual cycle and the drug also has weaker dopamine transporter inhibition property which increases dopamine in synapse minimally which also has impact on libido. But at the same time, serotonin regulates dopamine release via 5HT- 1A, 2A, 2C receptors, and norepinephrine release via 5HT- 2C receptor. So, the impact on sexual cycle is a complex outcome of interactions of multiple neurotransmitters based on receptor blockage.

PHASE SPECIFIC SEXUAL DYSFUNCTION⁶⁹:

The following diagram represents SSRI induced dysfunction in each phase.



GENDER DIFFERENCES:

Desire phase of the sexual response cycle is measured by assessing frequency and interest in participating in sexual activity (intercourse and self-stimulation). Through assessment with standard questionnaire and self-report, males report a higher level of dysfunction than women in this phase⁶⁹. So, this emphasizes hypoactive desire in both genders following use of SSRI.

Arousal phase of sexual response cycle is measured by excitement and physical changes related to arousal such as vaginal lubrication in female and erections in male. Females report higher dysfunction with arousal phase⁶⁹.

The orgasmic phase is measured by respondent's ability to orgasm and its related pleasure. Males report higher dysfunction related to orgasmic phase than females⁶⁹.

Hence, global sexual dysfunction reveals its possible for SSRI to cause dysfunction in one or all three phases of sexual response cycle.

ANTIPSYCHOTICS AND SEXUAL DYSFUNCTION:

Similar to antidepressants, antipsychotics also cause potential side effects. But rates are low in spontaneous reporting, whereas in structured reporting the reporting rates are fairly high⁷¹. Reluctance to discuss with clients or patients regarding sexual health is the major reason for under-reporting^{71,72}.

The impact on sexual functioning is a combined outcome of sexual dysfunction due to primary illness, social effects of the illness, and treatment emergent ones⁷³. Always it's difficult to delineate a single cause for the same.

Antipsychotics are potent dopamine blockers, resulting in secondary hyperprolactinemia⁷⁴. This may directly affect sex hormones and endocrine system, causing dysfunction at various phases. Also, their impact on various neurotransmitter has cumulative effects on outcome of sexual function.

NEUROTRANSMITTER AND IMPACT OF SEXUAL FUNCTIONING⁷⁵

dopamine receptor antagonism-
reduced desire

dopamine D2
blockade(tuberoinfundibular
pathway)- affects all 3 stages
secondary to hyperprolactinemia

histamine receptor antagonism-
impaired arousal

cholinergic antagonism -
erectile dysfunction.

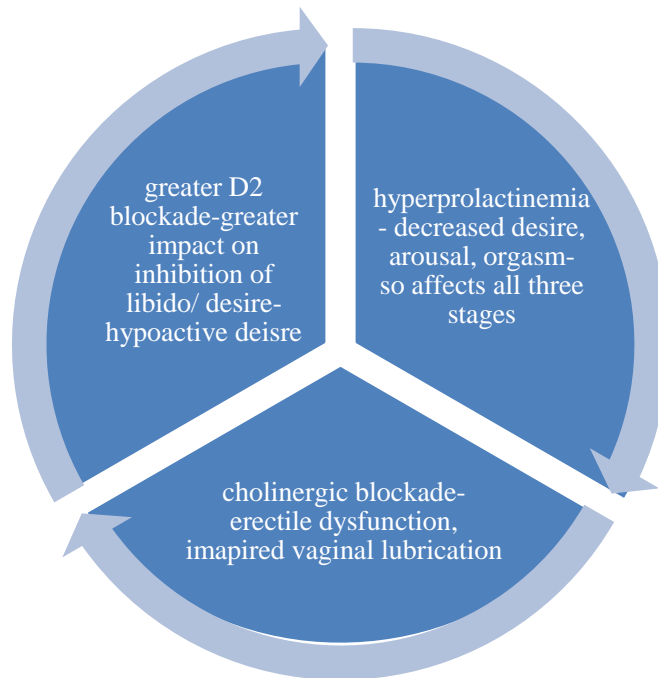
sex hormones changes
secondary to impact on HPA
axis- affects all phases

serotonin - affects all
phases, but particularly orgasm

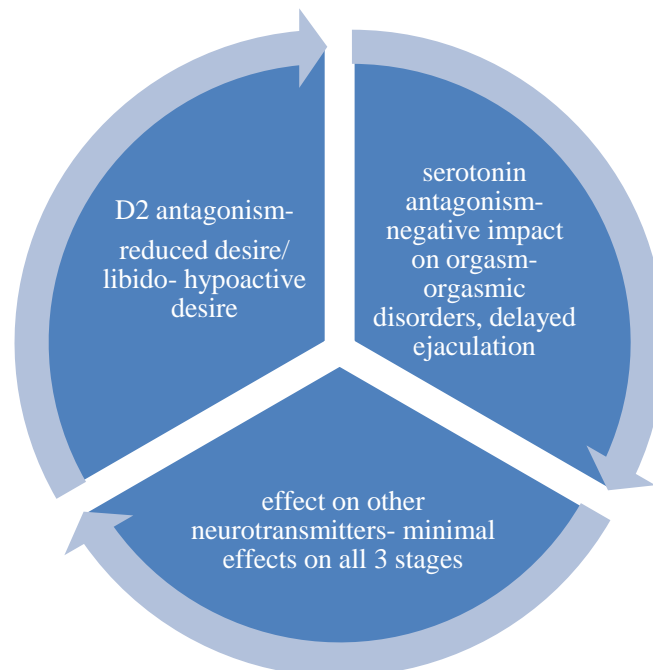
alpha adrenergic blockade-
priapism, problems with
erection, ejaculation
lubrication

PHASE SPECIFIC SEXUAL DYSFUNCTION⁷⁵

TYPICAL ANTIPSYCHOTICS



ATYPICAL ANTIPSYCHOTICS



GENDER SPECIFIC & DRUG SPECIFIC DIFFERENCES ON SEXUAL DYSFUNCTION:

Both class of drugs affects different neurotransmitters to varying severity, hence there lies a difference in the side effect profile of sexual dysfunction.

Regarding conventional anti-psychotics, the side effects are result of hyperprolactinemia due to dopamine D2 receptor blockade⁷⁶. Hence, men report more of erectile and ejaculation dysfunction, whereas women report more of decreased desire and decreased pleasure/ satisfaction after sexual activity⁷⁷.

Regarding second generation antipsychotics, there lies an effect on both dopamine and serotonin. So, there lies an effect much on desire and orgasm phases of sexual cycle. Those much effect on arousal has not been described, it's obvious that the stages preceding and forthcoming stages are impaired which results in global sexual dysfunction, affecting all stages, similar in both gender⁷⁹. According to studies both men and women report desire and orgasmic dysfunction^{77,78}. A specific mention by women on reduced genital and non-genital sensations has been made.

SEXUAL DYSFUNCTION AND ASSOCIATED SOCIO-CULTURAL FACTORS IN INDIA

IN MEN:

Sexual misconception in men are significant problems among both rural and urban population in India. The majority of the sample learnt about sex from friends⁸⁰. The men interviewed held diverse beliefs about the causes of their sexual problems (masturbation, nocturnal emission, disease, punishment by God, karma, black magic and lack of privacy)⁸¹.

They also believed in diverse treatments (herbal remedies, traditional healers, special diet and medical treatment)⁸¹. The factors associated consistently with erectile dysfunction were financial problems, a history of diabetes mellitus, a past history of psychiatric treatment and a current diagnosis of common mental disorder (anxiety and depression). Half of who reported of having sexual dysfunction had sexual misconception⁸¹.

Among participants a minority believed that the physical problems for which they had visited a secondary care hospital were due to the loss of semen through masturbation and nocturnal emission^{80,81}. The majority also reported sexual concerns but were satisfied with their sex life, had a single sexual partner. This signifies the need for sex education in schools and the empowerment of physicians in primary and secondary care to manage such problems⁸⁰.

Male sexual disorders are more prevalent in upper and lower class of socioeconomic status than when compared to middle class⁸². Those who reported sexual dysfunction in hospital settings had chronic medical comorbidity or chronic use of substance male sexual disorders were prevalent among illiterates than literates⁸².

IN WOMEN:

Women's education and socioeconomic status do play a role in her outlook toward sexual life. There are various factors responsible for FSD including psychological status of a person, gynaecological or medical problems, long use of certain drugs, and social beliefs⁸³.

Cultural expectations and taboos alter women's perception and expectation about sexuality⁸⁴. Lack of privacy, sexual openness and freedom coupled with ignorance of issues pertaining to sex and sexuality overlapped by poor communication regarding sexual matters all together

makes it even more a complex issue. A “culture of silence”, a woman is expected to maintain when confronted with issues of sexuality and considering the access to information about the same as a damage to reputation, negatively affects women’s sexual life⁸⁵.

Studies states female sexual dysfunction were more prevalent in women with higher education, when compared with women with no formal education⁸⁶. Female sexual disorders were found to be highest among upper socioeconomic class females and least among lower socioeconomic class. Females with some form of employment (daily wage labourer / salaried / business) had lesser prevalence of sexual disorder⁸⁶. The difficulties or dysfunction related to desire were more common. Post-menopausal women obviously had more problems than women of younger age group.

SEXUAL DYSFUNCTION IN INDIA

IN GENERAL POPULATION:

The study on prevalence of sexual dysfunction in India are limited. The following provides the overview about prevalence in general population. The following study quotes the results from a rural population in south India. The interpretation of results must take into consideration all aspects of sociodemographic details along with sex education, medical comorbidity and cultural aspects of sexuality.

21.15% of the men were diagnosed to have one (or more) sexual disorder. Prevalence of erectile dysfunction was found to be 15.77%, which is considered to be more common and prevalent among other disorders but severity varies between mild to moderate⁸². Only very few cases have severe erectile dysfunction. Other disorders like male

hypoactive sexual desire disorder (HSDD) accounts for 2.56%, premature ejaculation was found to be prevalent in 8.76% of the males⁸².

When looking into female sexual dysfunction, 14% of the female subjects were diagnosed to have female sexual disorders. Prevalence of female arousal dysfunction was found to be 6.65%, among which female hypoactive sexual desire disorder was found to be 8.87%, orgasmic disorders was found to be 5.67%, female dyspareunia was around 2.34% (which now is categorised under Genito pelvic pain/ penetration disorder)⁸².

Another study which exclusively looked into male sexual dysfunction, the following results were obtained. Erectile dysfunction was found among 29.9% and premature ejaculation about 19.4%⁸⁰. Another study focusing on men reporting to secondary care hospitals in rural India, premature ejaculation and erectile dysfunction were reported by 43.0% and 47.8% of men, respectively⁸¹. The most common perceived causes were loss of semen due to masturbation and nocturnal emission.

Another study which looked exclusively into female sexual dysfunction states prevalence of any one of the disorders is as high as 55.55% among fertile women. It also states psychological stress as a reason for high rate of prevalence. It also portrays to look into overlapping or masking picture of other gynaecological disorder in relation to sexual dysfunction.

TREATMENT EMERGENT OR DRUG INDUCED SEXUAL DYSFUNCTION

Anti-psychotics (65.06%) are the most common class of drugs causing sexual dysfunction followed by antidepressants (30.12%)⁸⁷.

In general population sexual dysfunction is higher in females as compared to males⁸⁸.

SUBSTANCE INDUCED SEXUAL DYSFUNCTION:

In alcohol dependent patients, premature ejaculation (37.5%), followed by low sexual desire (36%) and erectile dysfunction (33.3%) were more commonly reported. Orgasmic difficulties were reported in 14.58%⁸⁹.

DIABETES MELLITUS AND SEXUAL DYSFUCTION

Though probability of having any form of sexual dysfunction in men is common with diabetes mellitus, the most common being erectile dysfunction. The prevalence of erectile dysfunction increases with age. The prevalence of ED is about 1%-10% in men younger than 40 years of age with highest reaching almost 50%-100% in men older than 70 years. Diabetic men have almost three-fold probability of having ED than non-diabetic men⁹⁰. Some form of sexual dysfunction is associated with women with any form of diabetes mellitus.

Increased risk of female sexual dysfunction is more common in premenopausal women than in post-menopausal women. Depression major predictor of sexual dysfunction in type 1 diabetic women. Psychological factors play a common role in sexual dysfunction both in type 1 & 2 diabetic females⁹⁰.

AIMS & OBJECTIVES

AIMS:

- To establish the changes in sexual functioning among patients in remission phase of illness taking antipsychotics and antidepressants.
- To establish the prevalence of sexual dysfunction among both group of patients.

OBJECTIVES:

- To study about the changes in sexual functioning after use of antipsychotics and antidepressants
- To study about the prevalence of sexual dysfunction among both groups
- To study about relationship between sociodemographic correlates with sexual functioning
- To study about relationship between illness related correlates with sexual functioning
- To study about sexual functioning in a sub-group of general population

MATERIALS AND METHODS

INCLUSION CRITERIA

- Patients must satisfy a diagnosis in ICD-10, which falls under psychotic spectrum disorders (cases generally taken are only first episode psychosis), depression and anxiety.
- Remission in the disease, indicated by fall in scores in appropriate scales pertaining to that disease.
- From 18 years of age
- Sexually active
- Monotherapy for 6 weeks
- Both males and female

EXCLUSION CRITERIA

- Poly pharmacy with other antipsychotics and antidepressants
- Co morbid medical illness
- Co morbid psychiatric illness

OUTCOME OF THE STUDY

- A comparison of sexual functioning in patients before and after medication (antipsychotics, antidepressants) use
- The prevalence of treatment emergent sexual dysfunction

- An association of socio demographic details like age, gender, marital status, socioeconomic status and employment status with sexual functioning
 - An association of illness related factors like diagnosis, type of drug, dose of drug and family history of mental illness with sexual functioning
 - An association of type of drug, dose of drug and its effects on various phases of sexual dysfunction
- Duration of study: one year

METHODOLOGY

- 1) Approval is obtained from the Institutional Ethical committee.
- 2) Patients diagnosed with first episode psychosis and depression or anxiety are started on antipsychotics and antidepressants respectively.
- 3) The patients who attain remission in 6-8 weeks of treatment are taken into the study. Selection will be done by random sampling method.
- 4) Patients satisfying the inclusion and exclusion criteria will be chosen for the study.
- 5) Patients will be explained about the nature of the study.
- 6) After getting informed consent, patients will be interviewed and details will be collected as per socio demographic proforma.

- 7) Sexual functioning of patients both before and after drug use are collected through appropriate scales- changes in sexual functioning questionnaire (male and female versions of scale available)
- 8) After which the relationship between socio demographic variables, illness related variables and sexual functioning are studied
- 9) The results are statistically analysed and final conclusion arrived at.

DESCRIPTIVE STATISTICS:

Total no of cases: 168

Total no. of individuals (from general population): 55

Total = $168+55= 223$

STATISTICAL ANALYSIS

- IBM SPSS version 21 used
- Descriptive statistics like frequency and percentage was used.
- Inferential statistics like chi-square test was used for association.

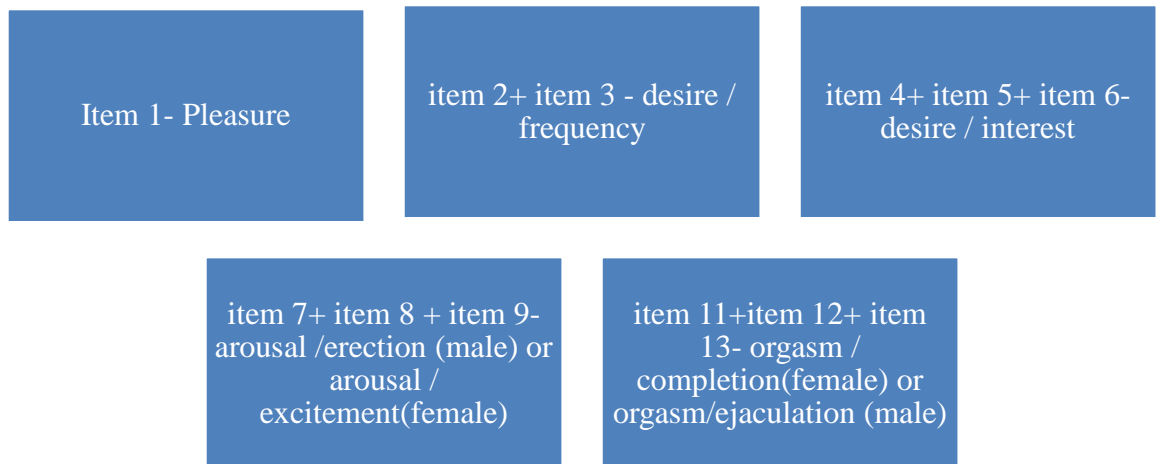
SCALES

- Changes in sexual functioning questionnaire (CSFQ) – male and female
- Hamilton rating scale for depression (HAM-D)
- Hamilton rating scale for anxiety (HAM-A)
- Brief psychiatric rating scale (BPRS)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE

(Clayton, McGarvey, Clavet & Piazza, used both in research and clinical settings)

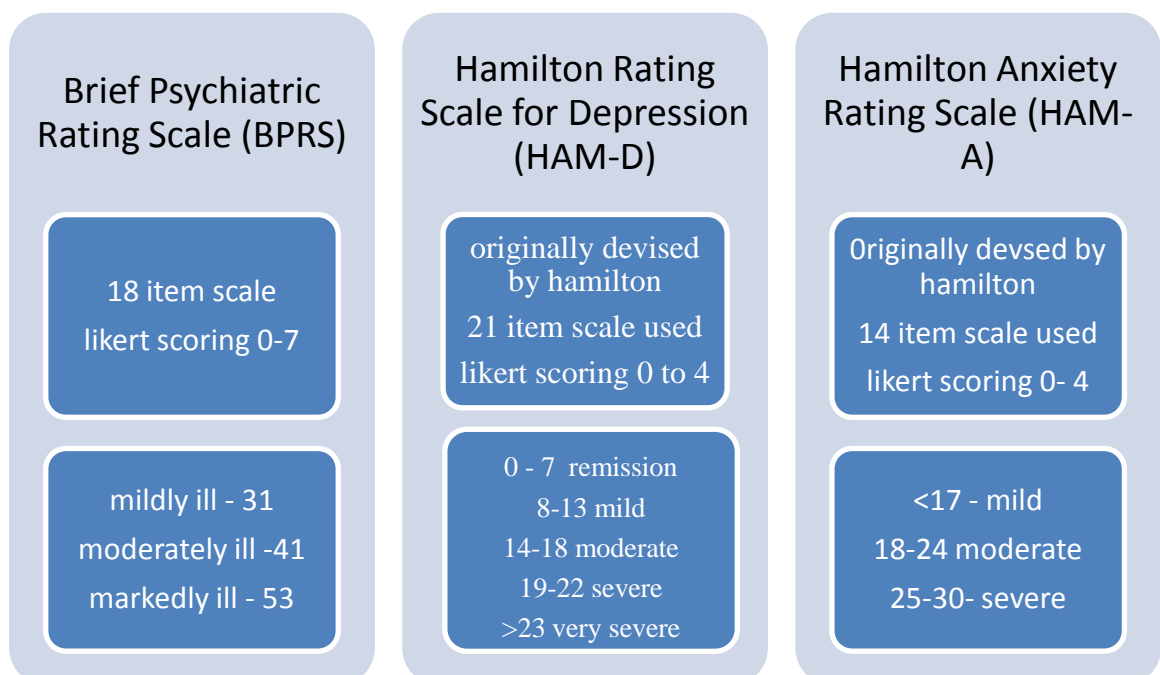
SCALE DOMAINS



Item 10- painful or prolonged erections(male) or aroused and lost interest(female); Item 14- painful orgasm

Total score (items 1 to 14) cut off for sexual dysfunction - 41 (female) and 47(male)

OTHER SCALES USED



RESULTS

SOCIODEMOGRAPHIC VARIABLES

Table 1: Age wise distribution of patients

Age	No. of patients	Percentage
19-20 Years	10	6.0
21-30 Years	65	38.7
31-40 Years	55	32.7
41-50 Years	24	14.3
51-60 Years	14	8.3
Total	168	100.0

From the above table, vast majority of patients fall in the age group between 21-30 years of age (38.7%), followed by 31-40 years of age (32.7%).

Table 2: Gender distribution

Gender	No. of patients	Percentage
Male	78	46.4
Female	90	53.6
Total	168	100.0

From the above table, female patients (53.6%) constitute a higher proportion than male patients (46.4%).

Table 3(a): Employment

Employment	Frequency	Percentage
Employed	123	73.2
Unemployed	26	15.5
Student	19	11.3
Total	168	100.0

From the above table, vast majority of population are employed (73.2%) against the unemployed group (15.5%)

Table 3(b): Type of employment

Type of employment	No. of patients	Percentage
Profession	8	6.5
Semi – profession	10	8.2
Clerical / shop owner	14	11.5
Skilled worker	29	23.8
Semi-skilled worker	21	17.2
Unskilled worker	40	32.8
Total	122	100

From the above table, vast majority of employed population are unskilled workers (32.8%)

Table 4: Socioeconomic class

Socioeconomic class	No. of patients	Percentage
Class 1	1	.6
Class 2	29	17.3
Class 3	99	58.9
Class 4	39	23.2
Class 5	0	0
Total	168	100.0

From the above table, vast majority of patient group lies in class 3 socioeconomic class (lower middle class- 58.9%)

Table 5: Marital status

Marital status	No. of patients	Percentage
Married	137	81.5
Unmarried	31	18.5
Total	168	100.0

From the above table, majority of the patient group are married (81.5%)

PERSONAL AND FAMILY VARIABLES RELATED TO ILLNESS

Table 6: Menstrual status

Menstrual status	No. of patients	Percentage
Regular	67	39.9
Irregular	2	1.2
Premenopausal	10	6.0
Menopause	11	6.5
Not Applicable	78	46.4
Total	168	100.0

From the above table, the subset of patients belonging to the group ‘not applicable’ are males, excluding which majority of female patients have regular menstrual cycles (39.9%).

Table 7: Family History

Family history	Frequency	Percentage
Present	22	13.1
Absent	146	86.9
Total	168	100.0

From the above table, the majority of patients did not have any family history of mental illness (86.9%).

ILLNESS RELATED VARIABLES

Table 8: Diagnosis

Diagnosis	No. of patients	Percentage
First episode psychosis	66	39.3
Depression	76	45.2
Anxiety	26	15.5
Total	168	100.0

From the above table, the subgroup of patients with depression are higher (45.2%) followed by first episode psychosis (39.3%).

Table 9: Type of drug

Drug	No. of patients	Percentage
Haloperidol	24	14.2
Risperidone	42	25.0
Escitalopram	52	31.0
Sertraline	50	29.8
Total	168	100.0

From the above table, patients on tablet escitalopram are the highest (31%) and the least is contributed by tablet haloperidol (14.2%). Cumulatively, patients on antidepressants (60.8 %) are higher than patients on antipsychotics (39.3%). There is no much differences between number of patients in antidepressants group between (escitalopram and sertraline) but in antipsychotic group – the difference almost/ nearly

doubles between risperidone and haloperidol group. This is because, haloperidol is not the preferred as a first line drug in first episode psychosis for various reasons.

Table 10: Dose of drug

Dose of drug	No. of patients	Percentage
1.5	2	1.2
3	13	7.7
5	7	4.2
10	43	25.6
2	14	8.3
6	7	4.2
4	18	10.7
8	2	1.2
15	2	1.2
20	9	5.4
30	1	0.5
50	34	20.2
75	7	4.2
100	9	5.4
Total	168	100.0

The above-mentioned table summarizes the dosage of all the drugs, individual drug and its dose are categorized below

(a) Dose of antidepressants

(i) Dose of tablet Escitalopram

Dose of drug (mg)	No. of patients	Percentage
5	1	1.92
10	39	75
15	2	3.85
20	9	17.31
30	1	1.92
Total	52	100.0

From the above table, for tablet escitalopram the minimum dose is 5 mg and maximum dose is 30 mg; the majority of patients are prescribed 10 mg (75%).

(ii) Dose of tablet Sertraline

Dose of drug	No. of patients	Percentage
50	34	68
75	7	14
100	9	18
Total	50	100

From the above table, the minimum dose of sertraline prescribed is 50 mg and maximum dose is 100 mg; majority of patients were prescribed 50 mg (68%).

(b) Dose of antipsychotics

(i) Dose of haloperidol

Dose of drug	No. of patients	Percentage
1.5	2	8.3
3	11	45.8
5	7	29.2
10	4	16.7
Total	24	100

From the above table, the minimum and maximum dose of haloperidol prescribed are 1.5 mg and 10 mg respectively; majority of patients were prescribed 3 mg (45.8%).

(ii) Dose of risperidone

Dose of drug	No. of patients	Percentage
2	14	33.3
3	1	2.4
4	18	42.8
6	7	16.7
8	2	4.8
Total	42	100

From the above table, the minimum and maximum dose of risperidone prescribed were 2mg and 8 mg respectively; majority of the patients were prescribed 4 mg (42.8%).

Table 11: Sexual functioning before drug use

Before drug use	No. of patients	Percentage
No sexual dysfunction	138	82.1
Sexual dysfunction	30	17.9
Total	168	100.0

From the above table, before initiation of drug treatment, scores suggestive of no sexual dysfunction in majority of Patients (82.1%), scores suggestive of sexual dysfunction in patients in late 4th decade and 5th decade even before drug treatment, indicating age related decline in sexual functioning, in which females are either premenopausal or in menopause.

Table 12: Sexual functioning after drug use

After drug use	No. of patients	Percentage
No changes	30	17.9
No sexual dysfunction	16	9.5
Sexual dysfunction	122	72.6
Total	168	100.0

From the above table, after drug initiation sexual dysfunction were reported in majority (72.6%).

DOMAINS OF SEXUAL FUNCTIONING

Table 13: Pleasure

Domain score	No. of patients	Percentage
No change	51	30.3
Less than 50% change	87	51.8
Greater than or equal to 50% change	30	17.9
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the domain of “Pleasure”, no changes were noted in 30.3%, ‘less than 50% change’ and ‘greater than or equal to 50% change’ in domain score were noted in 51.8% and 17.9% respectively.

Table 14: Desire/ Frequency

Domain score	No. of patients	Percentage
No change	74	44.1
Less than 50% change	82	48.8
Greater than or equal to 50 % change	12	7.1
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the domain of “Desire / Frequency”, no changes were noted in 44.1%, ‘less than 50% change’ and ‘greater than or equal to 50% change’ in domain score were noted in 48.8% and 7.1% respectively.

Table 15: Desire / Interest

Domain score	No. of patients	Percentage
No change	82	48.8
Less than 50% change	80	47.6
Greater than or equal to 50% change	6	3.6
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the domain of “Desire/ Interest”, no changes were noted in 48.8%, ‘less than 50% change’ and ‘greater than or equal to 50% change’ in domain score were noted in 47.6% and 3.6% respectively

**Table 16: Arousal / Erection (in male) & Arousal /
Excitement (in female)**

Domain score	No. of patients	Percentage
No change	51	30.3
Less than 50% change	114	67.9
Greater than or equal to 50% change	3	1.8
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the domain of “Arousal/ Erection (in male) & Arousal / Excitement (in female)”, no changes were noted in 30.3%, ‘less than 50% change’ and ‘greater than or equal to 50% change’ in domain score were noted in 67.9% and 1.8% respectively.

**Table 17: Orgasm / Ejaculation (in male) &
Orgasm/ Completion (in female)**

Domain score	Frequency	Percent
No change	42	25.0
Less than 50% change	116	69.0
Greater than or equal to 50% change	10	6.0
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the domain of “Orgasm / Ejaculation (in male) & Orgasm/ Completion (in female)”, no changes were noted in 25%, ‘less than 50% change’ and ‘greater than or equal to 50% change’ in domain score were noted in 69% and 6% respectively.

**Table 18: Item 10 (How often you have been
aroused and then lose interest(female) and prolonged erections
(male)?)**

Domain score	Frequency	Percent
Never	148	88.1
Rarely	13	7.7
Sometimes	5	3.0
Often	2	1.2
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients in the item of “getting arousal and then losing interest in female or experiencing prolonged erections in

male”, majority reported to have no changes (88.1%). A few proportion of female patients reported described such events to be rare (7.7%), sometimes (3%) or often (1.2%). Male patients have never reported such events.

Table 19: Item 14 (how often you have a painful orgasm?)

Domain score	Frequency	Percent
Never	167	99.4
Rarely	1	.6
Total	168	100.0

From the above table, after drug use, comparing with previous level of sexual functioning of individual patients, majority reported ‘never of having a painful orgasm’ after drug use (99.4%).

Table 20: Delayed Ejaculation

Domain	No. of patients	Percentage
No delayed ejaculation	51	30.3
Delayed ejaculation	27	16.1
Not Applicable	90	53.6
Total	168	100.0

From the above table, reporting of ‘Delayed Ejaculation’ after drug use constitutes 16.1%. To be accurate, men reporting delayed ejaculation is 34.6 % (percentage calculated with exclusion of female patients). The delayed ejaculation is reported with antidepressants, not with antipsychotics.

SOCIODEMOGRAPHIC AND OTHER VARIABLES IN GENERAL POPULATION

Table 21: Age

Age (in years)	Frequency	Percentage
19-20	3	5.5
21-30	18	32.7
31-40	18	32.7
41-50	12	21.8
51-60	4	7.3
Total	55	100.0

From the above table, majority of general population included in the study lies between age group of 2nd and 3rd decade (32.7%).

Table 22: Gender

Gender	Frequency	Percentage
Male	30	54.5
Female	25	45.5
Total	55	100.0

From the above table, proportion of male population into the study is comparatively higher (54.5%).

Table 23: Marital status

Marital status	Frequency	Percentage
Married	44	80.0
Unmarried	8	14.5
Separated	3	5.5
Total	55	100.0

From the above table, majority of population selected were married (80%).

Table 24: Employment

Employment	Frequency	Percentage
Employed	47	85.5
Unemployed	3	5.5
Student	5	9
Total	55	100.0

From the above table, majority of the population were employed (85.5%).

Table 25: Socioeconomic class

SEC	Frequency	Percentage
Class 1	1	1.8
Class 2	9	16.4
Class 3	31	56.4
Class 4	14	25.4
Class 5	0	0
Total	55	100.0

From the above table, vast majority of population falls into class 3 socioeconomic status (56.4%).

Table 26: Menstrual status

Menstrual Status	Frequency	Percentage
Regular	20	36.4
Premenopausal	1	1.8
Menopause	4	7.3
Not Applicable	30	54.5
Total	55	100.0

From the above table, excluding the male population, 20 out of 25 females has regular menstrual cycles. So, majority of population has regular menstrual cycles (80%). The group constituting the ‘not applicable’ domains are males.

Table 27: Sexual functioning

Sexual functioning	Frequency	Percentage
No sexual dysfunction	41	74.5
Sexual dysfunction	14	25.5
Total	55	100.0

From the above table, general population had a sexual dysfunction of 25.5%.

Table 28: Gender and Sexual functioning

Domains	Male	Female
No sexual dysfunction	22	19
Sexual dysfunction	8	6

From the above table, in general population, male and female sexual dysfunctions were found to be 26.6% and 24 % respectively. Sexual dysfunction in general population, on an average amount to 25.4%.

Table 29: Sociodemographic details comparison

PATIENTS

Age	Gender		Employment			Marital Status			Socioeconomic Class					Diagnosis			Family History	
	Male	Female	Employed	Unemployed	Student	married	Unmarried	Separated	class 1	class 2	class 3	class 4	class 5	first episode psychosis	depression	Anxiety	yes	no
19-20	6	4	0	3	7	1	9	0	0	4	5	1	0	4	5	1	2	8
21-30	30	35	44	11	10	46	19	0	1	12	41	11	0	28	28	9	11	54
31-40	23	31	44	10	0	54	0	0	0	11	27	16	0	20	22	12	7	47
41-50	12	12	22	2	0	23	1	0	0	2	10	12	0	8	13	3	1	23
51-60	7	8	12	3	0	13	2	0	0	2	9	4	0	6	8	1	1	14
total	78	90	122	29	17	137	31	0	1	31	92	44	0	66	76	26	22	146

GENERAL POPULATION

	Age	Gender		Employment			Marital status			Socioeconomic class				
		Male	Female	Employed	Unemployed	Student	married	Unmarried	Separated	class 1	class 2	class 3	class 4	class 5
29	19-20	2	1	2	0	1	1	2	0	0	0	2	1	0
	21-30	8	10	13	1	4	14	4	0	0	4	10	4	0
	31-40	10	8	16	2	0	15	2	1	1	3	10	4	0
	41-50	8	4	12	0	0	10	0	2	0	1	7	4	0
	51-60	2	2	4	0	0	4	0	0	0	1	2	1	0
	total	30	25	47	3	5	44	8	3	1	9	31	14	0

From the above table (which summarises the overall sociodemographic details)

- The majority of patients falls in the age group of 2nd (38.7%) and 3rd (32.1%) decade with general population contributing 32.7% in both 2nd and 3rd decade.
- The percentage of unemployed males and females is proportionately lower in both patient (17.2%) and general population (5.4%) with sub-group contributing to 'being student'
- The majority falls in married category (81.5 % among patients; 80% among general population) in terms of marital status.
- Socioeconomic class of majority of patients (54.8%) and general population (56.3%) falls in class 3, nil entries in class 5
- The patients taking antipsychotics is 66 (39.3%) and antidepressants is 102 (60.7%), with majority diagnosed with first episode psychosis. Patients on antidepressants contribute both from depression (45.2%) and anxiety (15.5%)
- The vast majority of patients do not have positive family history for mental illness (86.9%).

Table 30: Correlation of Age and Sexual functioning

		Before drug use		Total	After drug use			Total
Age		No sexual dysfunction	Sexual dysfunction		No changes	No sexual dysfunction	Sexual dysfunction	
19-20 Years	Count	10	0	10	2	1	7	10
	% within before drug use	7.20 %	0.00%	6.00%	6.70%	6.20%	5.70%	6.00%
21-30 Years	Count	65	0	65	9	11	45	65
	% within before drug use	47.10%	0.00%	38.70%	30.00%	68.80%	36.90%	38.70%
31-40 Years	Count	53	2	55	7	4	44	55
	% within before drug use	38.40%	6.70%	32.70%	23.30%	25.00%	36.10%	32.70%
41-50 Years	Count	10	14	24	5	0	19	24
	% within before drug use	7.20 %	46.70%	14.30%	16.70%	0.00%	15.60%	14.30%
51-60 Years	Count	0	14	14	7	0	7	14
	% within before drug use	0.00 %	46.70%	8.30%	23.30%	0.00%	5.70%	8.30%
	Count	138	30	168	30	16	122	168
		100.00%	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %
					p value= <0.001			
					Pearson chi square= 18.944			

From the above table, scores correlate to sexual dysfunction in 4th and 5th decade prior to drug intake, which indicates age related decline in sexual functioning. After drug intake, majority experience sexual dysfunction.

Table 31: Age * Menstrual status

Crosstab								
			Menstrual status					Total
			Regular	Irregular	Pre-menopause	Menopause	Not Applicable	
age	19-20 Years	Count	4	0	0	0	6	10
		% within group	6.0%	0.0%	0.0%	0.0%	7.7%	6.0%
	21-30 Years	Count	35	0	0	0	30	65
		% within group	52.2%	0.0%	0.0%	0.0%	38.5%	38.7%
	31-40 Years	Count	28	2	1	0	24	55
		% within group	41.8%	100.0%	10.0%	0.0%	30.8%	32.7%
	41-50 Years	Count	0	0	7	5	12	24
		% within group	0.0%	0.0%	70.0%	45.5%	15.4%	14.3%
	51-60 Years	Count	0	0	2	6	6	14
		% within group	0.0%	0.0%	20.0%	54.5%	7.7%	8.3%
	Total	Count	67	2	10	11	78	168
		%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

From the above table, women falling in the age group of 4th and 5th decade belongs to either premenopausal or menopausal status.

Table 32: Menstrual status and Sexual functioning

	sexual functioning					
	before drug use		after drug use			
menstrual status	No sexual dysfunction	Sexual dysfunction	No changes	No sexual dysfunction	Sexual dysfunction	Total
Regular	67	0	11	7	49	67
Irregular	2	0	0	0	2	2
Premenopause	0	10	2	0	8	10
Menopause	0	11	5	0	6	11
total						90

From the above table, patients in menopause group, half of them reported no changes and the other half reported sexual dysfunction. Patients in pre- menopause, majority reported sexual dysfunction after drug use. The scores correlating to sexual dysfunction before drug use, falls in pre-menopausal and menopausal group, suggesting age related decline in sexual functioning and correlation with their menstrual status.

Table 33: Sexual functioning before and after drug use

			Group		Total
			Drug Taking Patients	General Public	
Sexual functioning	No changes	Count	30	0	30
		% within group	17.9%	0.0%	13.5%
	No sexual dysfunction	Count	16	41	57
		% within group	9.5%	74.5%	25.6%
	Sexual dysfunction	Count	122	14	136
		% within group	72.6%	25.5%	61.0%
Total		Count	168	55	223
		% within group	100.0%	100.0%	100.0%

Pearson Chi-Square=93.470** p<0.001

From the above table, 72.6% of remitted patients taking drug reported sexual dysfunction either in one or in multiple domains, which is statistically significant (Pearson Chi-Square=93.470** p<0.001)

Table 34: Descriptive statistics

Descriptive Statistics								
	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75 th
Before drug use	168	3.1786	.38414	3.00	4.00	3.0000	3.0000	3.0000
After drug use	168	3.3690	1.14547	1.00	4.00	3.0000	4.0000	4.0000

Z Value = 2.151* p=0.032

From the above table, descriptive statistics reveal statistically significant results showing sexual dysfunction after drug use.

Table 35: Before and After drug use - cross tabulation

Before drug use * After drug use Crosstabulation						
			After drug use			Total
			No changes	No sexual dysfunction	Sexual dysfunction	
Before Drug use	No sexual dysfunction	Count	19	16	103	138
		%	63.3%	100.0%	84.4%	82.1%
	Sexual dysfunction	Count	11	0	19	30
		%	36.7%	0.0%	15.6%	17.9%
Total		Count	30	16	122	168
		%	100.0%	100.0%	100.0%	100.0%

From the above table, depicting crosstabulation of before & after drug use, a minority of patients for whom scores correlated to sexual dysfunction prior to drug intake, reported no changes in sexual functioning after drug use (36.7%). A majority of patients reported sexual dysfunction (84.4%), who prior to drug use had no sexual dysfunction.

Table 36: Drug and Sexual dysfunction

		After drug use			Total
		No changes	No sexual dysfunction	Sexual dysfunction	
Drug	Count	3	9	12	24
	Haloperidol				
	% within after drug use	10.0%	56.2%	9.8%	14.3%
	Count	14	3	25	42
	Risperidone				
	% within after drug use	46.7%	18.8%	20.5%	25.0%
	Count	3	0	49	52
	Escitalopram				
	% within after drug use	10.0%	0.0%	40.2%	31.0%
	Count	10	4	36	50
	Sertraline				
	% within after drug use	33.3%	25.0%	29.5%	29.8%
Total	Count	30	16	122	168
	% within after drug use	100.0%	100.0%	100.0%	100.0%

Pearson Chi-Square=41.480** p<0.001

From the above table, majority falls into the group of sexual dysfunction after drug use, which shows antipsychotics and antidepressants causes changes in sexual functioning, which amounts to sexual dysfunction, which is statistically significant.

Table 37: Sexual functioning domains & Drug

drug & domain		pleasure			desire/ frequency			desire/ interest			arousal/ erection or excitement			orgasm or ejaculation/ completion			delayed ejaculation		
		no changes	less than 50% change	>=50% change	no changes	less than 50% change	>=50% change	no changes	less than 50% change	>=50% change	no changes	less than 50% change	>=50% change	no changes	less than 50% change	>=50% change	no	yes	Not applicable
haloperidol	count	9	9	6	9	13	2	11	11	2	9	15	0	8	15	1	11	0	13
	% within drug	37.5	37.5	25	37.5	54.2	8.3	45.8	45.8	8.3	37.5	62.5	0	33.3	62.5	4.2	45.8	0	54.2
risperidone	count	21	17	4	23	16	3	21	20	1	18	24	0	17	23	2	20	0	22
	% within drug	50	40.5	9.5	54.8	38.1	7.1	50	47.6	2.4	42.9	57.1	0	40.5	54.8	4.8	47.6	0	52.4
escitalopram	count	6	30	16	10	35	7	17	32	3	7	42	3	6	41	5	9	13	30
	% within drug	11.5	57.7	30.8	19.2	67.3	13.5	32.7	61.5	5.8	13.5	80.8	5.8	11.5	78.8	9.6	17.3	25	57.7
sertraline	count	15	31	4	32	18	0	33	17	0	17	33	0	11	37	2	11	14	25
	% within drug	30	62	8	64	36	0	66	34	0	34	66	0	22	74	4	22	28	50
	total	51	87	30	74	82	12	82	80	6	51	114	3	42	116	10	51	27	90
	% across drug	30.3	51.8	17.9	44	48.8	7.1	48.8	47.6	3.6	30.4	67.9	1.8	25	69	6	30.4	16.1	53.6
statistically significant		p= <0.001			p= <0.001			p= 0.028			p= 0.011			p= 0.049			p= <0.001		
		Pearson chi-square=25.046			Pearson chi-square=26.099			Pearson chi-square=14.109			Pearson chi-square=16.481			Pearson chi-square=12.652			Pearson chi-square=27.993		

From the above table, in all 5 domains in sexual functioning, drug induced decline in functioning is noted and found to be statistically significant. All domains show at least 50% changes in scores. Greater than or 50 % decline in sexual functioning is reported by few proportion of population only. One striking feature is that none reported 'greater than or equal to 50% changes' with arousal, except as reported by very few in escitalopram group. When questioned about delayed ejaculation, they were reported only in antidepressant group and not in antipsychotic group. All the above-mentioned findings were statistically significant.

Table 38: Correlation of drug and item 10

Crosstab							
			Drug				Total
			Haloperidol	Risperidone	Escitalopram	Sertraline	
Item10 (how often you become aroused and lose interest)	Never	Count	20	41	45	42	148
		% within drug	83.3%	97.6%	86.5%	84.0%	88.1%
	Rarely	Count	3	0	3	7	13
		% within drug	12.5%	0.0%	5.8%	14.0%	7.7%
	Sometimes	Count	1	1	2	1	5
		% within drug	4.2%	2.4%	3.8%	2.0%	3.0%
	Often	Count	0	0	2	0	2
		% within drug	0.0%	0.0%	3.8%	0.0%	1.2%
Total		Count	24	42	52	50	168
		% within drug	100.0%	100.0%	100.0%	100.0%	100.0 %

Pearson Chi-Square=12.269 p=0.199

Table 39: Correlation of drug and item 14

			Drug				Total
			Haloperidol	Risperidone	Escitalopram	Sertraline	
Item14 (painful orgasm)	Never	Cou nt	24	42	51	50	167
		% within drug	100.0%	100.0%	98.1%	100.0%	99.4%
	Rarely	Count	0	0	1	0	1
		% within drug	0.0%	0.0%	1.9%	0.0%	0.6%
Total		Count	24	42	52	50	168
		% within drug	100.0%	100.0%	100.0%	100.0%	100.0%

Pearson Chi-Square=2.244 p=0.523

From the above two table, in the domains of problems with arousal (aroused and lose interest) and painful orgasm, the results were not statistically significant. So, drug induced painful orgasm and drug induced arousal defects were considered to be least or may have some others factors for causation.

Table 40: Correlation between Dose of drug and Sexual domains

		pleasure			desire/ frequency			desire/ interest			arousal/ erection or excitement			orgasm or ejaculation/ completion			delayed ejaculation		
Dose		no changes	less than 50% change	≥50% change	no changes	less than 50% change	≥50% change	no changes	less than 50% change	≥50% change	no changes	less than 50% change	≥50% change	no changes	less than 50% change	≥50% change	no	yes	not applicable
1-5 mg	count	31	20	3	32	22	0	33	20	1	28	26	0	26	28	0	26	0	28
	%	57.4	37	5.6	59.3	40.7	0	61.1	27	1.9	51.9	48.1	0	48.1	51.9	0	48.1	0	51.9
6-10mg	count	5	31	16	10	35	7	15	34	3	5	47	0	4	44	4	13	8	31
	%	9.6	59.6	30.8	19.2	67.3	13.5	28.8	65.4	5.8	9.6	90.4	0	7.7	84.6	7.7	25	15.4	59.6
11-30mg	count	0	5	7	0	7	5	1	9	2	1	8	3	1	7	4	1	5	6
	%	0	41.7	58.3	0	58.3	41.7	8.3	75	16.7	8.3	66.7	25	8.3	58.3	33.3	8.3	41.7	50
50 mg	count	15	19	0	23	11	0	26	8	0	17	17	0	11	23	0	9	9	16
	%	44.1	55.9	0	67.6	32.4	0	76.5	23.5	0	50	50	0	32.4	67.6	0	26.5	26.5	47.1
75 mg	count	0	6	1	4	3	0	4	3	0	0	7	0	0	7	0	1	2	4
	%	0	85.7	14.3	57.1	42.9	0	57.1	42.9	0	0	100	0	0	100	0	14.3	28.6	57.1
100 mg	count	0	6	3	5	4	0	3	6	0	0	9	0	0	7	2	1	3	5
	%	0	66.7	33.3	55.6	44.4	0	33.3	66.7	0	0	100	0	0	77.8	22.2	11.1	33.3	55.6
		p<0.001			p<0.001			p<0.001			p<0.001			p<0.001			p=0.001		
		Pearson chi-square=63.948			Pearson chi-square=57.155			Pearson chi-square=35.985			Pearson chi-square=76.700			Pearson chi-square=54.327			Pearson chi-square=28.830		

The following inferences were made:

In the antipsychotic group, when prescribed with minimal effective doses, there were no changes noted in sexual functioning in majority in both genders, which includes 2 mg risperidone, 1.5 mg and 3 mg in haloperidol. In minority with changes in sexual functioning scores, the change is very little and individuals with higher baseline scores, do not correlate to sexual dysfunction after drug intake.

In antidepressant group, with 10 mg of escitalopram and 50 mg of sertraline patients reported sexual dysfunction in both genders including delayed ejaculation in male.

With higher doses, sexual dysfunction occurs in majority, and affects all the domains of sexual functioning with scores declining greater than or equal to 50% from baseline in both antipsychotics and antidepressant group, in one or more domains.

In the domains of painful orgasm and defects in arousal, there were no correlation noted with particular dose of each drug.

OBSERVATIONS AND INFERENCES MADE DURING DATA COLLECTION AND ENTRY:

During initial collection of data, difficulty in using Tamil terms for explaining each phases of sexual dysfunction. Females were more reluctant in discussing about sexual functioning than males. Most of the patients questioned about one of their doubtful sexual myths at the end of the interview, which were explained accordingly. A trail of native medicine for improving sexual functioning in general population were tried, despite their scores do not correlate to sexual dysfunction. The ejaculatory delay was reported initially by patients themselves when an

open question was posed about changes in sexual functioning after drug use. A proportion of patients themselves stopped using drug on days of planned sexual activity even though not instructed by therapist. Masturbatory activity was prevalent in both gender and reported more by unmarried population. Some patients deferred to disclose about their masturbatory activity. Patients show decline in scores in sexual functioning after drug use, which varies with various factors. Patients with baseline higher scores show no sexual dysfunction scores after drug intake but reports reduced sexual satisfaction than before. Some young individual (patients and general population) scores correlate to sexual dysfunction, but they report no sexual dissatisfaction. So, there arises a question of defining “normalcy” in sexual functioning. Patients with anxiety disorder reports delay in ejaculation after drug use but they report no dissatisfaction in overall sexual functioning, instead report better sexual satisfaction after drug intake. The study is done within a span of 6 - 8 weeks of drug use, with patients who attain remission, so changes in sexual functioning after prolonged use of drug could not be made out. The patients taken into the study also had short duration of untreated illness. Reporting of sexual dysfunction by themselves, without interviewing about the same is comparatively less. Patients treated with minimal effective dose of the particular drug reports no changes or minimal in sexual functioning but reports no dissatisfaction.

DISCUSSION

The study was aimed to assess the prevalence of drug induced sexual dysfunction and factors associated with it, as sexual side effects was identified as one of the reasons for drug discontinuation (promoting relapse) and reduced quality of life. The study was also aimed to look at the correlation between sociodemographic variables (age, gender, marital

status, menstrual status, employment socioeconomic class), illness variables (diagnosis, family history of mental illness, type of drug, dose of particular drug) and sexual functioning (pre and post drug use).

The study was done at outpatient department at Institute of Mental Health (IMH), Madras Medical College (MMC). The patients who report to the outpatient department for their first episode of mental illness, who are drug naïve, receiving a diagnosis of first episode psychosis, depression and anxiety remains the target sample group. These patients are started on antidepressants or antipsychotics according to their illness, and those who attain remission within a period of 6-8 weeks are taken into the study (remission as indicated by both clinical evaluation and scores on individual scales - HAM-D, HAM-A and BPRS).

So, on an average, these patients would have been on psychiatric medications for about 2 months. The add-on drugs like benzodiazepines and anticholinergics like trihexyphenidyl (in low dose) were also included in their drug schedule. Patients whose drug schedule includes other drug causing sexual dysfunction (e.g. Propranolol) were not included in the study. Patients with comorbid physical illness (like diabetes and hypertension) were also not included in the study to eliminate confounding.

The patients were interviewed about their sexual functioning before and after drug use. While interviewing about the sexual functioning before drug use, they are specifically asked about their sexual functioning in their premorbid states, as illness may also impair sexual functioning. A tinge of recall bias may occur at this stage. Availing consent for enrolling in study, privacy, sufficient time for interview, looking out for consistency in their answering, questioning in various ways (including

both open and closed questions) and summarising their answers were carried out to reduced recall errors. When patients present with their spouses, they are cross interviewed about sexual functioning. Any discrepancy in reporting is again cross-verified with the patient. The foremost requests made by patients participating are, not to reveal their identity. Often patients come out with various myths about mental illness and sexuality, for which they seek some medical advice, usually which happens at the interview closure.

Patients were fairly able to elaborate on the sexual functioning but use of colloquial Tamil terms were difficult. Majority of patients reported changes in sexual functioning after drug use with the initial open-ended question posed - “does you feel any change in sexual functioning after drug use?”

Immediately the next question in the queue would be like “why you would say it’s because of drugs?”. Though there were many replies for this question, a fairly considerable population explains that skipping of drugs on days on planned sexual activity improves their functioning and satisfaction.

Then, patients are scored on changes in sexual functioning questionnaire for male and females, respectively. After drug use, patients report a decline in sexual functioning, scores correlating to sexual dysfunction, which in-turn prevent them from attaining sexual satisfaction as before. Some individuals though their scores correlate to sexual dysfunction, they do not report any grievances with respect to sexual functioning. Such patients when revealed about the interpretation of their scores, they claim that there was no subjective dysfunction, which are supported by their spouses. Discrepancy between sexual needs,

satisfaction and functioning becomes evident. e.g. a middle age employed woman, in her late 3rd decade, who has reduced sexual needs than before, with minimal effective dose of drug, report no gross changes in sexual satisfaction after drug use, but able to acknowledge her age-related decline in needs. Despite all this her scores correlate to sexual dysfunction.

Age plays an important role in defining baseline sexual functioning, sexual needs, sexual satisfaction and their scheduling (frequency, sexual fantasies, sexual stimuli). As age increases, the frequency of sexual activity is reduced due to various factors. Hence, baseline sexual functioning varies with each age group. In females, it even more correlates with their menstrual status. Female in perimenopausal (pre- menopause & menopause) group report decline in sexual needs and functioning. Also, report lubrication and pain issues than earlier. Scores correlated to sexual dysfunction for women, in or above 4th decade. Men too report, higher the age, lesser the sexual functioning.

The differences in gender on sexual functioning were not obvious. But higher scores (scores greater than 55) were reported by very few women than compared to men. One thing must be looked into is, the cut off score for defining sexual dysfunction is higher for men (CSFQ score = 47) and lower for woman (CSFQ score = 41), though the total score is the same (CSFQ score = 70). Does that indirectly indicate impact of gender on sexual functioning, needs to be explored!

The marital status of an individual also has an impact of sexual functioning, which are noted more during the initial years of marriage, which also can be correlated to procreation. The pattern of sexual

functioning changes in the post marital era, based on the needs of their spouses. Both married and unmarried individuals, indulge in masturbatory activities.

Correlation between sexual functioning, employment and socioeconomic class needs further assessment, as results were not statistically significant. One factor is that individuals with higher educational status might have an access for awareness about sexual health. But sexual myths were predominant in all ages despite their educational status.

The age of onset of illness (first occurrence of mental illness) predominates in 1st and 2nd decade of life, which is more consistent with psychosis, but depression and anxiety often have their first episode in mid-life (in 3rd and 4th decade). So, which again proves the mean age of onset of psychosis is earlier than depression or anxiety. One striking feature in this study is that delayed ejaculation is reported with antidepressants only. The majority of population taking antidepressants falls in or above 3rd decade. So, will that be due to exacerbation of mid-life sexual issues after drug intake?

The minimal effective doses of various drugs have varied sexual side effects. Taking into consideration, tablet risperidone (2mg) reports no changes in sexual functioning in both gender groups.

Tablet haloperidol (1.5 mg) has no changes in sexual functioning. The same tablet haloperidol showed varied results with 3mg of drug, but changes in sexual functioning predominates. Statistical significance could not be established due to low sample size in each gender group. Sufficient sample could not be obtained as the preference of tablet haloperidol as first line drug is least, due to availability of better drugs.

Taking into consideration tablet escitalopram reported no changes in sexual functioning with 5 mg of drug. But with 10 mg of tablet escitalopram, sexual functioning changes are obvious. Changes correlate to less than 50 % score reduction in majority of domains of sexual functioning. Around one third (30.8%) report greater than 50% reduction in pleasure (statistically significant- $p < 0.001$), whereas all other domains of sexual functioning show less than 50% changes in majority. In this study, it's also noted that among the four drugs taken into the study, only tablet escitalopram showed greater than 50% score reduction in arousal domain of sexual functioning (though it's reported by only 5.7%), contrary to none of the other drugs reporting greater than 50% score reduction in arousal domain.

Taking into consideration tablet sertraline (50 mg), looking into each specific domain, none of patients reported greater than 50% score reduction in three domains – desire/frequency, desire/ interest, arousal/ excitement (female) or erection (male). Also 64% and 66% of patients, reported no changes in desire/ frequency and desire/ interest respectively i.e. approximately only one-third reports changes with less than 50% score reduction.

The reporting of delayed ejaculation, from a sub-group of male patients on antidepressants, amounts to one-third, 34.6% (percentage calculated excluding female population). No differences in prevalence were noted between the two antidepressants, escitalopram and sertraline.

With higher doses of drug, sexual dysfunction is obvious. But few patients with maximum doses of drug are included in the study. This is because higher dose indicates illness severity and remission for such patients in a period of 2 months is questionable. All the patients with

higher doses of drugs (10 mg of haloperidol, 8 mg of risperidone, 30 mg of escitalopram, 100 mg of sertraline) experience some form of sexual dysfunction. On the contrary, none of the study participants showed greater than 50% reduction in 3 domains - desire/frequency, desire/interest, arousal/ excitement (female) or erection (male). Similarly, none of the participants reported - no changes.

A general population was analysed for establishing age related baseline sexual functioning. Sample from general population consists of individuals with no known physical and psychiatric co-morbidities with adequate socio-occupational functioning. Scores suggestive of sexual dysfunction for majority of females in perimenopausal group, in or above 4th decade of life. For men, scores correlated to sexual dysfunction in or above 4th decade in majority. So, the 4th decade marks a borderline for major changes in sexual life. To assess their changes in sexual functioning after drug use, a proportion of patients in 4th and 5th decade was included in all drug groups, so as to establish results which could be generalised. Those patients had similar changes as experienced with individuals with 2nd and 3rd decade i.e. their baseline functioning remained unchanged with minimal effective doses and with higher doses sexual dysfunction was obvious. One point to be marked is that their baseline functioning correlates to dysfunction, even though they don't subjectively report any form of sexual dysfunction, hence further decline with scores impairs their sexual life.

In patients with anxiety disorder, who experience ejaculatory delay due to antidepressants, report sexual satisfaction better after drug intake. More often patients with anxiety disorder, have acquired premature ejaculation as a part of their illness⁹⁹. Due to antidepressants intake, the delay corrects their premature ejaculation, as a result of which they report

better sexual satisfaction. Painful orgasm and experiencing a loss in interest after arousal following drug use is rarely reported.

The percentage of medication induced sexual dysfunction with in each drug groups- haloperidol, risperidone, escitalopram, sertraline is found to be 50%, 59.5%, 94.2%, 72% respectively, in this study. On an average reported to be 72.6 % (122 out of 168 remitted patients) among four drugs. Strictly considering patients with no sexual dysfunction prior to drug use with sexual dysfunction after drug use 61.3%. The above-mentioned discrepancy in percentage is because of inclusion of patients from 4th and 5th decade, whose baseline sexual functioning varies. Similar studies quote SSRI induced sexual dysfunction between 60-70%⁹²; 36%-43%⁹³; 72.8%⁹⁴(38.3% concerned about sexual dysfunction and discontinued medication; another 34.5% experienced sexual dysfunction but did not discontinue drugs). Sexual dysfunction associated with risperidone is 96% as quoted by one study in India, and also states that among antipsychotics risperidone is more potent in causing sexual dysfunction⁹⁵. A study with various psychotropics quotes, sexual dysfunction more with antidepressants than antipsychotics, with dysfunction in more than one domain, our study results replicates this⁹⁶. Marrit et al and Kotin et al quotes antipsychotic induced sexual dysfunction about 16-60% and 49% respectively^{97,98}.

CONCLUSION

- Why sexual dysfunction needs to be addressed? Adequate sexual functioning contributes to quality of life and sexual dysfunction contributes to poor drug compliance, thereby increasing relapse rates.
- From the study, it is noted that, there is a decline in sexual functioning after use of antipsychotics and antidepressants which mainly depends on baseline sexual functioning, dose of drug and type of drug.
- The decline in sexual functioning (drug induced) is often less than 50% scores in sexual functioning domains.
- For individuals with higher baseline scores in sexual functioning domains, experience less or no dysfunction with minimal effective doses.
- Patients with higher baseline sexual functioning report decline in sexual satisfaction than before, but their scores do not correlate to sexual dysfunction.
- With maximum doses of individual drug, sexual dysfunction is obvious.
- Each drug affects a particular prototype neurotransmitter, but the dysfunction is not related to particular phase of sexual functioning. Delay or changes in one phase, in turn disturbs the upcoming phases. Changes in one neurotransmitter also disturbs the neural balance of another neurotransmitter which contributes to sexual dysfunction too. So, drug induced single phase specific dysfunction could not be established.

- Delayed ejaculation is more commonly reported with antidepressants in this study.
- Patients with anxiety disorders, experiencing delay in ejaculation after drug use, report sexual satisfaction, as because anxiety disorder patients have premature ejaculation more often, which gets corrected.
- Patients themselves try drug holidays on days of planned sexual activity.
- The myths around mental illness and sexual dysfunction, both in general population and patients' needs to be clarified which plays a role in better outcome in sexual functioning.
- Alternative treatment strategies – both pharmacological (minimum effective dose of drug potent enough to cause sexual dysfunction along with an add on drug not causing sexual dysfunction or alternative effective drug without side effects on sexual functioning) and non-pharmacological (drug holidays on days of planned sexual activity) should be psychoeducated to patients and their partners in prior.
- The individuals (both patients and general population) falling in or above 4th decade (in terms of age) have a decline in baseline sexual functioning, which also has a correlation to their menstrual status in females.
- Majority of individuals with increasing age do not report sexual dysfunction, but their scores correlates to sexual dysfunction. The discrepancy may be because of decline in sexual needs.

- The normalcy in sexual functioning, the discrepancy in sexual functioning and sexual satisfaction needs to be explored and studied in detail.

LIMITATIONS

- The sample size for each drug is small, needs an extensive research with a large sample. And also, only 4 drugs are taken for study.
- Understanding about their own sexual functioning in patients and general population has not been studied.
- Awareness and education about sexual health of patients and population has not been assessed.
- Cultural and other factors associated with perception of sexual functioning needs to be studied.
- The psychopathology and severity of illness, their impact on sexual functioning has not been studied.
- The sample size for haloperidol is less when compared with other drug groups, as the preference of haloperidol as the first line agent for first episode psychosis is least due to availability of better drugs.
- Duration of drug intake (e.g.: long term use, for about more than year) and its impact on sexual functioning have not been studied, which is significant because even for first episode illness, psychiatric drugs are prescribed for more than a year.

- Maximum doses of each drug have not been included, because such high prescription of dose indirectly indicates disease severity and their remission rate in specified time is less.
- Quality of life in remission and its influence by sexual functioning needs to be explored.
- The approach to native treatments, despite who do not match up the scores for sexual dysfunction might provide a better way for exploring the arena of sexual satisfaction.

FUTURE DIRECTIONS

- This study has many future implications like assessment of cut off score for sexual dysfunction in various age groups and baseline sexual functioning for people falling in and above 4th decade for Indian population needs to be defined, by assessing sexual functioning in general population.
- The effective treatment strategies, both pharmacological and non-pharmacological for people experiencing drug induced sexual functioning needs to be studied.
- The study in large scale, will pave way for addressing sexual issues associated with treatment, in prior, such as preventive measures.

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ANNEXURE 1

SOCIODEMOGRAPHIC PROFORMA

NAME:

AGE/GENDER:

ADDRESS:

EDUCATION:

- illiterate
- primary school
- middle school
- high school
- higher secondary/ diploma
- graduate / postgraduate
- professional

OCCUPATION

- Profession
- Semi – profession
- Clerical / shop owner
- Skilled worker
- Semi-skilled worker
- Unskilled worker
- Unemployed

INCOME

- Greater than 41,430
- 20,715 – 41,429
- 15,536 – 20,714
- 10, 357 – 15,535
- 6,214 – 10,356
- 2,092 - 6,213
- < 2,091

SOCIOECONOMIC CLASS

- Upper
- Upper middle
- Lower middle
- Upper lower
- lower

MARITAL STATUS

- unmarried or never married
- married
- separated

LANGUAGE:

RELIGION:

ILLNESS RELATED HISTORY

- DIAGNOSIS
- DRUG & DOSE
- DURATION OF DRUG INTAKE
- FAMILY HISTORY
- SCORING ON SCALES
 - HAMILTON RATING SCALE FOR DEPRESSION (HAM-D)
 - HAMILTON RATING SCALE FOR ANXIETY (HAM-A)
 - BRIEF PSYCHIATRIC RATING SCALE
 - CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE – MALE
 - CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE – FEMALE

ANNEXURE - 2

CLIENT NAME: _____
CLIENT ID#: _____

DATE: _____
MD: _____

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Please enter the score for the term which best describes the patient's condition.

0 = not assessed, 1 = not present, 2 = very mild, 3 = mild, 4 = moderate, 5 = moderately severe, 6 = severe, 7 = extremely severe

<p>1. SOMATIC CONCERN Degree of concern over present bodily health. Rate the degree to which physical health is perceived as a problem by the patient, whether complaints have a realistic basis or not.</p> <p>SCORE <input type="text"/></p>	<p>10. HOSTILITY Animosity, contempt, belligerence, disdain for other people outside the interview situation. Rate solely on the basis of the verbal report of feelings and actions of the patient toward others; do not infer hostility from neurotic defenses, anxiety, nor somatic complaints. <i>(Rate attitude toward interviewer under "uncooperativeness")</i>.</p> <p>SCORE <input type="text"/></p>
<p>2. ANXIETY Worry, fear, or over-concern for present or future. Rate solely on the basis of verbal report of patient's own subjective experiences. Do not infer anxiety from physical signs or from neurotic defense mechanisms.</p> <p>SCORE <input type="text"/></p>	<p>11. SUSPICIOUSNESS Brief <i>(delusional or otherwise)</i> that others have now, or have had in the past, malicious or discriminatory intent toward the patient. On the basis of verbal report, rate only those suspicions which are currently held whether they concern past or present circumstances.</p> <p>SCORE <input type="text"/></p>
<p>3. EMOTIONAL WITHDRAWAL Deficiency in relating to the interviewer and to the interviewer situation. Rate only the degree to which the patient gives the impression of failing to be in emotional contact with other people in the interview situation.</p> <p>SCORE <input type="text"/></p>	<p>12. HALLUCINATORY BEHAVIOR Perceptions without normal external stimulus correspondence. Rate only those experiences which are reported to have occurred within the last week and which are described as distinctly different from the thought and imagery processes of normal people.</p> <p>SCORE <input type="text"/></p>
<p>4. CONCEPTUAL DISORGANIZATION Degree to which the thought processes are confused, disconnected, or disorganized. Rate on the basis of integration of the verbal products of the patient; do not rate on the basis of patient's subjective impression of his own level of functioning.</p> <p>SCORE <input type="text"/></p>	<p>13. MOTOR RETARDATION Reduction in energy level evidenced in slowed movements. Rate on the basis of observed behavior of the patient only; do not rate on the basis of patient's subjective impression of own energy level.</p> <p>SCORE <input type="text"/></p>
<p>5. GUILT FEELINGS Over-concern or remorse for past behavior. Rate on the basis of the patient's subjective experiences of guilt as evidenced by verbal report with appropriate affect; do not infer guilt feelings from depression, anxiety or neurotic defenses.</p> <p>SCORE <input type="text"/></p>	<p>14. UNCOOPERATIVENESS Evidence of resistance, unfriendliness, resentment, and lack of readiness to cooperate with the interviewer. Rate only on the basis of the patient's attitude and responses to the interviewer and the interview situation; do not rate on basis of reported resentment or uncooperativeness outside the interview situation.</p> <p>SCORE <input type="text"/></p>
<p>6. TENSION Physical and motor manifestations of tension "nervousness", and heightened activation level. Tension should be rated solely on the basis of physical signs and motor behavior and not on the basis of subjective experiences of tension reported by the patient.</p> <p>SCORE <input type="text"/></p>	<p>15. UNUSUAL THOUGHT CONTENT Unusual, odd, strange or bizarre thought content. Rate here the degree of unusualness, not the degree of disorganization of thought processes.</p> <p>SCORE <input type="text"/></p>
<p>7. MANNERISMS AND POSTURING Unusual and unnatural motor behavior, the type of motor behavior which causes certain mental patients to stand out in a crowd of normal people. Rate only abnormality of movements; do not rate simple heightened motor activity here.</p> <p>SCORE <input type="text"/></p>	<p>16. BLUNTED AFFECT Reduced emotional tone, apparent lack of normal feeling or involvement.</p> <p>SCORE <input type="text"/></p>
<p>8. GRANDIOSITY Exaggerated self-opinion, conviction of unusual ability or powers. Rate only on the basis of patient's statements about himself or self-in-relation-to-others, not on the basis of his demeanor in the interview situation.</p> <p>SCORE <input type="text"/></p>	<p>17. EXCITEMENT Heightened emotional tone, agitation, increased reactivity.</p> <p>SCORE <input type="text"/></p>
<p>9. DEPRESSIVE MOOD Despondency in mood, sadness. Rate only degree of despondency; do not rate on the basis of inferences concerning depression based upon general retardation and somatic complaints.</p> <p>SCORE <input type="text"/></p>	<p>18. DISORIENTATION Confusion or lack of proper association for person, place or time.</p> <p>SCORE <input type="text"/></p>

Annexure 3

THE HAMILTON RATING SCALE FOR DEPRESSION

(to be administered by a health care professional)

Patient's Name _____

Date of Assessment _____

To rate the severity of depression in patients who are already diagnosed as depressed, administer this questionnaire. The higher the score, the more severe the depression.

For each item, write the correct number on the line next to the item. (Only one response per item)

- _____ **1. DEPRESSED MOOD** (Sadness, hopeless, helpless, worthless)
- 0= Absent
 - 1= These feeling states indicated only on questioning
 - 2= These feeling states spontaneously reported verbally
 - 3= Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep
 - 4= Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication
- _____ **2. FEELINGS OF GUILT**
- 0= Absent
 - 1= Self reproach, feels he has let people down
 - 2= Ideas of guilt or rumination over past errors or sinful deeds
 - 3= Present illness is a punishment. Delusions of guilt
 - 4= Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
- _____ **3. SUICIDE**
- 0= Absent
 - 1= Feels life is not worth living
 - 2= Wishes he were dead or any thoughts of possible death to self
 - 3= Suicidal ideas or gesture
 - 4= Attempts at suicide (any serious attempt rates 4)
- _____ **4. INSOMNIA EARLY**
- 0= No difficulty falling asleep
 - 1= Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour
 - 2= Complains of nightly difficulty falling asleep
- _____ **5. INSOMNIA MIDDLE**
- 0= No difficulty
 - 1= Patient complains of being restless and disturbed during the night
 - 2= Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

6. INSOMNIA LATE

_____ 0= No difficulty

1= Waking in early hours of the morning but goes back to sleep

2= Unable to fall asleep again if he gets out of bed

7. WORK AND ACTIVITIES

_____ 0= No difficulty

1= Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

2= Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

3= Decrease in actual time spent in activities or decrease in productivity

4= Stopped working because of present illness

8. RETARDATION: PSYCHOMOTOR (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

_____ 0= Normal speech and thought

1= Slight retardation at interview

2= Obvious retardation at interview

3= Interview difficult

4= Complete stupor

9. AGITATION

_____ 0= None

1= Fidgetiness

2= Playing with hands, hair, etc.

3= Moving about, can't sit still

4= Hand wringing, nail biting, hair-pulling, biting of lips

10. ANXIETY (PSYCHOLOGICAL)

_____ 0= No difficulty

1= Subjective tension and irritability

2= Worrying about minor matters

3= Apprehensive attitude apparent in face or speech

4= Fears expressed without questioning

11. ANXIETY SOMATIC: Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

_____ 0= Absent

1= Mild

2= Moderate

3= Severe

4= Incapacitating

12. SOMATIC SYMPTOMS (GASTROINTESTINAL)

_____ 0= None

1= Loss of appetite but eating without encouragement from others. Food intake about normal

2= Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. SOMATIC SYMPTOMS GENERAL

_____ 0= None

1= Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability

2= Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

_____ 0= Absent

1= Mild

2= Severe

15. HYPOCHONDRIASIS

_____ 0= Not present

1= Self-absorption (bodily)

2= Preoccupation with health

3= Frequent complaints, requests for help, etc.

4= Hypochondriacal delusions

16. LOSS OF WEIGHT

_____ A. When rating by history:

0= No weight loss

1= Probably weight loss associated with present illness

2= Definite (according to patient) weight loss

3= Not assessed

17. INSIGHT

_____ 0= Acknowledges being depressed and ill

1= Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.

2= Denies being ill at all

18. DIURNAL VARIATION

_____ A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none

0= No variation

1= Worse in A.M.

2= Worse in P.M.

_____ B. When present, mark the severity of the variation. Mark "None" if NO variation

0= None

1= Mild

2= Severe

19. DEPERSONALIZATION AND DEREALIZATION (Such as: Feelings of unreality;
Nihilistic ideas)

- _____ 0= Absent
 1= Mild
 2= Moderate
 3= Severe
 4= Incapacitating

20. PARANOID SYMPTOMS

- _____ 0= None
 1= Suspicious
 2= Ideas of reference
 3= Delusions of reference and persecution

21. OBSESSIVE AND COMPULSIVE SYMPTOMS

- _____ 0= Absent
 1= Mild
 2= Severe

Total Score _____

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Hamilton Anxiety Rating Scale (HAM-A)

Reference: Hamilton M. The assessment of anxiety states by rating. *Br J Med Psychol* 1959; 32:50–55.

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. *J Affect Disord* 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. *J Clin Consult Psychol* 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 **Anxious mood** 0 1 2 3 4

Worries, anticipation of the worst, fearful anticipation, irritability.

2 **Tension** 0 1 2 3 4

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 **Fears** 0 1 2 3 4

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 **Insomnia** 0 1 2 3 4

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 **Intellectual** 0 1 2 3 4

Difficulty in concentration, poor memory.

6 **Depressed mood** 0 1 2 3 4

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 **Somatic (muscular)** 0 1 2 3 4

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 **Somatic (sensory)** 0 1 2 3 4

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 **Cardiovascular symptoms** 0 1 2 3 4

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 **Respiratory symptoms** 0 1 2 3 4

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 **Gastrointestinal symptoms** 0 1 2 3 4

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 **Genitourinary symptoms** 0 1 2 3 4

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 **Autonomic symptoms** 0 1 2 3 4

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 **Behavior at interview** 0 1 2 3 4

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

ANNEXURE - 5

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-F-C)

Patient Name _____

Today's Date _____

NOTE: This is a questionnaire about sexual activity and sexual function. By sexual activity, we mean sexual intercourse, masturbation, sexual fantasies and other activity.

1. Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

2. How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

3. How often do you desire to engage in sexual activity?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

4. How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

5. Do you enjoy books, movies, music or artwork with sexual content?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

6. How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

7. How often do you become sexually aroused?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

8. Are you easily aroused?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

9. Do you have adequate vaginal lubrication during sexual activity?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

10. How often do you become aroused and then lose interest?

- ☐ 5-Never
- ☐ 4-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 2-Often (much more than half the time)
- ☐ 1-Always

11. How often do you experience an orgasm?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

12. Are you able to have an orgasm when you want to?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

13. How much pleasure or enjoyment do you get from your orgasms?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

14. How often do you have painful orgasm?

- ☐ 5-Never
- ☐ 4-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 2-Often (more than twice a week)
- ☐ 1-Every day

_____ = Pleasure (Item 1)

_____ = Desire/Frequency (Item 2 + Item 3)

_____ = Desire/Interest (Item 4 + Item 5 + Item 6)

_____ = Arousal/Excitement (Item 7 + Item 8 + Item 9)

_____ = Orgasm/Completion (Item 11 + Item 12 + Item 13)

_____ = Total CSFQ Score (Items 1 to 14)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-M-C)

Patient Name _____

Today's Date _____

NOTE: This is a questionnaire about sexual activity and sexual function. By sexual activity, we mean sexual intercourse, masturbation, sexual fantasies and other activity.

1. Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

2. How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

3. How often do you desire to engage in sexual activity?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

4. How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

5. Do you enjoy books, movies, music or artwork with sexual content?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

6. How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

7. How often do you have an erection related or unrelated to sexual activity?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

8. Do you get an erection easily?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

9. Are you able to maintain an erection?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

10. How often do you experience painful, prolonged erections?

- ☐ 5-Never
- ☐ 4-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 2-Often (more than twice a week)
- ☐ 1-Every day

11. How often do you have an ejaculation?

- ☐ 1-Never
- ☐ 2-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 4-Often (more than twice a week)
- ☐ 5-Every day

12. Are you able to ejaculate when you want to?

- ☐ 1-Never
- ☐ 2-Rarely (much less than half the time)
- ☐ 3-Sometimes (about half the time)
- ☐ 4-Often (much more than half the time)
- ☐ 5-Always

13. How much pleasure or enjoyment do you get from your orgasms?

- ☐ 1-No enjoyment or pleasure
- ☐ 2-Little enjoyment or pleasure
- ☐ 3-Some enjoyment or pleasure
- ☐ 4-Much enjoyment or pleasure
- ☐ 5-Great enjoyment or pleasure

14. How often do you have painful orgasm?

- ☐ 5-Never
- ☐ 4-Rarely (once a month or less)
- ☐ 3-Sometimes (more than once a month, up to twice a week)
- ☐ 2-Often (more than twice a week)
- ☐ 1-Every day

_____ = Pleasure (Item 1)

_____ = Desire/Frequency (Item 2 + Item 3)

_____ = Desire/Interest (Item 4 + Item 5 + Item 6)

_____ = Arousal/Erection (Item 7 + Item 8 + Item 9)

_____ = Orgasm/Ejaculation (Item 11 + Item 12 + Item 13)

_____ = Total CSFQ Score (Items 1 to 14)

INSTRUCTIONS FOR COMPLETING AND SCORING THE CSFQ

Ask the patient to complete all 14 items on the clinical version of the CSFQ. The patient should place a check (✓) in the box corresponding to the response for that particular item. The patient should choose only one response per item.

To score items on the CSFQ, take the numerical value or weight indicated for a particular response. For example, in Item 1, a response of "some enjoyment or pleasure" has a numerical value of 3, whereas a response of "much enjoyment or pleasure" has a numerical value of 4. Some items have responses that are reverse-scored: for example, on Item 14 in the CSFQ-F-C version, a response of "never" has a numerical value of 5, whereas a response of "every day" has a value of 1.

To calculate the Total CSFQ score, add up the values of the responses for all 14 items. To calculate subscale scores, add up the values for only the items that correspond to a particular subscale (see shaded box on front side). To determine if sexual dysfunction is present, refer to the gender-specific scoring protocols below.

Scoring for CSFQ-F-C: (Female Clinical Version)

If the female patient obtains a score at or below the following cut-off points* on any of these scales, it is indicative of sexual dysfunction:

Total CSFQ score:	41.0 (range: 14 to 70)
Sexual Desire/Frequency score:	6.0 (range: 2 to 10)
Sexual Desire/Interest:	9.0 (range: 3 to 15)
Sexual Pleasure:	4.0 (range: 1 to 5)
Sexual Arousal/Excitement:	12.0 (range: 3 to 15)
Sexual Orgasm/Completion:	11.0 (range: 3 to 15)

Scoring for CSFQ-M-C: (Male Clinical Version)

If the male patient obtains a score at or below the following cut-off points* on any of these scales, it is indicative of sexual dysfunction:

Total CSFQ score:	47.0 (range: 14 to 70)
Sexual Desire/Frequency score:	8.0 (range: 2 to 10)
Sexual Desire/Interest:	11.0 (range: 3 to 15)
Sexual Pleasure:	4.0 (range: 1 to 5)
Sexual Arousal/Excitement:	13.0 (range: 3 to 15)
Sexual Orgasm/Completion:	13.0 (range: 3 to 15)

REFERENCES:

Clayton, A.H., McGarvey, E.L., & Clavet, G.J. (1997). The Changes in Sexual Functioning Questionnaire (CSFQ): Development, Reliability, and Validity. *Psychopharmacology Bulletin*, 33(4), 731-745.

Clayton, A.H., McGarvey, E.L., Clavet, G.J., & Piazza, L. (1997). Comparison of sexual functioning in clinical and non-clinical populations using the Changes in Sexual Functioning Questionnaire (CSFQ). *Psychopharmacology Bulletin*, 33(4), 747-753.

Clayton, A.H., Owens, J.E., & McGarvey, E.L. (1995). Assessment of paroxetine-induced sexual dysfunction using the Changes in Sexual Functioning Questionnaire. *Psychopharmacology Bulletin*, 31(2), 397-413.

* Based on comparisons of non-depressed participants and clinically depressed patients

INFORMATION SHEET

- You have been selected to participate in this study.
- We are conducting a study **“A comparative study of sexual dysfunction in remitted taking antipsychotics versus antidepressants”** in Institute of Mental Health under Madras Medical College and for that your participation may be of value to us.
- Antipsychotics and Antidepressants affect sexual functioning. Hence, to assess the prevalence, severity and type of sexual functioning are assessed. All possible details associated with it are collected.
- We will be asking you set of questions from standard questionnaires approved by ethical committee on one to one basis and your responses will be recorded. The interview will take about 30 minutes.
- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.
- Signature of investigator
- Signature of participant
- Date:

ANNEXURE - 7

INFORMATION TO PARTICIPANTS

TITLE:

"A COMPARATIVE STUDY ON SEXUAL DYSFUNCTION BETWEEN
ANTIPSYCHOTICS AND ANTIDEPRESSANTS OF PATIENTS IN
REMISSION"

PRINCIPAL INVESTIGATOR:

Dr.K.SUBASHREE

First year,MD Postgraduate(PSYCHIATRY)
INSTITUTE OF MENTAL HEALTH,
Madras Medical College,
Chennai - 600 010.

PARTICIPANT DETAILS:

Name :

Age/ Sex:

Address:

Telephone:

PLACE OF STUDY: INSTITUTE OF MENTAL HEALTH, MMC, Chennai.

You are invited to take part in this research. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

PURPOSE OF RESEARCH

The purpose of study is to address the major side effect of sexual dysfunction in all possible ways, and hence with the study results to choose the drug based on side effect profile. We have obtained permission from institutional ethical committee

THE STUDY DESIGN:

You will be interviewed while you are attending our hospital.

STUDY PROCEDURES:

We will be interviewing you with various questionnaires. You will be required to spare roughly one hour for a one-time interview.

POSSIBLE BENEFITS TO OTHER PEOPLE:

The results of research may provide benefits to the society in terms of advancement of medical knowledge and / or therapeutic benefit to future patients.

CONFIDENTIALITY OF THE INFORMATION OBTAINED FROM YOU:

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigations, other study personnel and the Institutional Ethics Committee, to view your data, if required. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

HOW WILL YOUR DECISION TO NOT PARTICIPATE IN THE STUDY AFFECT YOU?

Your decision not to participate in this research study will not affect your medical care or your relationship with the investigator or the institution. You will be taken care of and you will not lose any benefits to which you are entitled.

CAN YOU DECIDE TO STOP PARTICIPATING IN THE STUDY ONCE YOU START?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping the treatment / discontinuing of procedures etc.

Signature of Investigator:

Signature of

Participant

Date :

Date :

INFORMED CONSENT FORM

Title:

"A COMPARATIVE STUDY ON SEXUAL DYSUNCTION BETWEEN
ANTIPSYCHOTIC AND ANTIDEPRESSANTS OF PATIENTS IN REMISSION"

Name of the Participant:

Name of Principal Investigator: Dr. K.SUBASHREE

Name of Institution: Institute of Mental Health, Chennai.

I _____(name of participant), have read the information
in this form or it has been read out to me. I was free to ask any questions and
they have been answered. I am exercising my free power of choice, hereby
voluntarily give my consent to be included as a participant in this study.

1) I have read and understood this consent form and the information provided
to me.

2) I have had the consent document explained to me.

3) I have been explained about the nature of the study.

4) I have been explained about my rights and responsibilities by the
investigator.

5) I have informed the investigator of all the treatments I am taking or have
taken in the past, including any native (alternative) treatments.

6) I am aware of the fact that I can opt out of the study at any time without
having to give any reason and this will not affect my future treatment in the
hospital.

7) I hereby give permission to the investigators to release the information obtained from me as a result of participation in this study to the regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.

8) I understand that my identity will be kept confidential if my data are publicly presented.

9) I have had my questions answered to my satisfaction.

10) I consent voluntarily to participate as a participant in the research study.

I am aware, that I can opt out of the study, I should contact the investigators. By signing this consent from, I attest that the information given in this document has been clearly explained to me and understood by me. I will be given a copy of this consent document.

Participant	Name	Signature	Date
Impartial Witness	Name	Signature	Date
Investigator or	Name	Signature	Date

ஆராய்ச்சி தகவல் கடிதம்

ஆராய்ச்சி தலைப்பு : நோய்த்தடுப்பு உள்ள நோயாளிகளுக்கு ஆன்டிசைகோடிக்ஸ் மற்றும் ஆன்டி - டிப்ரசென்ட்ஸ் உட்கொண்ட நோய்களுக்கு இடையே பாலியல் செயலிழப்பு பற்றி ஒப்பீட்டு ஆய்வு

பங்கு கொள்பவர் பெயர் :

ஆராய்ச்சியாளர் : மரு.க.சுபாநீ

மருத்துவ நிலையம் : அரசு மனநல காப்பகம்
சென்னை - 600 010.

தாங்கள் இந்த ஆய்ச்சியில் பங்கு கொள்வதற்கேற்ப தகவல்கள் கொடுக்கப் பட்டுள்ளது. தங்கள் சந்தேகங்களை கேட்டு அறிந்த கொள்ளலாம்.

ஆராய்ச்சியின் நோக்கம் :

மருந்து உட்கொண்ட நோயாளிகளுக்கும் பாலியல் தொற்றுக்களுக்குமான அனைத்து வகையான வழிகளிலும் பாலியல் செயலிழப்பு விளைவுகளை ஒப்பிட்டு பார்ப்பதே இந்த ஆராய்ச்சியின் நோக்கம்.

ஆராய்ச்சியின் முறை :

எங்களுடைய மருத்துவமனையை அணுகும் பொழுது உங்கள் விருப்பத்துடன் நோர்காணல் செய்யப்படும். நீங்களும். இந்த ஆராய்ச்சியில் பங்கேற்க விரும்புகிறோம்.

நான் இதுவரை எடுத்துக்கொண்ட அனைத்து மருத்துவ முறைகளைப் பற்றி தெரிவித்திருக்கிறேன்.

இந்த ஆராய்ச்சியில் இருந்து எந்தநேரமும் பின் வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்துக்கொண்டேன்

என்னை பற்றிய எந்த தகவல்களும், அடையாளமும், வெளியிடப்பட மாட்டாது என்பதை புரிந்துக்கொண்டேன்.

என்னை பற்றிய எந்த தகவல்களும் அடையாளமும் வெளியிடப்பட மாட்டாது என்பதை நான் புரிந்துக்கொண்டேன் என்னுடைய முழு சுதந்திரத்துடன் இந்த ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதிக்கின்றேன்.

பங்கேற்பாளர் பெயர்
கையொப்பம்

ஆராய்ச்சியாளர் பெயர்
கையொப்பம்

தேதி :

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு :

நோய்த் தடுப்பு உள்ள நோயாளிகளுக்கு
ஆன்டிசை கோடிக்ஸ் மற்றும் ஆன்டி -
டிப்ரசென்ட்ஸ் உட்கொண்ட நோய்களுக்கு
இடையே பாலியல் செயலிழப்பு பற்றி ஒப்பீட்டு
ஆய்வு

பங்கு கொள்பவர் பெயர் :

ஆராய்ச்சியாளர் : மரு.க.சுபாநீ

மருத்துவ நிலையம் : அரசு மனநல காப்பகம்
சென்னை - 600 010.

.....எனும் நான் எனக்கு கொடுக்கப்பட்ட தகவல்
தாளினை படித்து புரிந்து கொண்டேன். என்னுடைய சுய நினைவுடனும்
மற்றும் முழு சுதந்திரத்துடனும் இந்த ஆராய்ச்சியில் என்னை
சேர்த்துக்கொள்ள சம்மதிக்கிறேன்.

எனக்கு இந்த ஆராய்ச்சியின் ஒப்புதல் படிவம் விளக்கப்பட்டது.

எனக்கு இந்த ஆராய்ச்சியின் நோக்கமும், விவரங்களும்
விளக்கப்பட்டது.

எனக்கு என்னுடைய உரிமைகளை பற்றி விளக்கப்பட்டுள்ளது.

இந்த ஆய்வின் முடிவுகளை ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிக்கப்படும். என்பதையும் தெரிவித்து கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்த நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின் வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதை தெரிவித்துக்கொள்கிறோம்.

பங்கேற்பாளர் பெயர்
கையொப்பம்

ஆராய்ச்சியாளர் பெயர்
கையொப்பம்

தேதி :

	sociodemographic details						illness related details				sexual functioning		domains							
sl.no	age	gender	menstrual status	marital status	employment	SEC	drug	dose (mg)	diagnosis	family h/o	before drug use	after drug use	A	B	C	D	E	item 10	item 14	others
1	2	1	5	2	1	4	1	2	1	1	3	1,3	1	1	1	1	1	1	1	0
2	3	1	5	1	1	3	1	4	1	2	3	4	3	3	2	2	2	1	1	0
3	4	1	5	1	1	3	1	3	1	2	3	4	3	2	2	2	2	1	1	0
4	2	1	5	1	1	3	1	2	1	2	3	2,3	2	2	1	2	2	1	1	0
5	5	1	5	1	1	3	1	3	1	2	4	1	1	1	1	1	1	1	1	0
6	1	1	5	2	2	2	1	2	1	2	3	4	2	2	1	2	2	1	1	0
7	3	1	5	1	1	3	1	4	1	2	3	4	3	2	2	2	2	1	1	0
8	4	1	5	1	1	4	1	2	1	2	3	4	1	2	2	2	2	1	1	0
9	5	1	5	1	1	4	1	2	1	2	4	1	1	1	1	1	1	1	1	0
10	2	1	5	1	1	3	1	2	1	2	3	3	1	1	1	1	1	1	1	0
11	3	1	5	1	1	3	1	2	1	2	3	3	2	2	1	1	2	1	1	0
12	2	1	5	2	1	3	2	5	1	2	3	1	1	1	1	1	1	1	1	0
13	3	1	5	1	1	3	2	7	1	2	3	4	2	2	2	2	2	1	1	0
14	2	1	5	1	1	3	2	7	1	2	3	4	2	2	2	2	1	1	1	0
15	3	1	5	1	1	2	2	5	1	2	3	1	1	1	1	1	1	1	1	0
16	3	1	5	1	1	4	2	5	1	2	3	1	1	1	1	1	1	1	1	0
17	3	1	5	1	1	4	2	5	1	1	3	2,3	2	1	1	1	1	1	1	0
18	3	1	5	1	1	3	2	6	1	2	3	4	2	2	2	2	2	1	1	0
19	3	1	5	1	1	3	2	7	1	2	3	4	1	1	2	2	2	1	1	0
20	4	1	5	1	1	4	2	7	1	2	3	4	2	2	2	2	2	1	1	0
21	5	1	5	1	1	4	2	7	1	2	4	1	1	1	1	1	1	1	1	0
22	2	1	5	1	1	3	2	7	1	2	3	4	2	2	1	2	2	1	1	0
23	2	1	5	2	1	2	2	5	1	2	3	1	1	1	1	1	1	1	1	0
24	4	1	5	1	1	4	2	7	1	2	3	4	1	2	2	2	1	1	1	0
25	3	1	5	1	1	2	2	7	1	2	3	2,3	2	2	2	2	2	1	1	0
26	4	1	5	1	1	4	2	5	1	2	3	1	1	1	1	1	1	1	1	0
27	3	1	5	1	1	3	2	5	1	2	3	1	1	1	1	1	1	1	1	0
28	2	1	5	1	1	3	2	6	1	2	3	4	3	2	2	2	2	1	1	0
29	2	1	5	2	3	3	2	7	1	2	3	4	1	1	2	2	2	1	1	0
30	2	1	5	2	3	2	2	5	1	2	3	1	1	1	1	1	1	1	1	0
31	2	1	5	1	1	3	2	6	1	2	3	4	3	3	2	2	2	1	1	0
32	2	1	5	1	1	3	3	9	2	2	3	4	3	2	2	2	2	1	1	1

33	2	1	5	1	1	4	3	4	2	2	3	4	3	2	2	2	2	1	1	1
34	2	1	5	1	1	3	3	4	2	2	3	4	2	2	1	2	2	1	1	1
35	4	1	5	1	1	3	3	4	2	2	3	4	2	2	1	2	2	1	1	1
36	4	1	5	1	1	3	3	4	2	2	3	4	2	2	2	2	2	1	1	1
37	5	1	5	1	1	3	3	4	2	2	4	2,4	1	1	1	2	2	1	1	1
38	3	1	5	1	1	2	3	4	2	2	3	4	2	2	2	2	2	1	1	1
39	3	1	5	1	1	3	3	9	2	1	3	4	2	2	2	2	2	1	1	1
40	1	1	5	2	3	2	3	4	3	2	3	4	2	2	2	2	2	1	1	0
41	1	1	5	2	3	3	3	4	2	2	3	4	2	2	2	2	2	1	1	0
42	1	1	5	2	3	4	3	4	2	2	3	4	3	2	2	2	2	1	1	1
43	3	1	5	1	1	2	3	4	2	2	3	4	2	2	2	2	2	1	1	1
44	3	1	5	1	1	4	3	4	2	2	3	4	2	2	2	2	2	1	1	0
45	2	1	5	1	1	2	3	10	2	2	3	4	3	2	2	2	2	1	1	1
46	3	1	5	1	1	4	3	10	2	2	3	4	2	2	2	2	2	1	1	1
47	2	1	5	1	1	3	3	11	2	1	3	4	3	2	2	2	2	1	1	1
48	3	1	5	1	1	3	3	10	2	2	4	2,4	2	2	2	2	2	1	1	0
49	3	1	5	1	1	3	3	4	3	2	3	4	2	2	2	2	2	1	1	0
50	3	1	5	1	1	4	3	4	3	2	3	4	3	2	2	2	2	1	1	0
51	4	1	5	1	1	3	3	4	3	2	4	2,4	2	2	1	2	2	1	1	0
52	5	1	5	1	1	4	3	4	3	2	4	2,4	2	2	1	2	2	1	1	0
53	2	1	5	1	1	3	3	4	3	1	3	4	3	2	2	2	2	1	1	0
54	2	1	5	2	1	4	4	12	2	2	3	4	2	1	1	2	2	1	1	1
55	2	1	5	1	1	3	4	12	2	2	3	4	2	1	1	2	2	1	1	1
56	2	1	5	1	1	3	4	14	2	2	3	4	3	2	2	2	2	1	1	1
57	3	1	5	1	1	4	4	12	2	2	3	4	2	2	2	2	2	1	1	1
58	1	1	5	2	3	2	4	13	2	2	3	4	2	2	1	2	2	1	1	1
59	2	1	5	1	1	3	4	12	3	2	3	4	1	1	1	1	2	1	1	1
60	3	1	5	1	1	3	4	12	3	2	3	4	2	2	1	2	2	1	1	1
61	4	1	5	1	1	3	4	12	3	2	4	1	1	1	1	1	1	1	1	0
62	3	1	5	1	1	3	4	12	2	2	3	4	2	2	2	2	2	1	1	0
63	2	1	5	2	3	2	4	12	2	2	3	2,3	2	1	1	1	2	1	1	1
64	2	1	5	1	1	3	4	12	2	2	3	4	2	2	2	2	2	1	1	1
65	1	1	5	2	3	3	4	12	2	2	3	2,3	2	2	1	2	2	1	1	0
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67	2	1	5	1	1	3	4	14	2	2	3	4	2	2	2	2	2	1	1	1
68	2	1	5	2	2	3	4	12	3	2	3	1	1	1	1	1	1	1	1	0

69	2	1	5	1	1	3	4	14	2	2	3	4	3	2	2	2	2	1	1	1
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71	3	1	5	1	1	4	4	12	2	2	3	4	2	2	2	2	2	1	1	0
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89	5	2	4	1	2	3	1	2	1	2	4	1	1	1	1	1	1	1	1	2
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138	3	2	1	1	2	3	3	10	2	2	3	4	3	3	2	2	3	1	1	2
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150	5	2	4	1	1	3	4	12	2	2	4	1	1	1	1	1	1	1	1	2
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168	3	2	1	1	1	4	4	14	3	1	3	4	2	1	1	2	3	2	1	2

Sl.no	age	gender	menstural status	marital status	employment	SEC	sexual functioning
1	2	1	5	1	1	2	3
2	3	1	5	1	1	3	3
3	5	1	5	1	1	2	4
4	3	1	5	1	1	3	4
5	2	1	5	2	3	3	3
6	4	1	5	1	1	4	4
7	3	1	5	3	1	3	3
8	4	1	5	1	1	4	4
9	3	1	5	1	1	1	3
10	4	1	5	1	1	3	4
11	1	1	5	2	3	3	3
12	2	1	5	1	1	3	3
13	2	1	5	1	1	3	3
14	4	1	5	1	1	4	3
15	4	1	5	1	1	3	4
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17	2	1	5	1	1	3	3
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22	3	1	5	1	1	3	3
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29	5	1	5	1	1	3	4
30	1	1	5	1	1	4	3
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34	5	2	4	1	1	4	4

35	3	2	1	1	1	3	3
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37	3	2	1	2	2	2	3
38	3	2	1	1	2	4	3
39	2	2	1	1	2	3	3
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41	2	2	1	1	3	3	3
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44	3	2	1	1	1	2	3
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53	2	2	1	1	1	2	3
54	4	2	4	3	1	2	4
55	2	2	1	1	1	2	3

KEY TO MASTER CHART

Age

19,20	1
21-30	2
31-40	3
41-50	4
51-60	5

Gender

Male	1
Female	2

Marital status

Married	1
Unmarried	2
Separated	3

Employment

Employed	1
Unemployed	2
Student	3

Menstrual status

Regular	1
Irregular	2
Pre-menopause	3
Menopause	4
Not applicable	5

Sexual functioning

No changes	1
Changes present	2
No sexual dysfunction	3
Sexual dysfunction	4

Socioeconomic status

Class 1	1
Class 2	2
Class 3	3
Class 4	4
Class 5	5

Diagnosis

First episode psychosis	1
Depression	2
Anxiety	3

Family history

Present	1
Not present	2

Drug dose (mg)

1.5 mg	1
3 mg	2
5 mg	3
10 mg	4
2 mg	5
6 mg	6
4 mg	7
8 mg	8
15 mg	9
20 mg	10
30 mg	11
50 mg	12
75 mg	13
100 mg	14

Domains

No change	1
Less than 50% change	2
> (greater than) nor equal to 50% change	3

Others

- | | |
|---|------------------------|
| 0 | no delayed ejaculation |
| 1 | delayed ejaculation |
| 2 | not applicable |

drug

- | | |
|--------------|---|
| haloperidol | 1 |
| risperidone | 2 |
| escitalopram | 3 |
| sertraline | 4 |

domains

- | | |
|---|---|
| pleasure | A |
| desire / frequency | B |
| desire /interest | C |
| arousal/ erection (in male) & arousal / excitement (in female) | D |
| orgasm / ejaculation (in male) & orgasm/ completion (in female) | E |

scoring for item 10,14 (item 10- aroused and lose interest (female) or prolonged erections(male); item 14- painful orgasm)

- | | |
|-----------|---|
| never | 1 |
| rarely | 2 |
| sometimes | 3 |
| often | 4 |