INCIDENCE AND RISK FACTORS FOR SEXUAL DYSFUNCTION IN MALE PATIENTS WITH PSYCHOTIC DISORDERS

Dissertation submitted to

The Tamil Nadu Dr. M.G.R. Medical University
In part fulfilment of the requirement for

M.D. branch XVIII - Psychiatry final examination

April 2014

CERTIFICATE

This is to certify that the dissertation titled “Incidence and Risk factors for sexual dysfunction in male patients with psychotic disorders” is the bonafide work of Dr.Dhananjayan R towards the MD Psychiatry Degree Examination of the Tamil Nadu Dr M.G.R Medical University to be conducted in April 2014. This work has not been submitted to any university in part or full.

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CERTIFICATE

This is to certify that the dissertation titled “Incidence and Risk factors for sexual dysfunction in male patients with psychotic disorders” is the bonafide work of Dr. Dhananjayan R towards the MD Psychiatry Degree Examination of Tamil Nadu Dr M.G.R Medical University to be conducted in April 2014 and that this study has been done under my guidance. This work has not been submitted to any university in part or full.

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DECLARATION

I hereby declare that this dissertation titled “Incidence and Risk factors for sexual dysfunction in male patients with psychotic disorders” is a bonafide work done by me under the guidance of Dr. Rajesh Gopalakrishnan, Professor of Psychiatry, Christian Medical College, Vellore. This work has not been submitted to any university in part or full.

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October 8, 2012

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Sub: **FLUID Research grant project NEW PROPOSAL:**
Incidence and risk factors for developing sexual dysfunction in male patients with psychosis on antipsychotic medication
Dr. Dhananjayan Ravichandran, PG Registrar, Psychiatry, Dr. Rajesh Gopalakrishnan, Psychiatry, Dr. Anju Kuruvilla, Psychiatry.

Ref: IRB Min. No. 7940 dated 02.08.2012

Dear Dr. Dhananjayan Ravichandran,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Incidence and risk factors for developing sexual dysfunction in male patients with psychosis on antipsychotic medication" on August 2, 2012.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Proforma
3. Consent form (English and Tamil)
4. Cvs of Drs. Dhananjayan Ravichandran.
5. A CD containing documents 1 - 4

The following Institutional Review Board (Research & Ethics Committee) members were present at the meeting held on July 4, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent. And on completion of the study you are expected to submit a copy of the final report.

A sum of ₹ 40,000/- (Rupees Forty thousand only) can be sanctioned for 12 months. A subsequent installment of 40,000/- will be released at the end of the first year following the receipt of the progress report (Total amount 80,000/-).

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

CC: Dr. Rajesh Gopalakrishnan, Associate Professor, Department of Psychiatry, CMC

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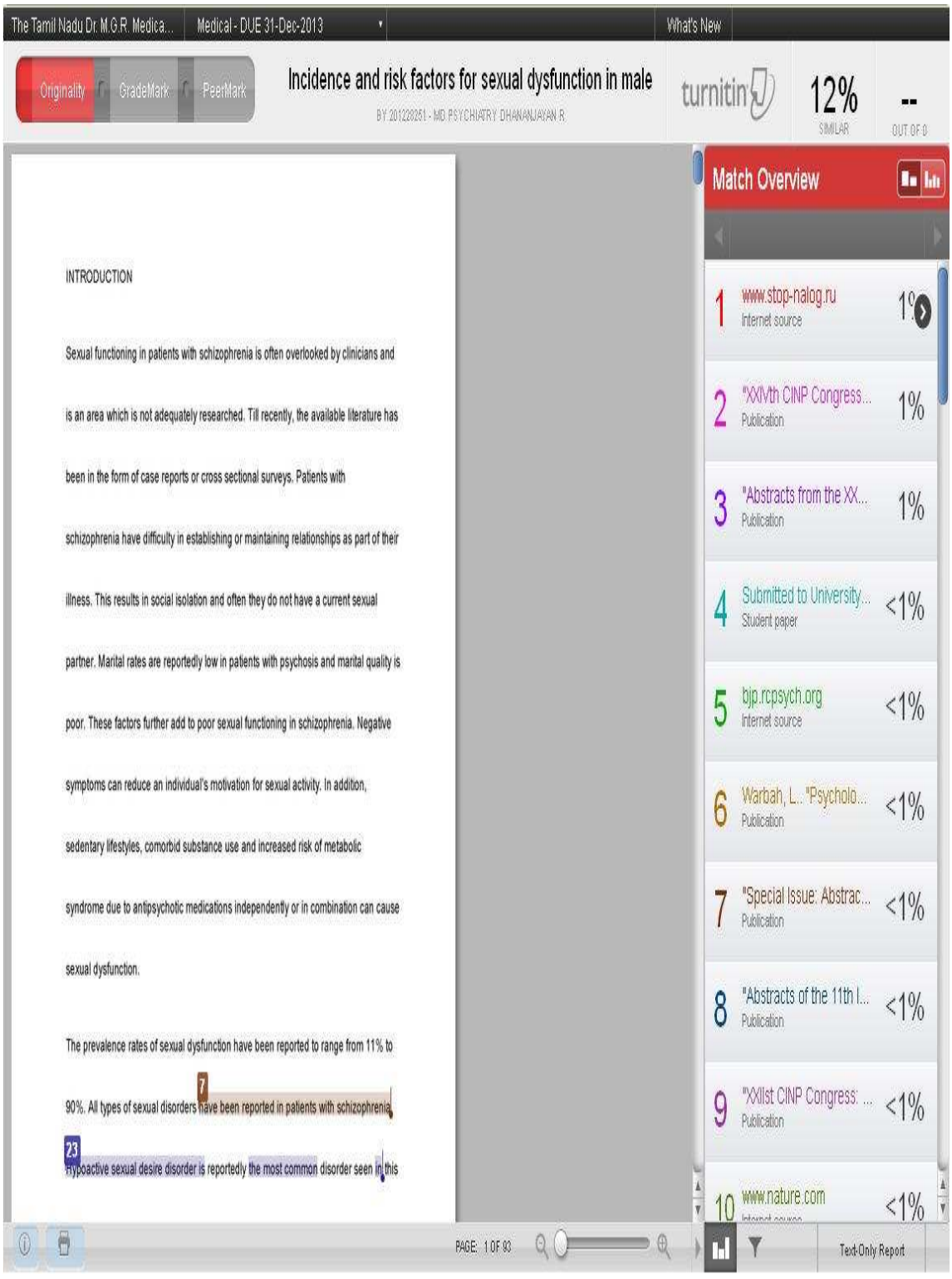
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INTRODUCTION
Sexual functioning in patients with schizophrenia is often overlooked by clinicians and is an area which is not adequately researched. Till recently, the available literature has been in the form of case reports or cross sectional surveys. Patients with schizophrenia have difficulty in establishing or maintaining relationships as part of their illness. This results in social isolation and often they do not have a current sexual partner. Marital rates are reportedly low in patients with psychosis and marital quality is poor. These factors further add to poor sexual functioning in schizophrenia. Negative symptoms can reduce an individual's motivation for sexual activity. In addition, sedentary lifestyles, comorbid substance use and increased risk of metabolic syndrome due to antipsychotic medications independently or in combination can cause sexual dysfunction.
The prevalence rates of sexual dysfunction have been reported to range from 11% to 90%. All types of sexual disorders have been reported in patients with schizophrenia.
Hypoactive sexual desire disorder is reportedly the most common disorder seen in this
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I.INTRODUCTION

Sexual functioning in patients with schizophrenia is often overlooked by clinicians and is an area which is not adequately researched. Till recently, the available literature has been in the form of case reports or cross sectional surveys. Patients with schizophrenia have difficulty in establishing or maintaining relationships as part of their illness. This results in social isolation and often they do not have a current sexual partner. Marital rates are reportedly low in patients with psychosis and marital quality is poor. These factors further add to poor sexual functioning in schizophrenia. Negative symptoms can reduce an individual's motivation for sexual activity. In addition, sedentary lifestyles, co-morbid substance use and increased risk of metabolic syndrome due to antipsychotic medications independently or in combination can cause sexual dysfunction.

The prevalence rates of sexual dysfunction have been reported to range from 11% to 90%. All types of sexual disorders have been reported in patients with schizophrenia. Hypoactive sexual desire disorder is reportedly the most common disorder seen in this population. The wide range in prevalence rates are probably due to the various methodological differences in these studies. Most of these studies are cross sectional in nature and have looked at prevalence in various subsets of this population like institutionalized patients, married subjects etc. Very few studies have looked at sexual difficulties in drug naïve patients. Other methodological limitations like using instruments which have not demonstrated sound psychometric properties and findings not backed with biological correlates of these studies limit their quality and generalizability. Moreover, these data are usually part of a secondary analyses; the primary objectives of these studies being another topic. To the best of our knowledge no study has looked at the incidence of sexual dysfunction in patients with psychosis.

Risk factors for developing sexual dysfunction in this population have not been systematically studied. It has been assumed that sexual side effects of antipsychotic medications account for the majority of these cases. It is also possible that the disease process by itself could cause dysfunction. The risk factors generally discussed have been age; duration of illness; type and duration of medications prescribed and raised serum prolactin levels. Race (Caucasian population has been reported to have higher prevalence than Asians) has also been reported as a risk factor.

Medications used to treat psychotic disorders are well known to cause sexual side effects. Antipsychotic medications have been classified as prolactin raising and prolactin sparing groups based on their potential for raising serum prolactin levels. A wide range of sexual side effects have been reported and mechanisms of these side effects have been described. However empirical proof for this is lacking.

There are two reports on sexual dysfunction in antipsychotic medications from India. One is a cross-sectional assessment and other one has looked at bipolar patients.

Sexual dysfunction in patients with schizophrenia leads to poor quality of life and treatment non adherence. Even though it causes significant distress, patients do not report this dysfunction unless specifically enquired.

II. REVIEW OF LITERATURE

II.1. INTRODUCTION

Sexual behavior is one of the basic drives in human beings and other organisms. While sexual activity serves majorly for reproduction in other species, feelings of pleasure and intimacy associated with sexual activity acts as an important motive for socialization in human beings.

Sexuality is determined by biological and psycho-social factors. Sexual organs and its associated physiological and neuro-endocrinological changes constitute the biological aspects. The psychological state of the individual, his/her relationship with others, developmental experiences through one's life, and societal and cultural influences are the psycho-social factors which impact on one's sexual functioning.

The National Health and Social Life Survey reported that the prevalence of sexual dysfunction is 31% in a cohort of men aged 18-59. The Massachusetts Male Aging Survey and similar studies have demonstrated that sexual dysfunction is a common problem among men and that the prevalence increases with age. Various risk factors have been associated with sexual dysfunction. Age, medical disorders (diabetes mellitus, hypertension, dyslipidemia, cardiovascular disorders etc), psychiatric disorders (depression, psychotic illness etc), medications (anti-hypertensive's, antipsychotics, antidepressants etc), lifestyle choices (smoking, obesity etc) and substance use disorders are commonly associated with sexual difficulties. Etiology of sexual dysfunctions has always been debated. Biological factors, psychological factors or a combination has been proposed. Medical illness, trauma, surgeries and medications are the common medical causes. Likewise, depression, anxiety, psychosis, psychological conflicts etc can cause functional sexual dysfunction. A combination of

these factors may also be seen. Psychological factors play an important role in all phases of sexual behavior. Any condition which affects, these phases can lead to sexual difficulties.

Schizophrenia is one of the most debilitating psychiatric syndromes which can result in a morbid dysfunctional state. It is a heterogeneous condition with various symptom domains like positive symptoms (such as delusions, hallucinations, disorganization in thought and behavior), negative symptoms (affective blunting, apathy, amotivation, asociality) and cognitive symptoms (poor attention and planning). Affective and behavioral disturbances can also be seen. Antipsychotic drugs are the first line choice of treatment for schizophrenia. Dopamine receptor blockade which is responsible for antipsychotic activity can also result in sexual dysfunction. Sexual dysfunction in people with psychotic disorders, apart from causing individual distress, also leads to partner dissatisfaction and marital disharmony, eventually affecting the quality of life. However patients with schizophrenia generally do not complain of this adverse effect unless specifically asked, in spite of this being one of the most distressing adverse effects. This results in higher rates of non-compliance to medications with subsequent relapse in psychotic symptoms.

II.2. NORMAL MALE SEXUAL FUNCTIONING

II.2.A. ANATOMY

MALE SEXUAL ORGANS

Male sex organs include both external genitalia and internal sex organs. Penis and scrotum along with testis constitutes the external genitalia. Internal sex organs include the vas deferens, seminal vesicles, prostate glands and their ducts.

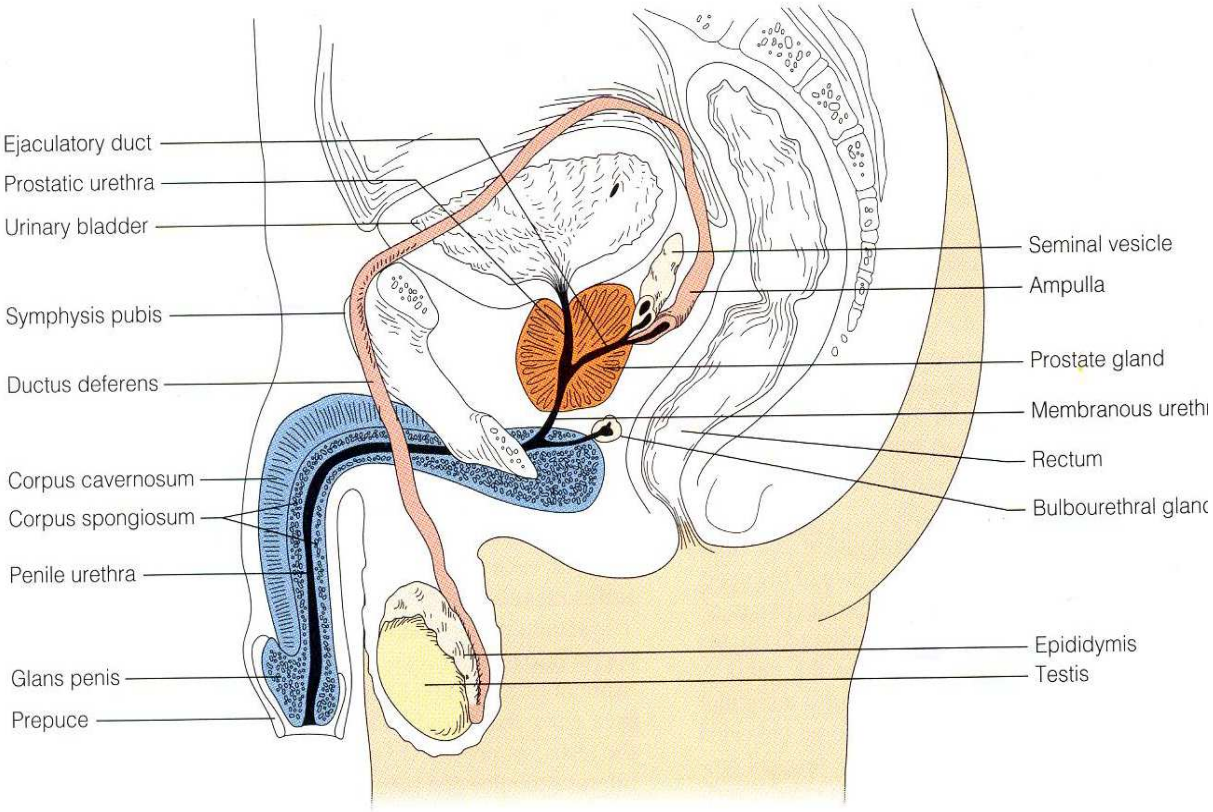
Penis has two parts, the root and the body. The root of the penis has three masses of erectile tissue - the bulb of the penis situated at the midline and a pair of crus. The bulb is covered on its outer surface by bulbospongiosus muscle and is traversed by urethra. Each crus is attached to the pubic arch and is covered by ischiocavernosus muscles. The bulb continues forward as the corpus spongiosum and the crura converge anteriorly to form the corpora cavernosa. The body of penis too has three cylinders of erectile tissue - corpora cavernosa dorsally and corpora spongiosa ventrally, enclosed within a thick fascia (Buck's fascia). The corpus spongiosum expands distally to form the glans penis.

Scrotum encloses the two testes. Sperm produced in the testis are transported through vas deferens, which ascends and joins the ducts of seminal vesicles to form the ejaculatory duct. Ejaculatory ducts opens into the posterior aspect of the prostatic urethra. Ducts from prostate gland also open into this part of urethra. The secretions of the seminal vesicles, and prostate, along with the sperm constitute the semen which is ejaculated through penile urethra during sexual stimulation. (1)

BLOOD SUPPLY AND INNERVATION

Blood supply of the penis comes from internal pudental arteries which are branches of the internal iliac artery. The internal pudental arteries continue as penile arteries which branch extensively to supply the penis. The dorsal arteries of penis supply the glans penis. The deep or cavernosal arteries run in the middle of each corpus cavernosum and directly open into the trabecular spaces.

Nerve supply to penis includes both the somatic nerves and the autonomic system. Somatic nerve supply comes from the pudental nerves which carry sensory fibers from the penis and motor fibers to perineal skeletal muscles. Autonomic innervation includes both the parasympathetic fibers and sympathetic fibers. Parasympathetic nerves come from sacral cord (S2-S4) and travels through the ‘nervi erigentes’. They supply vasodilatory innervation to the corpora cavernosum. Sympathetic innervation comes from thoraco-lumbar outflow and mediates ejaculation and penile detumescence.(2)



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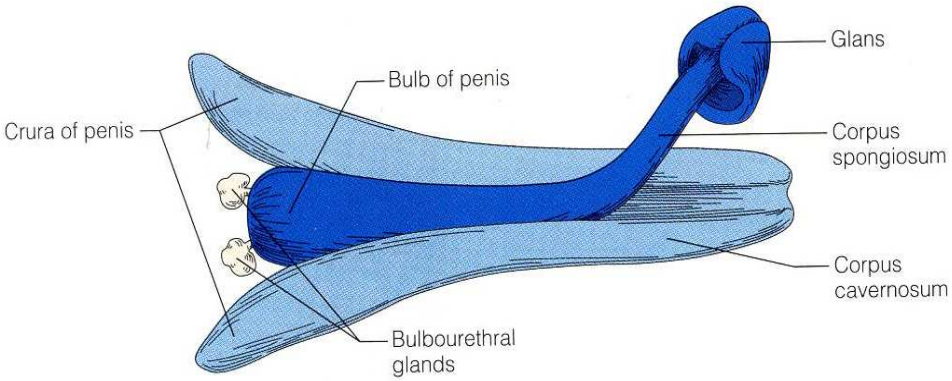

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II.2.B. PHASES OF MALE SEXUAL RESPONSE

Alfred Kinsey (1894-1956) and later William Masters and Virginia Johnson (1957-1990) who did pioneering work in the area of human sexuality, described stages in the human sexual response after direct observation of experimental subjects in their laboratory performing sexual activity.

The Diagnostic and Statistical Manual IV Textbook Revision (DSM-IV TR) describes four phases in human sexual response cycle

1. Desire
2. Excitement
3. Orgasm
4. Resolution

DESIRE PHASE

Desire phase is a psychological phase, which depends on an individual's personality and drives, apart from the biological and psychological states. This phase is characterized by fantasies and a conscious wish to have sexual activity.

EXCITEMENT PHASE

Excitement phase is brought on by either by direct stimulation of body parts as in kissing, stroking or by fantasies regarding sexual activity or the presence of object of love or a combination of these. It involves a subjective sense of pleasure and objective signs of sexual excitement. This phase is characterized by penile tumescence which leads to erection in men. The nipples become erect; however this is more common and prominent in females. This phase of initial excitement can last for several minutes to hours. On continued stimulation, testes increase in size by 50 percent and elevates. The

colour of the penis changes to deep or bright red due to continued engorgement. There is an increase in heart rate, respiratory rate and blood pressure. Voluntary contractions of large muscle groups occur. Heightened excitement can last from half a minute to several minutes.

ORGASM PHASE

Sexual pleasure peaks during orgasmic phase. Release of sexual tension occurs with rhythmic contractions of the perineal muscle groups and pelvic reproductive organs. A subjective sense of ejaculatory inevitability occurs followed by forceful emission of semen through the penile urethra. It is also associated with few (4-5) rhythmic contractions of the prostate gland, seminal vesicles, vas deferens, and the urethra which aid in the emission and ejaculation of semen. Involuntary contractions of the anal sphincters (external and internal sphincters) occur in both genders. The contractions during orgasm occur at an interval of 0.8 seconds. Other manifestations include voluntary and involuntary movements of the large muscle groups. Facial grimacing and carpopedal spasm has been reported. Cardiovascular changes include rise in blood pressure up to 20-40 mm Hg and increase in heart rate up to 150-160 per minute. Orgasmic phase can last from 3 to 25 seconds and is usually associated with a transient and minimal clouding of consciousness.

RESOLUTION PHASE

Resolution phase involves detumescence (the disgorgement of blood from the genitalia). Resolution occurs rapidly if there is an orgasm. Otherwise, it may take a few (2-6) hours and can be associated with irritability and discomfort. Resolution which follows orgasm is characterized by general body and muscular relaxation, and a

subjective feeling of pleasure and well being. Following orgasm, men go through a refractory period which varies within and across individuals. This may last from several minutes to many hours; and during the refractory period men cannot be stimulated to another orgasm.

Thus sexual response is a complex psychological and physiological experience. Psychosexual development, attitude toward sexuality and one's sexual partner are directly involved with and affect the physiology of human sexual response.(3)

II.2.C. NEUROPHYSIOLOGY OF MALE SEXUAL RESPONSE

NEUROPHYSIOLOGY OF ERECTION

LOCAL MECHANISMS

Penile erection is a hydrodynamic response. It involves balancing between arterial inflow and venous drainage. As has been described earlier penile corpora cavernosa contains cavernous spaces which are in a contracted state when penis is flaccid. The smooth muscles of corpora cavernosa relax during erection thereby decreasing arterial resistance and increasing blood flow. Venous outflow is reduced by passive occlusion of subtunical veins which are pressed against the tunica albuginea.

The vascular events which occur during the initiation and maintenance of erection are controlled by the nerves supplying the penis and local mediators. Parasympathetic cholinergic nerves have a major role in erection. While parasympathetic system is proerectile, simultaneous inhibition of sympathetic vasoconstrictor nerves results in increasing blood flow to penis. Contraction of perineal skeletal muscles is also required for full rigidity of the erect penis.

Nitric oxide (NO) is considered to be the local mediator of cavernosal vasodilatation during erection. NO stimulates the production of cyclic GMP (cGMP), which is a second messenger molecule causing smooth muscle relaxation. cGMP is degraded by the enzyme phosphodiesterase. Several subtypes of this enzyme exist and phosphodiesterase-5 (PDE-5) is relatively specific for penis. This enzyme is blocked by drugs like Sildenafil, Vardenafil and Tadalafil which results in increased bioavailability of cGMP, which helps in maintenance of erection.(1)

SPINAL MECHANISMS

Erection occurs, either following tactile stimulation of penis (reflexive erection) or by supraspinal stimuli (psychogenic erection). Sacral spinal cord is involved in the integration and coordination of excitatory and inhibitory impulses from both supraspinal and peripheral areas. This is supported by the absence of erection following complete destruction of sacral spinal cord or its outflow. However supraspinal cord transection can still cause reflexive erection through local spinal reflex.

SUPRASPINAL MECHANISMS

Supraspinal mechanisms involved in erection are complex and not yet completely understood. Psychogenic erection which occurs in response to visual, olfactory, tactile and imaginative stimuli arise from supraspinal centres. The main areas implicated are the hypothalamus and the limbic system.

Hypothalamic medial preoptic nucleus and paraventricular nucleus have been shown to influence erection in animal studies. Paraventricular nucleus receives inputs from medial preoptic area and integrates the inputs before sending downstream impulses to spinal cord. Stimulation of paraventricular nucleus results in erection. Other centres

which have been implicated are ventral tegmental area, medial dorsal nucleus of thalamus, cingulate gyrus and hippocampal region. Of particular importance is the nucleus paragigantocellularis which is located in the ventral medullary region. This nucleus sends descending inhibitory impulses to spinal sexual reflex.

Thus it appears that there exist many supraspinal centres which are extensively interconnected. The higher centre descending pathways which exerts strong excitatory and inhibitory control over the spinal mechanisms, are also involved in erection.(4)

NEUROPHYSIOLOGY OF EJACULATION

Normal ejaculation is under the control of autonomic nervous system. Ejaculatory process occurs in a two phase manner which includes emission and expulsion. Epididymis, vas deferens, seminal vesicles, prostate gland, prostatic urethra and bladder neck are involved in the emission phase, whereas expulsion phase involves bladder neck and urethra, and pelvic muscles.

EMISSION PHASE

Emission phase involves ejection of spermatozoa mixed with secretions from accessory sexual glands into the posterior prostatic urethra. It is mediated by smooth muscle contractions of the involved organs. Sympathetic innervation plays a major role in this phase. Sympathetic innervation comes from inferior hypogastric plexus. Nor-adrenaline is the primary neurotransmitter involved apart from acetylcholine, vasoactive intestinal peptide, neuropeptide Y and nitric oxide.

EXPULSION PHASE

During expulsion phase semen is ejected from posterior prostatic urethra to external urethral meatus. There occurs contraction of bladder neck to prevent retrograde ejaculation. The pelvic floor muscles, bulbospongiosus and ischiocavernosus also contract to generate rhythmic contractions to propel semen. Expulsion is a spinal cord reflex which occurs when ejaculatory process reaches a point of no return. Supraspinal sites are involved in the modulation of ejaculatory process. The areas identified are nucleus paragigantocellularis, paraventricular nucleus of the hypothalamus, and medial preoptic nucleus.(5)

ROLE OF SEROTONIN IN EJACULATION

Although various neurotransmitters are involved in the process of ejaculation, the role of serotonin has been consistently proved. The overall effect of serotonin on ejaculation is inhibitory. There are several receptor subtypes with opposing effects with some facilitating and others inhibiting ejaculation. $5HT_{1A}$, $5HT_{1B}$, $5HT_{2A}$ and $5HT_{7}$ are the receptor subtypes involved in control of ejaculation.(6)

ENDOCRINOLOGY OF MALE SEXUAL RESPONSE

Sexual activity is under the control of various hormones such as androgens, estrogens, and peptides such as prolactin, oxytocin, and endorphins. The role of these hormones and peptides in sexual activity are explained below.

ANDROGENS

Testosterone is an androgen which is essential for normal sexual activity. The role of androgens in sex differentiation is well established. Testosterone is essential for normal

sexual desire and this has been proven by studies wherein exogenous administration of testosterone in people with hypogonadism significantly increases libido and erectile response.(7)

OESTROGENS

Oestrogens have a negative effect on male sexuality. Exogenous administration of estrogens has shown to reduce sexual interest, erectile response and masturbatory behavior to erotic stimuli. (8)

PROLACTIN

Prolactin is a peptide hormone secreted from the anterior pituitary. Dopamine acts on the tubero-infundibular pathway and inhibits prolactin secretion. Serotonin increases the release of prolactin. The reproductive effects of chronic elevation of prolactin levels include reduced sexual drive, erectile and ejaculatory disturbances. This may partly explain the sexual adverse effects of antipsychotic drugs and SSRIs. The exact mechanism of hyperprolactinemia inducing sexual dysfunction, in not clearly understood. Although it is often associated with low testosterone levels, low sexual desire has been observed in even men with normal gonadal steroid hormone. This has evoked interest in the direct effect of prolactin in suppression of sexual activity.

The effects of oxytocin and endorphins in human sexual activity is also not clearly understood, however they may have possibly an inhibitory effect.

II.2.E. ROLE OF NEUROTRANSMITTERS

DOPAMINE

The overall effect of dopamine on sexual activity is facilitatory. It increases libido and erections. This has been proven by the fact that there is increase in sexual desire and erection in people taking antiparkinsonian medications which acts by increasing dopamine and low sexual desire and erectile dysfunction associated with antipsychotic medication which decrease central dopaminergic transmission.

SEROTONIN

Serotonin has variable effects on sexual functioning depending on the receptor subtype involved. Stimulation of $5HT_2$ subtype results in impaired sexual functioning while activation of $5HT_{1A}$ subtype results in facilitation of sexual activity. The evidence for the role of serotonin in sexual activity comes from the fact that SSRIs which increase serotonergic transmission can cause varied sexual side effects such as decreased libido, erectile dysfunction, delayed ejaculation and orgasmic difficulties.

ADRENALINE

Adrenaline plays a role in maintaining the penis in a flaccid state. Penis contains α_1 adrenergic receptors, the blockade of which produces penile erection. It also plays a role in penile detumescence following erection.

NORADRENALINE

Studies have shown that noradrenaline is important for sexual activity in men. There exists a positive correlation between plasma noradrenaline levels, sexual arousal and

erection in men. However the exact role of noradrenaline in phases of human sexual activity remains unclear.

ACETYLCHOLINE

Acetylcholine is a neurotransmitter released at parasympathetic nerve endings. Acetylcholine causes corpus cavernosal smooth muscle relaxation thereby facilitating penile erection. Animal studies have shown that increased cholinergic transmission causes rapid ejaculation.

II.3. TYPES OF MALE SEXUAL DYSFUNCTION

DSM IV TR has classified disorders of male sexual activity into those that are correlated with phases of sexual cycle and those that are not correlated with phases of sexual cycle. These disorders fall under seven main categories.

1. Sexual desire disorders.
2. Sexual arousal disorders.
3. Orgasm disorders.
4. Sexual pain disorders.
5. Sexual dysfunction caused by a general medical condition.
6. Substance induced sexual dysfunction.
7. Sexual dysfunction not otherwise specified.(9)

Table 2.1: DSM IV TR types of male sexual dysfunction

CATEGORY	DISORDER
Disorders of desire phase	Hypoactive sexual desire disorder Sexual aversion disorder
Disorders of excitement phase	Male erectile disorder
Disorders of orgasmic phase	Male orgasmic disorder Premature ejaculation
Disorders of resolution phase	Postcoital dysphoria Postcoital headache
Sexual pain disorders	Dyspareunia
Sexual dysfunction not otherwise specified	Orgasmic anhedonia Genital pain during masturbation

DSM IV-TR DIAGNOSTIC CRITERIA FOR INDIVIDUAL MALE SEXUAL DISORDERS

The DSM IV TR criteria (10) for diagnosing various types of sexual dysfunction are given in the following tables

Table 2.2: DSM IV TR Diagnostic criteria for various types of male sexual dysfunction

DSM-IV-TR Diagnostic Criteria for Hypoactive Sexual Desire Disorder

A. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity. The judgment of deficiency or absence is made by the clinician, taking into account factors that affect sexual functioning, such as age and the context of the person's life.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The sexual dysfunction is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

DSM-IV-TR Diagnostic Criteria for Sexual Aversion Disorder

A. Persistent or recurrent extreme aversion to, and avoidance of, all (or almost all) genital sexual contact with a sexual partner.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The sexual dysfunction is not better accounted for by another Axis I disorder (except another sexual dysfunction).

DSM-IV-TR Diagnostic Criteria for Male Erectile Disorder

A. Persistent or recurrent inability to attain, or to maintain until completion of the sexual activity, an adequate erection.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The erectile dysfunction is not better accounted for by another Axis I disorder (other than a sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

DSM-IV-TR Diagnostic Criteria for Male Orgasmic Disorder

A. Persistent or recurrent delay in, or absence of, orgasm following a normal sexual excitement phase during sexual activity that the clinician, taking into account the person's age, judges to be adequate in focus, intensity, and duration.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The orgasmic dysfunction is not better accounted for by another Axis I disorder (except another sexual dysfunction) and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

DSM-IV-TR Diagnostic Criteria for Premature Ejaculation

A. Persistent or recurrent ejaculation with minimal sexual stimulation before, on or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The premature ejaculation is not due exclusively to the direct effects of a substance (e.g., withdrawal from opioids).

DSM-IV-TR Diagnostic Criteria for Dyspareunia

A. Recurrent or persistent genital pain associated with sexual intercourse in either a male or a female.
B. The disturbance causes marked distress or interpersonal difficulty.
C. The disturbance is not caused exclusively by vaginismus or lack of lubrication, is not better accounted for by another Axis I disorder (except another sexual dysfunction), and is not due exclusively to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

Note: Each of the above disorders can be further specified depending on the following

1. Lifelong or acquired type
2. Generalized or situational type
3. Due to psychological factors or combined factors

II.4. PREVALENCE AND RISK FACTORS FOR MALE SEXUAL DYSFUNCTION IN GENERAL POPULATION

There are various physical and psychological factors which predispose, precipitate or maintain male sexual dysfunction. The Massachusetts Male Aging Study, a community based study, which was conducted in the United States from 1987 to 1989 showed that the overall prevalence of impotence was 52% in males aged 40 - 70 years. The prevalence of impotence increased from 5% at 40 years to 15% at 70 years. This study reported that age as the most strongly associated variable for impotence. Other risk factors identified were systemic hypertension, diabetes mellitus, cigarette smoking, heart disease, higher index of depression and anger, and concomitant medication use. The factors which were inversely associated with impotence were high density lipoprotein levels, serum dehydroepiandrosterone levels and dominant personality traits. (11)

Thus age constitutes an unmodifiable risk factor for sexual dysfunction in males, with the incidence of sexual dysfunction increasing as the individual's age increase. Apart from general changes in vascular endothelium associated with aging, various factors such as higher rate of medical comorbidities, increased use of prescription medications, increasing psychological problems etc can affect sexual functioning in this population.

Other studies have also described risk factors such as obesity, diabetes mellitus, elevated lipids, injuries or surgery of genitourinary tract and spinal cord, psychiatric and psychological conditions and substance abuse commonly alcohol and tobacco, and medications to correlate with sexual dysfunction.(1)(12)

II.4.A. SEXUAL DESIRE DISORDERS

The prevalence of sexual desire disorders is often underreported. A US based study shows a prevalence of 15% in one year in males aged 18-59 years.(13) Conditions which cause lifelong hypoactive sexual desire disorder include primary hypogonadism, gender identity disorder, developmental abnormalities, overly conservative cultural background, and sexual abuse. Acquired hypoactive sexual desire disorder can occur in both medical and psychological conditions. Medical disorders in which decreased sexual desire occurs are diabetes mellitus, hypothyroidism, Addison's disease, Cushing's disease, temporal lobe lesions, and chronic renal failure. Psychological conditions such as schizophrenia or depression can lead to decreased sexual desire as part of the clinical syndrome. In addition, drugs used to treat both these psychiatric conditions like antipsychotics, antidepressants or mood stabilizers can reduce libido.(14)

II.4.B. ERECTILE DYSFUNCTION

Erectile dysfunction is the second most common sexual disorder in men. The prevalence of erectile dysfunction varies across the age. A systematic review on population based studies showed the prevalence ranging from 2-9% in those younger than forty years to 18-86% in those above eighty years.(15) The table given below shows common etiological factors associated with erectile dysfunction.

Table 2.3: Etiology of erectile dysfunction

Psychological condition	Performance anxiety, discord with partner, depression.
Neurological conditions	Cerebrovascular diseases, Parkinson's disease, Alzheimer's disease, multiple sclerosis.
Endocrine conditions	Elevated prolactin, androgen deficiency, hypothyroidism, Diabetes Mellitus.
Vascular conditions	Hypertension, atherosclerosis.
Drugs and substance abuse	Beta-blockers, thiazide diuretics, antipsychotics, antidepressants, anti-androgens, alcohol and nicotine abuse.
Others	Pelvic surgery and irradiation, trauma to genitourinary tract.

II.4.C. DISORDERS OF EJACULATION

Disorders of ejaculation include a varied spectrum ranging from the most common type, premature ejaculation, to delayed ejaculation, retrograde ejaculation or anejaculation. Epidemiological data on premature ejaculation is not widely available due to problems in the definition of the disorder itself with various practitioners following different criteria. Available evidence suggests an overall prevalence of 5-40% in sexually active men. The exact prevalence of retarded ejaculation is also not available but some reports suggest it to be about 3% in the general population. The causes of retarded ejaculation includes medications such as antidepressants,

antipsychotics, diseases and trauma which affect sympathetic innervations and psychological factors(5)

II.4.D. PRIAPISM

Priapism is one of the rarest sexual disorders seen in male. It has an incidence rate of 1-5 per 100000 people and can occur at all age groups. Common causes for priapism include drugs such as antidepressants, antipsychotics, antihypertensive agents, phosphodiesterase inhibitors; hematological conditions such as sickle cell anemia, leukemia, thalassaemias; metabolic conditions such as Fabry's disease, amyloidosis, gout; trauma and tumors involving the genitourinary tract.(16)(17)

II.5. ASSESSMENT OF MALE SEXUAL DYSFUNCTION

A comprehensive assessment of an individual with sexual dysfunction includes a detailed history (medical, sexual, and psychiatric), physical examination, laboratory investigations and use of questionnaires to assess severity of sexual dysfunction**.**

HISTORY

A comprehensive sexual history includes relevant socio-demographic details, relationship status, sexual orientation, current sexual functioning (satisfaction – self & partner), type of dysfunction, onset (lifelong or acquired) and whether it is generalized or situational. If it is situational, whether it is only with one partner, only during masturbation, in socially proscribed situations, or in other definable circumstances such as late night, parental home, and for partner initiated sexual activity. Frequency of sexual activity and description of sexual interaction pattern (manner of initiation, foreplay, coital techniques and positions, and emotions after sex) also needs to be

elicited. Past sexual history should focus on previous relationships, success/failure and associated anxiety (spectator, performance and anticipatory anxiety). History related to sexual development across childhood, adolescence and adulthood including sexual misconceptions needs to be explored. Special issues like history of sexual abuse, rape, incest; partner abuse; presence or fear of sexually transmitted diseases; history of infertility; past abortions, fear of unwanted pregnancies; paraphilias and gender identity issues should be explored if relevant.

Psychiatric history should focus on coexisting psychiatric conditions such as psychosis, depression, anxiety, stressors, personality traits, and substance dependence. Medical history should focus on eliciting various medical causes for the condition, and current medications.

PHYSICAL EXAMINATION

General physical examination should focus on development of secondary sexual characteristics, assessment of peripheral pulses for vascular causes, breast examination for gynaecomastia, local penile examination for injuries, deformities, penile plaques etc, testicular examination for descent, asymmetry, atrophy or tumors, per rectal examination of prostate gland and complete neurological examination including cremasteric and anal reflexes.(18)

LABORATORY INVESTIGATIONS

The commonly done laboratory tests include fasting glucose and lipid profile, early morning serum testosterone (and if possible bioavailable testosterone measurement), prolactin, FSH and LH levels (if testosterone levels are low) and prostate specific antigen. In specific cases, special diagnostic tests like nocturnal penile

tumescence/rigidity testing, intracavernosal injections, duplex ultrasound of penile arteries and arteriography and dynamic infusion cavernosography may be required.(19)(20)

ORGANIC VERSUS FUNCTIONAL SEXUAL DISORDERS

Non-organic sexual disorders are commonly encountered in psychiatric practice. At times even when there is an organic causes, psychological element may be clearly seen. Distinguishing organic from psychogenic causes is an integral part of the evaluation process. Young age, absence of predisposing factors, sudden onset of symptoms, fluctuating course, situational or partner specific, presence of normal erection during masturbation or non coital sexual activity, and presence of nocturnal penile tumescence generally suggests psychogenic origin.(21)(22) Table 2.4 shows features which help differentiate the two.

Table 2.4: Features to differentiate organic versus functional sexual disorders

Factor	**Organic sexual dysfunction**	**Psychogenic sexual dysfunction**
Age	Usually older age	Usually younger age
Onset	Usually gradual in onset (except trauma or surgery related)	Usually acute onset
Course	Static or progressive	Fluctuating
Predisposing medical factors	Yes	May or may not be
Predisposing psychological factors	May or may not be	Yes
Exposure to offending drugs	Yes	May not be
Nature	Generalized to all situations	Situational
Type	Lifelong or acquired	Usually acquired
Nocturnal penile tumescence	Usually absent	Present
Investigations	Reveals a possible risk factor for organic cause.	Usually within normal limits.
Papaverine induced penile erection	No response	Positive response

II.6. RATING SCALES FOR ASSSESSING MALE SEXUAL DYSFUNCTION

There are various instruments that assess sexual functioning in men. These are discussed in brief below.

- Arizona Sexual Experience scale (ASEX) is a five item questionnaire with a six point Likert scale. It is a validated instrument but does not measure changes over time. It is either self or clinician administered. Items include sexual drive, arousal, penile erection/vaginal lubrication, ability to reach orgasm and satisfaction from orgasm.(23)(24)
- Derogates Interview for Sexual functioning (DISF) – It is a standardized 258-item self rated questionnaire assessing nine sexual domains. One of its criticisms has been that it is lengthy and time consuming.(25)
- International Index of Erectile Function (IIEF) is a reliable 15 item instrument which has been validated in many languages. It assesses sexual functioning in five domains ie erectile function, orgasmic function, sexual desire, sexual satisfaction and intercourse satisfaction.(26)
- The Changes in Sexual Functioning Questionnaire (CSFQ) is a 36 item instrument useful in both clinical and research setting. It has five domains and has been validated in several populations.(27)
- The Antipsychotics and Sexual Functioning Questionnaire (ASFQ) is a semi structured interview that can be completed in ten minutes. Preliminary evidence shows good face and content validity and reasonable reliability.(28)
- Antipsychotic Non Neurological Side Effect Rating Scale (ANNSERS) has a sexual side effect subscale which measures various domains of sexual dysfunction for both males and females on a four point severity scores. (29)
- Various other tools are available but their psychometric properties have not been systematically studied.

II.7. SEXUALITY IN SCHIZOPHRENIA

Schizophrenia is a heterogeneous psychotic disorder with varied symptom clusters and prognosis. Although it affects both the sexes equally, the age of onset is earlier and prognosis reported to be poorer in men. The peak age of onset of schizophrenia in men is between 15-25 years which is also the time when sexuality develops.

The symptom clusters in schizophrenia include positive symptoms such as delusions, hallucinations, disorganized behaviour; negative symptoms such as amotivation, alogia, asociality, affective flattening; and cognitive symptoms such as impairment in attention, memory disturbances, decreased speed of information processing, and visuospatial disturbances.

Sexual functioning in people with schizophrenia has received scant attention. The frequency of the problem and patient's distress are widely underestimated.(30) This is complicated by various misconceptions which existed, even among clinicians, till recently. It was believed that discussing sexual issues with people schizophrenia is inappropriate as they should not involve in sexual activity and that excess sexual activity could contribute to the development of illness. This is further complicated by the poor understanding of the natural history of sexuality in this population.(31)

Any effort in addressing sexual issues in schizophrenia should first look into the prevalence of the same and the burden imposed by it. Various studies have shown that the prevalence of sexual dysfunction in this population is around 50%. However, more recent studies have reported that up to 80% of patients with schizophrenia who are on medications have some form of sexual difficulty. Sexual dysfunction, apart from causing individual distress and partner dissatisfaction, is also an important reason for non adherence to prescribed medications. It has also been associated with decreased subjective quality of life.(32)

There is a complex relationship between sexuality and schizophrenia. The age of onset of illness parallels with that of the reproductive age group. It is during this period that the plasma levels of reproductive hormones peak. Studies have shown that as compared to normal subjects, males with schizophrenia have lower levels of gonadotrophins and testosterone even in those who are not exposed to antipsychotic medications. Therefore it is possible that these patients might have an underlying hypogonadism even before treatment with antipsychotic drugs. Whether the observed hypogonadism has a causative role in the illness or its part of the illness is not yet completely understood(31)

Lack of sexual activity in people with untreated schizophrenia has been reported. This could be due to lack of interest and anhedonia as part of negative syndrome. Lack of social relationships, secondary to deficits in social skills or associated low self confidence may be another reason for this. Psychotic symptoms can itself be a reason for not involving in sexual activity. Personality traits (neuroticism) have been proven to be a significant predictor of sexual functioning in this population.(33)(34)

II.8. ANTIPSYCHOTIC MEDICATIONS

The therapeutic options in the treatment of schizophrenia and other psychotic disorders have increased tremendously over the past fifty years, since the introduction of chlorpromazine. In current practice, pharmacological and psychosocial approaches are part of a comprehensive treatment program. However, antipsychotic drugs continue to be the mainstay of treatment in patients with acute psychosis or schizophrenia. Its role in control of acute symptoms and maintenance of remission and relapse prevention is well documented.

Antipsychotic drugs are broadly classified into typical or first generation antipsychotics and atypical or second generation antipsychotic drugs.

MECHANISM OF ACTION OF TYPICAL ANTIPSYCHOTIC MEDICATIONS

In vitro and functional neuroimaging studies have consistently shown the role of dopamine receptor blockade as the mechanism of action for antipsychotic effect and adverse effects of typical antipsychotics. Dopaminergic neurons project through various pathways in the central nervous system. The four major pathways of central dopaminergic system include the mesolimbic, mesocortical, tubero-infundibular and nigrostriatal pathways. First generation antipsychotics block the D_2 dopamine receptors in these pathways. Antagonism of dopamine receptors in the mesolimbic pathway accounts for clinical improvement in psychotic symptoms. Nigrostriatal and tubero-infundibular pathway blockade results in extra pyramidal symptoms and hyperprolactinemia respectively.(35)

MECHANISM OF ACTION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Atypical antipsychotic drugs, also called serotonin dopamine antagonists has a differential action on both dopamine and serotonin receptors. There exist two theories regarding its mechanism of action – serotonin dopamine antagonism and fast off D_2 theory.

Serotonin dopamine antagonism theory proposed by Meltzer states that there exists a differential blockade with higher affinity for $5HT_{2A}$ receptors than the D_2 receptors. This might explain the lower propensity of atypical antipsychotics to produce extrapyramidal side effects(36). Functional neuroimaging studies show that at

therapeutic doses atypical drugs occupy 70% of D_2 receptors and 80% of $5HT_{2A}$ receptors. However Clozapine and quetiapine occupy less than 70% of dopamine receptors.

The other theory which explains action of atypical antipsychotic drugs is fast dissociation theory. Under this theory it is hypothesized that for clinical efficacy of drugs, a sustained blockade of dopamine receptors is not required. Atypical antipsychotics exhibit faster dissociation rate from D_2 receptor thereby mimicking endogenous dopamine transmission with resultant reduced extrapyramidal adverse effects.(37)

II.9. ANTIPSYCHOTIC DRUGS AND SEXUAL ADVERSE EFFECTS

It is well known that antipsychotic medications cause sexual dysfunction. Even though it is one of the most distressing adverse effects, it is not very commonly reported. Clinicians often do not ask patients about their sexual functioning. This may in part be due to their bias, lack of skills or knowledge. Patients with schizophrenia are often reticent to discuss their sexual difficulties. Sexual adverse effects have been reported to be one of the reasons for noncompliance to medications and poor quality of life.(38)

MECHANISMS OF SEXUAL DYSFUNCTION DUE TO ANTIPSYCHOTIC DRUGS

As has been described earlier, antipsychotic drugs have their action on various receptors like dopamine, serotonin, muscarinic acetylcholine, noradrenergic and histaminergic receptors. The effects on various receptors can affect various phases of sexual activity in different manner as described in table 2.5. Moreover extrapyramidal side effects by impairing motor activity can also mimic sexual dysfunction. In addition

to the above mechanisms, metabolic adverse effects such as diabetes mellitus, elevated lipids etc are individual risk factors for erectile dysfunction.(39)

Table 2.5: Mechanisms of sexual dysfunction with antipsychotic medications

RECEPTOR ACTION	PHYSIOLOGICAL ACTION	SEXUAL ADVERSE EFFECT
Histamine receptor blockade	Sedation	Impaired sexual arousal
Dopamine receptor blockade	Reduced motivation and reward	Decreased sexual desire
Dopamine D2 receptor blockade (tubero-infundibular pathway)	Elevated prolactin level	Decreased sexual desire, erectile dysfunction, orgasmic disturbance
Acetylcholine receptor antagonism	Reduced peripheral vasodilatation	Erectile dysfunction
Alpha adrenergic receptor antagonism	Reduced peripheral vasodilatation	Erectile dysfunction, impaired ejaculation

II.10. HYPERPROLACTINEMIA AND SEXUAL DYSFUNCTION

Hyperprolactinemia has been consistently shown as an important cause for sexual dysfunction due to antipsychotic medication. Under physiological conditions prolactin secretion is under tonic inhibition from hypothalamic input. Dopamine is a mediator of this inhibitory action. Hyperprolactinemia is diagnosed if the prolactin level exceeds the upper limits of normal range which in males and prepubertal girls is 18 ng/ml; and 29 ng/ml for premenopausal women; 20 ng/ml in postmenopausal women. Antipsychotics by antagonizing D_2 receptors take away this inhibitory control and leads to hyperprolactinemia. The trajectory of prolactin rise is such that it increases to 2-10 folds within a week of commencing antipsychotic drug and continues to be elevated until the drug is discontinued. Prolactin levels return to normal within two to three weeks after stoppage of treatment but may take a longer duration in case of depot

preparations. (40). Thus there is both a short term rise of prolactin levels with a single dose and long term rise with continued use of antipsychotic medications(41). Inder WJ and Castle D in a review found up to 70% of patients with schizophrenia had antipsychotic drug induced hyperprolactinemia(42). Although the incidence of hyperprolactinemia is greater with typical antipsychotics, serotonin dopamine antagonists also can cause prolactin rise.(43) (44) Risperidone has the highest potential to cause hyperprolactinemia among the atypical antipsychotics probably due to poor crossing of blood brain barrier thereby exposing tubero-infundibular pathway to higher concentrations of drug. Higher prolactin levels are thought to result from prolonged exposure at high doses and more with high potency typical antipsychotic medications.(45) Hyperprolactinemia in males causes secondary decrease in testosterone due to feedback inhibition of FSH and LH.(46)(47)(48). Hyperprolactinemia with levels greater than 35 ng/ml has been shown to negatively impact sexual functioning with reduced desire and erectile dysfunction.(49). Hyperprolactinemia apart from causing sexual dysfunction has other adverse effects involving reproductive system, cardiovascular disease and bone mineral density. (50)(51)

In a study which compared the effect of Risperidone and Olanzapine on reproductive hormone levels, Konarzewska et al reported that the Risperidone group had higher prolactin levels. More subjects in the Risperidone group (10%) had testosterone levels below lower limits than Olanzapine group (2.6%).(52). Similar results were obtained by Westheide et al in a four week open trial of Quetiapine versus Risperidone with the latter raising prolactin levels much higher than the former.(53) In contrast, a cross sectional study by Johnsen et al in male patients with psychosis, hyperprolactinemia

was not significantly associated with sexual dysfunction. This study was done on a small group of patients and its sample size was a limitation.(54)

II.11. PREVALENCE AND TYPES OF SEXUAL DYSFUNCTION WITH ANTIPSYCHOTIC MEDICATIONS

Antipsychotic medications can cause various types of male sexual dysfunction. In patients taking conventional antipsychotics commonly reported adverse sexual effects are erectile disturbance and ejaculatory disturbances. The prevalence ranges from 30 to 60% in patients treated with either typical antipsychotic medication or Risperidone(55). Decreased libido and orgasmic difficulties have also been reported. Priapism is a rare antipsychotic related sexual dysfunction. Almost 20% of all drug induced priapism is attributable to antipsychotic medication. Antipsychotic drugs with a high α adrenergic blocking activity has higher risk for causing priapism.(56)

Bhui et al in a study on 53 patients with chronic psychosis found that 47.5% of the men had sexual difficulties. This study included patients who were managed in the community and used structured diagnostic interview for sexual and marital satisfaction and a semi structured clinical interview to confirm diagnosis.(57)

Kockkott and Pfeiffer found that 49% of outpatients with schizophrenia had sexual dysfunction as compared to 36.2 % in those with mood disorders (n = 58) and 13.3% in control groups. This study recruited outpatients who were relatively stable. Control group was those patients who were on dermatological treatment.(58)

Smith et al in a cross sectional study, assessing sexual dysfunction in patients taking conventional antipsychotic medications found that 45% of subjects reported sexual dysfunction as compared to 16% among normal controls. This study demonstrated that

age, depressive symptoms, greater anticholinergic and anti-adrenergic side effects and higher doses of medications were associated with sexual dysfunction. However, this association ceases if the patient develops raised prolactin levels. The authors also describe the role of sexual side effects in non-compliance with prescribed medications. (59)

Mac Donald et al in a case control study as part of Nithsdale Schizophrenia Survey in Scotland, found that 82% of males with schizophrenia reported at least one sexual dysfunction, 27% patients did not masturbate or have sexual intercourse; 52% reported reduced sexual desire, 52% had erectile dysfunction, 35% reported premature ejaculation and 33% reported orgasmic dissatisfaction. Sexual functioning was assessed using a self completed questionnaire specific for each gender in this survey(60)

Khawaja assessed sexual dysfunction using Arizona Sexual Experience Scale compared patients on antipsychotics and normal controls in Pakistan found erectile dysfunction (48%) and ejaculatory disturbances (45%) as two major sexual dysfunctions associated with antipsychotic therapy.(61)

Compton and Miller reviewed existing literature on antipsychotic induced priapism. They found Thioridazine and Chlorpromazine to be more frequently associated with priapism due to their higher alpha adrenergic blockade. They concluded that all antipsychotics have been reported to cause this urological emergency as a rare side effect.(62)

Acuna et al compared sexual functioning among patients with schizophrenia (institutionalized and living in the community) and normal control group. 71.2% males in the institutionalized group reported some form of sexual dysfunction.(63) Similarly Harley reported 74% of male patients had at least one type of sexual dysfunction defined by ICD-10 in a cross sectional study from United Kingdom. (64)

Mahmoud et al assessed sexual functioning and its correlation to quality of life in patients with schizophrenia who were switched from a first generation antipsychotic to another antipsychotic (FGA or SGA) in a randomized trial. All patients completed the twelve weeks trial and it was reported that sexual functioning improved in those who were switched to a second generation antipsychotic as compared to a first generation antipsychotic. However there was no correlation between quality of life and sexual functioning in this study. (65) These authors in a subsequent report of a cross sectional study on 144 subjects aged 18 -65 years found that the prevalence of sexual dysfunction among those on first generation antipsychotic agents and second generation antipsychotic did not show a significant difference between the groups. Both the groups were on medications for at least twelve weeks. (66)

Baggaley in a recent review concluded that the relative impact on sexual dysfunction by antipsychotic medication can be summarized as Risperidone> Typical antipsychotic (Haloperidol) > Olanzapine > Quetiapine > Aripiprazole; with Risperidone causing most side effects and Aripiprazole the least.(67)

Kelly and Conley randomized twenty seven patients in a twelve week randomized double blind trial to receive Fluphenazine, Risperidone or Quetiapine. They reported rates of sexual dysfunction rates as 78%, 42% and 50% respectively.(68)

Kheng et al found a high prevalence of sexual dysfunction (78.4%-91.1%) in a study where 144 remitted male patients with schizophrenia were assessed with the Malay version of IIEF. Orgasmic dysfunction was the least affected while intercourse satisfaction was the most affected. These investigators also found a significant association between race and educational status with orgasmic dysfunction; total PANSS positive score was found to be protective for the same.(69)

Marques et al studied the prevalence of sexual dysfunction in three groups of patients – thirty one people who were at high risk for a psychotic disorder, thirty seven with first episode psychosis and a control group involving fifty seven healthy subjects using the Sexual Function Questionnaire. The prevalence rate was 65% in the first episode psychosis group, 50% in ultra high risk group for psychotic disorders and 21% in healthy controls. There was no significant difference between those taking prolactin sparing versus prolactin raising antipsychotic medication among the first episode psychosis group.(70)

In European First Episode Schizophrenia Trial (EUFEST), Malik et al found higher age, higher prolactin levels and higher PANSS general psychopathology scores were predictors of erectile and ejaculatory dysfunction in men. This study was done as part of EUFEST, a multi-centric study across Europe. Patients with first episode of schizophrenia (n = 498) were randomized into five treatment groups (Haloperidol, Olanzapine, Amisulpiride, Quetiapine and Ziprasidone) and sexual functioning assessment was done over a one year period, using a part of UKU scale at baseline and at five follow up periods. However, they did not find a significant change in the prevalence of sexual dysfunctions from baseline to one year. The differences in prevalence between the medications groups were also not significant. (71)

A large study on sexual dysfunction in patients with schizophrenia treated with antipsychotics for the first time was done by Bitter and his colleagues. This study included 570 patients with schizophrenia who were part of Intercontinental Schizophrenia-Outpatient Health Outcome Observational study (IC - SOHO). Evaluations were done at baseline, three and six months of antipsychotic treatment. Patients and the investigator were asked to rate sexual functioning and effects related to antipsychotic drug. This study while acknowledging the possible limitations reported

that significant differences in sexual dysfunction across the medication groups were present with Olanzapine treated patients showing least prevalence.(72)

Oyekanmi et al studied sexual dysfunction among south western Nigerian male patients on conventional antipsychotic medication. They found 40.4% of the study participants had at least one type of sexual dysfunction and erectile dysfunction was the most prevalent type. Significant associations were found between sexual dysfunction and age, marital status, employment status, haloperidol usage, dose of the medications and the presence of psychopathology.(73)

Serretti and Chiesa in a meta-analysis on sexual dysfunction in patients treated with antipsychotics found significant differences in prevalence between the prolactin sparing (16-27%) and raising groups (40-60%). The primary outcome in this analysis was the overall rate of sexual dysfunction whereas the secondary outcomes were the rates of specific types of sexual dysfunction like decreased libido, erectile dysfunction and orgasmic dysfunction. The lowest rate of sexual dysfunction was found among the Quetiapine group. Ziprasidone, Perphenazine and Aripiprazole were associated with an increased likelihood of sexual dysfunction although relatively low. Increasing associations for higher rate of sexual dysfunction was found for Olanzapine, Risperidone, Haloperidol, Clozapine and Thioridazine in this order. (74)

Howes et al studied the rates of hypogonadism and sexual dysfunction and their relationship in antipsychotic treated patients with schizophrenia or schizoaffective disorder. They found the odds ratio of patient having sexual dysfunction was 3.7 in men as compared to controls. The study also showed 28% of men had hypotestosteronism but didn’t find association between the sexual functioning scores and gonadal hormone levels.(75)

Bobes et al in the EIRE study assessed sexual and other reproductive adverse effects in patients taking Haloperidol, Risperidone, Olanzapine and Quetiapine found the highest rate of sexual dysfunction with Risperidone (43.2%) followed by Haloperidol (38.1%), Olanzapine (35.3%) and Quetiapine (18.2%). The authors concluded that none of the atypical agents studied improved the sexual dysfunction profile except for Quetiapine on a short term therapy.(76)

Cutler reviewed antipsychotic treatment and sexual dysfunction and found atypical drugs had several advantages over the typical in terms of sexual functioning. The author opined that Quetiapine's tolerability profile might benefit many patients.(77)

Nebhinani et al compared sexual dysfunction among Indian patients who were on stable dose of Olanzapine, Risperidone or Trifluoperazine. They assessed sexual functioning using three scales - ASEX, Psychotropic Related Sexual Dysfunction Questionnaire and UKU and found variable prevalence 25%, 37% and 40% respectively across the scales. The highest rate of sexual dysfunction was in the Risperidone group followed by Trifluoperazine and Olanzapine.(78)

In the STAR study, a multi-centric open label trial, 555 patients with schizophrenia were randomized to two groups, to receive either Aripiprazole or standard care (Risperidone, Olanzapine and Quetiapine) for twenty six weeks. Outcome assessments were done using ASEX. The study results revealed that the patient report of sexual dysfunction was significantly lower with Aripiprazole than the other drugs. The mean serum prolactin level was also lower in the Aripiprazole group.(79)

In an open label study by Montejo AL et al on patients who were treated with Aripiprazole either as first line agent or switched to due to lack of efficacy, found that none of these patients developed sexual dysfunction at the end of three months of therapy. (80)

Although Clozapine is an atypical antipsychotic agent, the rate of sexual adverse effects is reported to be similar to that of typical antipsychotics. This was demonstrated in a longitudinal study of schizophrenic or schizophreniform disorder (based on DSM III criteria) by Hummer et al between 1989-1996 comparing rates of sexual dysfunction among the two groups of patients (Haloperidol n = 53 or Clozapine n = 100). Sexual adverse effects were assessed using UKU side effect rating scale.(81) However, Wirshing et al prospectively assessed sexual functioning in three different medication groups - Clozapine, Risperidone and Haloperidol/Trifluoperazine. The overall sexual dysfunction rate ranged from 40-71% among the three groups. Decreased libido was highest in the typical agent group. Risperidone treated patients had highest decline in erectile frequency and orgasmic dysfunction. Clozapine had a relatively lesser side effects across all domains of sexual functioning.(82)

La Torre A et al reviewed existing literature on antipsychotic related sexual dysfunction. The criticisms about current literature has been small sample sizes, cross sectional nature of studies, absence of a control group, and that most studies have not used validated instruments for assessment. However, they reported consistent evidence that a majority of antipsychotic medications adversely affects one or more phases of sexual response cycle, with prolactin raising antipsychotics being the most widely associated.(83)

II.12. METHODOLOGICAL LIMITATIONS OF CURRENT LITERATURE IN THIS TOPIC

In the early part of this century there were only case reports of sexual dysfunction in the mentally ill. Most of these were attributed to as drug induced. However, there is a large volume of evidence to suggest sexual difficulties in patients with schizophrenia. But there are several methodological issues which weaken previously published reports on sexual dysfunction in patients with schizophrenia.

These include cross sectional nature of designs, absence of any large longitudinal studies, absence of control groups, focus on one gender, involving only married subjects or subjects with a partner, including long stay inpatients only or patients taking conventional antipsychotic medications and using instruments which are not validated for assessment. Literature on sexual dysfunction on drug naïve patients with schizophrenia is limited and there are literally no studies from the Indian subcontinent.

Patients with schizophrenia generally do not complain of this side effect unless specifically asked, in spite of this being one of the most distressing adverse effects. The problems in assessing sexual functioning in schizophrenic patients include poor co-operation from the patient due to psychopathology or poor motivation to discuss these issues due to lack of distress. Moreover cognitive disturbances, either due to illness per se or secondary to medications impair their ability to comprehend aspects of sexual history thus making the assessment process difficult and impairing the validity of their responses. In addition poor social skills with related anxiety might inhibit them from discussing the sexual issues with the therapist.

Thus sexual dysfunction in schizophrenia has multiple aetiological factors. Antipsychotic induced sexual dysfunction constitutes an important cause which often is under recognised due to poor reporting by patients and also therapist attitude of not

routinely asking for such adverse effects. This is highlighted by the results of the survey conducted by Nnaji in Lincolnshire, who reported that two thirds of psychiatrists didn't routinely enquire for sexual dysfunction despite a majority (88%) agreeing about the importance of good sexual functioning to their patients. Only 17% of them felt competent in assessing sexual functioning.(84)

II.13. TREATMENT OF ANTIPSYCHOTIC INDUCED SEXUAL DYSFUNCTION

A comprehensive approach to the treatment of antipsychotic induced sexual dysfunction involves careful history taking including the nature of the dysfunction, and a detailed physical and/or laboratory examination to rule out other organic causes. Psychogenic factors should be evaluated as it can be an important maintaining factor.

The available literature on management of antipsychotic induced sexual dysfunction is scarce with only a few well controlled randomised trials existing.

Schmidt et al reviewed the existing literature on various strategies for the treatment of antipsychotic induced sexual dysfunction. Their review included four pioneering studies. One study used Sildenafil and the other study tried Selegiline in managing sexual dysfunction. The third study looked at switching to Quetiapine from Risperidone. The fourth study switched to Olanzapine either from Risperidone or a typical agent. The authors concluded that Sildenafil may be effective in the treatment of antipsychotic induced erectile disorder. Furthermore they stated that switching to Olanzapine might improve sexual function functioning in both genders.(85)

Costa systematically reviewed and described a step wise algorithm for the management of antipsychotic induced sexual dysfunction. The successive steps involve reducing the dosage of the offending antipsychotic drug, switching to another antipsychotic

medication or using concomitant medication targeting the sexual symptoms.(86) There is evidence from a small open label study by Mir et al that switching or adding Aripiprazole reduced sexual dysfunction.(87)

Gopalakrishnan et al in a randomised cross over trial studied the efficacy of flexible dose of sildenafil on thirty two patients with antipsychotic induced erectile dysfunction. Sildenafil significantly improved the number of adequate erections, duration of erections and sexual intercourse satisfaction among these patients. No major adverse effects or drug interactions were reported. The authors concluded that sildenafil is safe, effective and tolerable in the treatment of erectile dysfunction induced by antipsychotic medication.(88) Other pharmacological agents that have been tried include Amantadine, Cabergoline, Cyproheptadine and Selegiline.(86) However the evidence for their efficacy is lacking.

III.AIM AND OBJECTIVES OF THE STUDY

III.1. AIM OF THE STUDY

- This study assessed sexual functioning in men with psychosis.

III.2. SPECIFIC OBJECTIVES OF THE STUDY

- To determine the prevalence, nature and risk factors of sexual dysfunction in drug naïve male patients with psychosis.
- To determine the incidence of sexual dysfunction in male patients with psychosis on antipsychotic medication.
- To identify risk factors that predict emergence of sexual dysfunction in male patients with psychosis on antipsychotic medication.

IV.METHODOLOGY

IV.1. STUDY DESIGN

This observational study involved a cohort of men with a diagnosis of psychosis, who were assessed prior to onset of treatment and again during the course of treatment.

IV.2. STUDY SETTING AND SITE

The study population was patients attending the outpatient clinics and/or admitted into the ward at the Department of Psychiatry, Christian Medical College, Vellore. This 122-bed hospital provides short-term care for patients with a range of psychiatric diagnoses from the town of Vellore and a wider rural area beyond. It also functions as a tertiary referral centre for management of patients with mental and behavioral disorders from different parts of India. The emphasis is on a multidisciplinary approach and eclectic care, using a wide variety of pharmacological and psychological therapies. The hospital has a daily outpatient clinic in which 450-500 patients are seen.

Patients were recruited over a period of 11 months from December 2012 to October 2013. Following recruitment participants were interviewed at three points in time. The first was at initial presentation to the hospital when in a drug naïve state or when off antipsychotic medications for at least six months. The second and third assessments were done at six weeks and six months after initiating antipsychotic medication. All patients received treatment as usual.

IV.3.SUBJECTS

Subjects were chosen from those attending the outpatient clinic at the Department of Psychiatry based on the following criteria:

Inclusion criteria

1. Men aged between 18 and 60 years.
2. Tamil speaking and resident of Tamil Nadu state, India.
3. Diagnosis of Acute and transient psychotic disorder (F 23) or Schizophrenia (F 20), based on International Classification of Diseases - 10 (ICD-10) research diagnostic criteria (WHO, 1992).

Exclusion criteria

1. Subjects with a history of antipsychotic exposure within the past six months.
2. Subjects with severe language, hearing or cognitive impairment.
3. Patients with a diagnosis of primary mood disorder, substance use disorder and organic disorders.
4. Co-morbid medical and surgical disorders which affect sexual functioning.
5. Concomitant use of other medications which can have adverse sexual effects.
6. Patients who were unable to participate due to severity of psychosis.

IV.4. PROCEDURE

IV.4.A. Sampling

Consecutive patients who attended the outpatient clinic, who fulfilled criteria for inclusion, were invited to take part in the study. Informed consent was obtained from the patient and his caregiver.

IV.4.B. Variables assessed

Sexual functioning of all subjects who consented to take part in the study was assessed at baseline, six weeks and six months using the Tamil version of the International Index of

Erectile Function scale (IIEF) and diagnoses were made in accordance to DSM IV TR criteria for male sexual dysfunctions. Neurological adverse drug effects were measured using UKU side effect rating scale. Sociodemographic data and clinical variables were recorded in a specially designed proforma. Severity of illness was assessed using the Positive and Negative Syndrome Scale (PANSS). All these assessments were done at three points of time. Serum testosterone and serum sex hormone binding globulin levels were tested at baseline and after six months of antipsychotic drug therapy. Free testosterone indices were calculated.

Table 4.1: List of assessments at the three points of time

Baseline	Six weeks	Six months
Sociodemographic variables	PANSS	PANSS
PANSS	IIEF	IIEF
IIEF	UKU	UKU
UKU	Height, weight and BMI	Height, weight and BMI
Height, weight and BMI	Medication dose and duration	Serum testosterone level
Serum testosterone level		Serum sex hormone binding globulin
Serum sex hormone binding globulin		Free testosterone index
Free testosterone index		Medication dose and duration

IV.4.C. Data measurement

The following instruments were used in the study

- Positive and Negative Syndrome Scale (PANSS) for assessing severity of psychopathology (Appendix: 4)

- UKU scale (Section 2: Neurological side effects) for assessing the severity of neurological adverse drug effects (Appendix: 8)

- International Index of Erectile Function scale (IIEF) for screening for sexual dysfunction (Appendix: 5)

- Additional questions to assess for diagnosis of male sexual dysfunction based on DSM IV TR (Appendix: 6)

- Proforma for recording socio-demographic and clinical variables (Appendix: 3)

IV.4.C.1 Positive and Negative Syndrome Scale (PANSS)

The PANSS (Kay et al, 1986) is designed to assess symptom profile. It is an operationalized, standardized, instrument which is widely used in clinical and research settings. It provides a balanced representation of positive and negative symptoms and assesses their relationship with one another and to global psychopathology. It is used to evaluate persons with schizophrenia and other psychotic disorders. It is a 30 item scale with subscales (Positive -7 items, Negative -7 items and General psychopathology -16 items). The severity scores range from 1-7 for each item. It serves for both typological evaluation of the symptoms and also its dimensions.(89)

IV.4.C.2 International Index of Erectile Function Scale (IIEF)

The IIEF (Rosen RC et al., 1997) is used to screen for sexual dysfunction in men. It is a 15-item questionnaire, which has been developed as a brief, multidimensional self-report instrument for assessing the key dimensions of sexual function in men. IIEF although primarily assesses the erectile functioning, it also has items for assessing sexual desire, orgasmic function, intercourse satisfaction and overall satisfaction It is psychometrically sound, easy to administer, and has demonstrated ability to discriminate between clinical and nonclinical populations. The questionnaire was designed and validated for assessment of male sexual function in clinical trials or

epidemiological studies. (26) It has been validated in ten languages. The validated Tamil version of IIEF was used in this study. The instrument is sensitive and specific for detecting changes in erectile dysfunction due to treatment.

IV.4.C.3. Udvalg for Kliniske Undersogelser Scale (UKU side effect rating scale)

UKU side effect rating scale (Lingjaerde, Ahlfors et al., 1987) is designed to have a comprehensive assessment of adverse effects due to psychopharmacological agents. It is a well defined and operationalized instrument. It is a 48 item semi-structured questionnaire assessing four domains of adverse drug effects viz psychic, neurological, and autonomic and others. Each item is rated on a four point severity scores (0-3). The neurological adverse effect domain has eight categories. The eight items are dystonia, rigidity, hypokinesia/ akinesia, hyperkinesia logic, tremor, akathisia, epileptic seizures and paraesthesias. The maximum possible score under this domain is 24 and the minimum score is zero.(90)

IV.4.C.4. Testosterone and Serum sex hormone binding globulin

Testosterone levels and serum sex hormone binding globulin levels were measured at baseline and at six months. Testosterone was measured using indirect chemiluminescence method with the machine Immulite 2000. Sex hormone binding globulin was measured using electrochemiluminescence method employing the machine Roche modulare 170. Free testosterone indices were calculated based on testosterone and sex hormone binding globulin levels using standardized formula given by this laboratory. The normal ranges of values for adult males as stated by this laboratory are as follows

Table 4.2: Normal biochemical ranges of testosterone, sex hormone binding globulin and free testosterone index

Testosterone	
Adult males aged 20-49 years:	270-1030 ng/dl
Adult males aged above 50 years:	212-755 ng/dl
Serum sex hormone binding globulin (adult males):	14.5 -48.4 nmol/L
Free testosterone index (adult males):	33.8 – 106%

IV.5. STATISTICAL METHODS

IV.5.A. DETERMINATION OF SAMPLE SIZE

The sample size for the study was determined using the computer package Epi Info (Version 6.0) (1993). The calculations were based on the following assumptions: Estimated prevalence of sexual dysfunction in men on antipsychotic medication 50% (based on an earlier study) (31) confidence interval 95%; power 80%. The sample size thus obtained was 100.

IV.5.B. DATA ANALYSIS

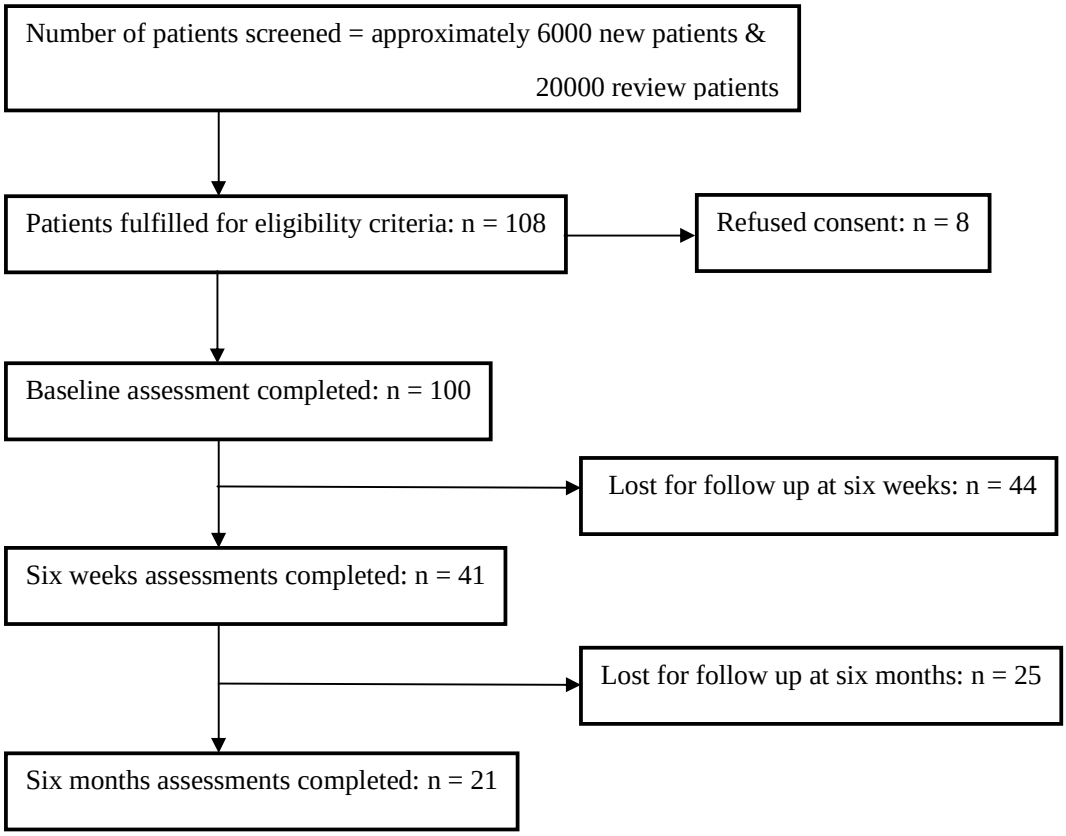
Mean, standard deviation and range were employed to describe continuous variables, while frequency distributions were obtained for di/polychotomous variables. The chi-squared test was used to assess the significance of associations for categorical data; student's t test was used to test associations for continuous variables. One way ANOVA with Tukey post hoc test was done to assess association for continuous variables for more than two groups. Pearson's correlation coefficient was employed to study the correlation between continuous variables. The statistical software package - SPSS for Windows (version 16.0.1) was employed for the analysis of data.

IV. RESULTS

The study, with a longitudinal prospective design, assessed sexual functioning in a cohort of men with psychotic disorders, who were either drug naïve or has been off antipsychotic medication for at least six months. One hundred and eight patients, who fulfilled the inclusion criteria, were invited to take part in the study. Eight patients refused consent and hence were not included. The most common cause (six out of eight) for refusing consent was unwillingness to participate in the study at that time.

One hundred patients were assessed after obtaining informed consent. Baseline assessments were done for all the hundred patients. Six week follow-up was conducted on 41 patients and six month follow-up on 21 patients. The study is ongoing at the time of this analysis.

Figure 5.1: FLOWCHART OF THE STUDY



The sociodemographic and clinical characteristics at baseline of the patients who refused consent and those who participated in the study were not statistically different.

V.1. SOCIODEMOGRAPHIC CHARACTERISTICS

Socio-demographic details are summarized in table - 5.1 & 5.2. The mean age of the participants was 31.09 years (SD ± 8.43). 58% of the study population was single, 36% were married and 5% were separated from their spouse and one participant was divorced. The mean age of the spouse was 31.56 years (SD ± 6.5). The mean duration of marriage was 11.62 years (SD ± 8.0). More than half of the study participants reported that they did not have a current sexual partner, whereas 41% reported having a single sexual partner and 4% reported multiple sexual partners.

The majority of the participants belonged to Hindu religion (88%), and 92% were from a rural background. 62% could only read, 22% could read and write and 16% were illiterate. The mean years of schooling was 9.51 (SD ± 4.5). However, 75% of the patients and 54% of the spouses were employed. Majority (76%) owned their house, and 73% lived in a concrete house. 49% of study subjects reported that they had a separate room for themselves.

The mean monthly income of the family and patient were 6113.00 INR (SD ± 8308.69) and 1785.00 INR (SD ± 4370.47) respectively. 69% reported having debt and 3% reported that they couldn’t afford food in the last one month.

Table 5.1: Socio-demographic characteristics

Data	Range	Mean	Standard deviation
Age of the patient in years (n = 100)	35	31.09	8.43
Age of the spouse in years (n = 39)	23	31.56	6.49
Duration of marriage in years (n = 40)	24.9	11.61	7.95
Years of schooling (n = 100)	19	9.51	4.49
Family's monthly income (INR) (n = 100)	40000	6113.00	8303.69
Patient's monthly income (INR) (n = 100)	30000	1785.00	4370.47

Table 5.2: Socio-demographic characteristics

Data	Frequency	Percentage
Marital status		
Single	58	58%
Married	36	36%
Separated	5	5%
Divorced	1	1%
No. of sexual partners		
No sexual partner	55	55%
Single sexual partner	41	41%
Multiple sexual partners	4	4%
Occupation of the patient		
Employed	75	75%
Unemployed	25	25%
Occupation of the spouse (n = 39)		
Employed	21	54%
Unemployed	18	46%
Religion		
Hindu	88	88%
Christian	6	6%
Muslim	6	6%
Separate bedroom		

Yes	49	49%
No	51	51%
Residence		
Rural	92	92%
Urban	8	8%
Literacy		
Illiterate	16	16%
Read only	62	62%
Read and write	22	22%
House ownership		
Own	76	76%
Rented	23	23%
Squatting	1	1%
Type of house		
Concrete with > 2 rooms	15	15%
Concrete with 2 or < 2 rooms	58	58%
Mud thatched house	27	27%
Unable to buy food in last one month		
No	97	97%
Yes	3	3%
Debt		
Yes	69	69%
No	31	31%

V.2. BASELINE CLINICAL CHARACTERISTICS

Majority (87%) of the patients was diagnosed to have schizophrenia. In most (89%) of the patients the age of onset of illness was below 40 years of age (mean of 28.27±7.59 years). The mean duration of illness was 33.19 months (SD = 49.41). A minority of patients reported using tobacco (30%) or alcohol (34%), but not in a dependence pattern.

59% of the study subjects were underweight (BMI < 20), 7% were overweight (BMI ≥ 25 but ≤ 30 and 1% was obese. At baseline assessment, the mean PANSS positive, negative, general psychopathology and total scores were 24.78 (SD ± 6.69), 28.51 (SD

± 7.17), 53.93 (SD ± 10.15) and 107.22 (SD ±19.36) respectively. Baseline clinical characteristics are summarized in table 5.3.

Table 5.3: Baseline clinical characteristics

Data (n = 100)	**Range**	**Mean**	**Standard deviation**
Age of onset of illness in years	33	28.27	7.59
Total duration of illness in months	299	33.19	49.41
Baseline Height (cm)	36	166.69	6.52
Baseline Weight (kg)	49.2	55.29	9.48
Baseline BMI	20.7	19.90	3.32
Baseline PANSS positive scale score	33	24.78	6.69
Baseline PANSS negative scale score	35	28.51	7.17
Baseline PANSS general psychopathology score	51	53.93	10.15
Baseline PANSS total score	94	107.22	19.36
Baseline IIEF score	67	35.38	24.47
Baseline testosterone level (ng/dL)	1478	431.68	210.16
Baseline serum sex hormone binding globulin level (nmol/L)	107.77	38.94	18.09
Baseline Free Testosterone Index (%)	155.35	43.78	24.34

The mean baseline testosterone level, serum sex hormone binding globulin level and free testosterone index were 431.68 ng/dl (SD ± 210.155), 38.94 nmol/l (SD ± 18.089)

and 43.78% (SD ± 24.341) respectively. At baseline 19% of the study subjects had low testosterone levels and 42% had baseline low free testosterone index.

V.3. SEXUAL DYSFUNCTION AT BASELINE

V.3.A. PREVALENCE OF SEXUAL DYSFUNCTION AT BASELINE

At the initial assessment 17% of the participants reported sexual dysfunction as diagnosed by DSM-IV TR criteria. The most common sexual dysfunction reported was hypoactive sexual desire disorder (14%). The other reported disorders were premature ejaculation (5%), male erectile disorder (4%) and orgasmic dysfunction (1%). Sexual aversion disorder and sexual pain disorder were not reported by any of the participants. (Table 5.4)

Table 5.4: Baseline sexual dysfunction associated with distress

Type of sexual dysfunction	Prevalence
Hypoactive Sexual Desire Disorder	14%
Premature Ejaculation	5%
Male Erectile Disorder	4%
Orgasmic Dysfunction	1%
Sexual Aversion Disorder	0%
Sexual Pain Disorder	0%
Overall prevalence	17%

DSM-IV TR diagnostic criteria stipulates that sexual difficulties should cause significant distress to the individual to make a diagnosis of sexual dysfunction. However patients with schizophrenia and other psychotic disorders often do not report distress even if they experience sexual dysfunction. If the distress criterion is not included, the overall baseline prevalence of sexual dysfunction increases to 70%. Table

5.5 describes the rates of sexual dysfunction if the distress criterion is not used. Hypoactive sexual desire disorder constituted 53% while 1 % had male erectile disorder and orgasmic dysfunction each.

Table 5.5: Baseline sexual dysfunction without associated distress

Type of sexual dysfunction	Prevalence
Hypoactive Sexual Desire Disorder	53%
Male Erectile Disorder	1%
Orgasmic Dysfunction	1%
Premature Ejaculation	0%
Sexual Aversion Disorder	0%
Sexual Pain Disorder	0%
Overall prevalence	53%

Table 5.6: Baseline prevalence of sexual dysfunction with or without associated distress

Sexual dysfunction	Prevalence
Associated with distress	17%
Without associated distress	53%
Total prevalence	70%

V.3.B. FACTORS ASSOCIATED WITH BASELINE SEXUAL DYSFUNCTION WITH DISTRESS

The factors which had significant association with baseline sexual dysfunction associated with distress were age of the patient (t-2.23, $p < 0.05$), age of onset of illness (t -3.24, $p < 0.05$), marital status (χ^2-10.63, $p < 0.05$), number of sexual partners (t – 2.62, $p < 0.05$) and number of people staying in the house (t – 1.91, $p < 0.05$). (Table 5.7 & 5.8)

Table 5.7: Factors associated with sexual dysfunction at baseline

Characteristic	Patients without sexual dysfunction (n = 83)		Patients with sexual dysfunction (n = 17		t value	p value
	Mean	SD	Mean	SD		
Age of the patient in years	30.25	8.27	35.18	8.23	-2.23	0.02*
Age of the spouse in years (n = 39)	32.11	6.29	30.33	7.05	0.78	0.43
Duration of marriage in years (n = 40)	11.75	8.26	11.29	7.50	0.16	0.86
Number of sexual partners	0.45	0.66	0.94	0.89	-2.62	0.01*
Years of schooling	9.83	4.31	7.94	5.10	1.59	0.11
Number of people living in the house	4.06	1.62	4.94	2.19	-1.91	0.05*
Illness duration in months	35.45	51.10	22.18	39.56	1.00	0.31
Age of onset of illness in years	27.20	7.00	33.47	8.38	-3.24	0.002*
PANSS baseline positive score	24.88	6.83	24.29	6.04	0.32	0.74
PANSS baseline negative score	28.81	7.13	27.06	7.39	0.91	0.36
PANSS baseline general psychopathology score	53.59	10.14	55.59	10.33	-0.73	0.46
PANSS baseline total score	107.28	19.34	106.94	20.03	0.06	0.94
Baseline serum testosterone level ng/dl	417.82	178.52	499.34	322.59	-1.46	0.14
Baseline SHBG level nmol/L	38.56	18.84	40.79	14.14	-0.46	0.64
Baseline free testosterone index %	43.72	24.91	44.06	22.00	-0.05	0.95
Baseline height (cm)	166.89	6.23	165.71	7.92	0.68	0.49
Baseline weight (kg)	54.68	9.50	58.24	9.03	-1.41	0.15
Baseline body mass index (BMI)	19.65	3.43	21.14	2.338	-0.05	0.95

SHBG – Sex hormone binding globulin; * p value ≤ 0.05

Table 5.8: Factors associated with sexual dysfunction at baseline

Characteristic	Patients without sexual dysfunction n	Patients with sexual dysfunction n	chi square value	p value
Marital status				
Married	24	12	10.63	0.002*
Others	59	5		
Literacy	70	14	0.04	1.00
Literate	13	3		
Illiterate				
Residence				
Urban	6	2	0.39	0.62
Rural	77	15		
Type of house				
Concrete	59	14	0.90	0.54
Mud-thatched	24	3		
Separate bedroom				
Yes	38	11	2.02	0.18
No	45	6		
Debt				
No	29	2	3.54	0.08
Yes	54	15		
Sexual misconception				
No	37	8	0.01	1.00
Yes	44	9		
Marital satisfaction				
No	14	3	1.44	0.29
Yes	15	8		
Unable to buy food				
Yes	3	0	0.63	1.00
No	80	17		
Substance use				
Nil	42	8	6.45	
Alcohol only	10	6		0.09
Nicotine only	18	2		
Both	13	1		

*$p < 0.05$; **$p \leq 0.001$

V.3.C. FACTORS ASSOCIATED WITH BASELINE SEXUAL DYSFUNCTION WITHOUT DISTRESS

If the distress criterion was not taken into consideration, the prevalence of sexual dysfunction was 70% at baseline. Age of the patient ($t = 3.48$; $p < 0.05$), age of onset of illness ($t = 2.59$; <0.05), duration of illness ($t = 2.05$; <0.05), baseline weight ($t = 2.63$; <0.05), baseline BMI ($t = 3.14$; <0.05), marital status (chi square value = 17.70; <0.001), number of sexual partners ($t = 3.49$; <0.05), number of children ($t = 2.32$; <0.05), separate bedroom status (chi square value = 7.80; <0.05) and type of house (chi square value = 8.624; <0.05) were the factors that were statistically significant, when this group was compared with patients without sexual dysfunction.

V.3.D. FACTORS ASSOCIATED WITH THE THREE GROUPS: SEXUAL DYSFUNCTION WITH DISTRESS, SEXUAL DYSFUNCTION WITHOUT DISTRESS AND NO SEXUAL DYSFUNCTION AT THE BASELINE.

One way ANOVA with Tukey post hoc test was performed to find association of socio-demographic and clinical variables between the three groups (no sexual dysfunction, sexual dysfunction without distress and sexual dysfunction with distress) at baseline. The results are summarized in the table 5.9.

Table 5.9: Factors associated between and within the groups: sexual dysfunction with distress, sexual dysfunction without distress and no sexual dysfunction at baseline (ANOVA)

		Sum of Squares	df	Mean Square	F	Sig.
Age of the patient in years	Between Groups	768.721	2	384.360	5.945	.004*
	Within Groups	6271.469	97	64.654		
	Total	7040.190	99			
Age of the spouse in years	Between Groups	53.076	2	26.538	.616	.546
	Within Groups	1550.513	36	43.070		
	Total	1603.590	38			
Duration of marriage in years	Between Groups	48.743	2	24.371	.373	.691
	Within Groups	2416.188	37	65.302		
	Total	2464.931	39			

Number of sexual partners	Between Groups	6.499	2	3.250	6.792	.002**
	Within Groups	46.411	97	.478		
	Total	52.910	99			
Number of people staying in the same house	Between Groups	10.952	2	5.476	1.809	.169
	Within Groups	293.638	97	3.027		
	Total	304.590	99			
Years of schooling	Between Groups	51.747	2	25.873	1.290	.280
	Within Groups	1945.243	97	20.054		
	Total	1996.990	99			
Patient income per month	Between Groups	3.238E7	2	1.619E7	.845	.433
	Within Groups	1.859E9	97	1.916E7		
	Total	1.891E9	99			
Total duration of illness in months	Between Groups	21757.638	2	10878.819	4.798	.010**
	Within Groups	219943.752	97	2267.461		
	Total	241701.390	99			
Age of onset of illness	Between Groups	621.067	2	310.534	5.924	.004**
	Within Groups	5084.643	97	52.419		
	Total	5705.710	99			
PANSS baseline positive total	Between Groups	10.466	2	5.233	.115	.892
	Within Groups	4414.694	97	45.512		
	Total	4425.160	99			
PANSS baseline negative total	Between Groups	208.107	2	104.053	2.065	.132
	Within Groups	4886.883	97	50.380		
	Total	5094.990	99			
PANSS baseline general psychopathology total	Between Groups	242.438	2	121.219	1.181	.311
	Within Groups	9956.072	97	102.640		
	Total	10198.510	99			
PANSS baseline overall total	Between Groups	834.465	2	417.233	1.116	.332
	Within Groups	36270.695	97	373.925		
	Total	37105.160	99			
Serum testosterone baseline	Between Groups	94239.277	2	47119.639	1.068	.348
	Within Groups	4278100.542	97	44104.129		
	Total	4372339.820	99			
Baseline free testosterone index	Between Groups	161.528	2	80.764	.134	.875
	Within Groups	58497.308	97	603.065		
	Total	58658.836	99			
Height baseline	Between Groups	54.441	2	27.221	.635	.532
	Within Groups	4154.949	97	42.835		
	Total	4209.390	99			

Weight baseline	Between Groups	637.443	2	318.722	3.747	.027*
	Within Groups	8251.864	97	85.071		
	Total	8889.307	99			
BMI baseline	Between Groups	111.452	2	55.726	5.527	.005**
	Within Groups	978.059	97	10.083		
	Total	1089.510	99			

* $P < 0.05$; **$P \leq 0.01$

Age of the patient

There was a statistically significant difference between the groups as determined by one way ANOVA ($F (2, 97) = 5.94$, $p = 0.004$). A Tukey post hoc test revealed statistically significant difference between the groups sexual dysfunction without distress and no sexual dysfunction ($p = 0.03$) and sexual dysfunction with distress and sexual dysfunction without distress ($p = 0.01$). There was no statistically significant difference between the groups: sexual dysfunction with distress and no sexual dysfunction.

Age of onset of illness

There was a statistically significant difference between the groups ($F (2, 97) = 5.92$, $p = 0.004$). A Tukey post hoc test revealed statistically significant difference between the group sexual dysfunction with distress and sexual dysfunction without distress ($p = 0.002$). There was no statistically significant difference between the groups: sexual dysfunction with distress and no sexual dysfunction and sexual dysfunction without distress and no sexual dysfunction.

Total duration of illness

There was a statistically significant difference between the groups ($F (2, 97) = 4.79$, $p = 0.01$). A Tukey post hoc test revealed a statistically significant difference between the group sexual dysfunction without distress and no sexual dysfunction ($p = 0.01$).

Number of sexual partners

There was a statistically significant difference between the groups F (2, 97) = 6.79, p = 0.002). A Tukey post hoc test revealed a statistically significant difference between the groups sexual dysfunction without distress and no sexual dysfunction (p = 0.03) and sexual dysfunction with distress and sexual dysfunction without distress (p = 0.002).

Baseline weight

There was a statistically significant difference between the groups (F (2, 97) = 3.74, p = 0.02). A Tukey post hoc test revealed a statistically significant difference between the groups sexual dysfunction without distress and no sexual dysfunction (p = 0.05).

Baseline BMI

There was a statistically significant difference between the groups (F (2, 97) = 5.52, p = 0.005). A Tukey post hoc test revealed a statistically significant difference between the groups sexual dysfunction without distress and no sexual dysfunction (p = 0.01) and sexual dysfunction with distress and sexual dysfunction without distress (p = 0.03)

V.4. SEXUAL DYSFUNCTION AT SIX WEEKS

V.4.A. PREVALENCE OF SEXUAL DYSFUNCTION AT SIX WEEKS

Out of the 100 participants, six weeks follow up was done for 41 patients. 44 patients (51.76%) were lost for follow up (15 patients had not finished six weeks of treatment at the time of this report). At six weeks, the overall prevalence of sexual dysfunction increased to 31.7%. Hypoactive sexual desire disorder constituted the major proportion (31.7%) followed by male erectile disorder (17.1%), orgasmic dysfunction (9.8%) and

premature ejaculation (7.3%). None of the patients reported sexual aversion disorder or sexual pain disorder. (Table 5.10)

Table 5.10: Prevalence of sexual dysfunction with distress at six weeks

Type of sexual dysfunction	Frequency
Hypoactive sexual desire disorder	31.7%
Male erectile disorder	17.1%
Premature ejaculation	7.3%
Orgasmic dysfunction	9.8%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall prevalence	31.7%

When the distress criterion was not applied the overall prevalence increased to 87.8% with 56.1% having hypoactive sexual desire disorder and 2.4% having male erectile disorder and orgasmic dysfunction each without distress. (Table 5.11)

Table 5.11: Prevalence of sexual dysfunction without distress at six weeks

Type of sexual dysfunction	Frequency
Hypoactive sexual desire disorder	56.1%
Male erectile disorder	2.4%
Premature ejaculation	0%
Orgasmic dysfunction	2.4%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall prevalence	56.1%

V.4.B. INCIDENCE OF SEXUAL DYSFUNCTION AT SIX WEEKS

Among the forty one patients who were followed up at six weeks, nine had reported sexual dysfunction at baseline and hence were excluded from the analysis. The overall incidence of sexual dysfunction was 15.6%; hypoactive sexual desire disorder 15.6%, male erectile disorder 12.5%, orgasmic dysfunction and premature ejaculation 6.2% each. (Table 5.12)

Table 5.12: Incidence of sexual dysfunction with distress at six weeks

Type of sexual dysfunction	Incidence
Hypoactive sexual desire disorder	15.6%
Male erectile disorder	12.5%
Premature ejaculation	6.2%
Orgasmic dysfunction	6.2%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall incidence at six weeks	15.6%

V.4.C. FACTORS ASSOCIATED WITH SEXUAL DYSFUNCTION AT SIX WEEKS WITH DISTRESS:

Age of the patient (t-2.34, $p<0.05$), patient's monthly income (t-2.09, $p<0.05$), age of onset of illness (t-2.59, $p<0.05$), BMI at baseline (t -2.53, $p<0.05$) and six weeks (t -2.25, $p<0.05$), and marital status (χ^2-15.54, $p<0.05$) were significantly associated with sexual dysfunction with distress at six weeks. (Table 5.13 & 5.14)

Table 5.13: Factors associated with sexual dysfunction at six weeks

Characteristic	Patients without sexual dysfunction (n = 27)		Patients with sexual dysfunction (n = 5)		t value	p value
	Mean	SD	Mean	SD		
Age of the patient in years	28.78	7.85	38.00	9.43	-2.34	0.02*
Age of the spouse in years (n = 10)	30.00	5.19	31.80	7.22	-0.45	0.66
Duration of marriage in years (n = 10)	8.60	5.77	10.60	9.01	-0.41	0.68
Number of sexual partners	0.48	0.89	1.20	0.44	-1.74	0.09
Years of schooling	9.59	4.06	10.00	6.67	-0.18	0.85
Number of people living in the house	4.07	1.23	3.60	1.14	0.79	0.43
Patient's monthly income INR	1248.15	3991.46	7400.00	12992.30	-2.09	0.04*
Illness duration in months	34.33	46.84	51.00	74.14	-0.66	0.51
Age of onset of illness in years	25.78	6.36	33.60	4.82	-2.59	0.01*
PANSS baseline positive score	24.30	6.11	24.40	8.29	-0.03	0.97
PANSS baseline negative score	30.26	6.43	24.60	2.70	1.91	0.06
PANSS baseline general psychopathology score	54.63	9.68	49.40	6.26	1.15	0.25
PANSS baseline total score	109.19	18.42	98.40	15.69	1.22	0.23
PANSS six weeks positive score	13.41	7.27	11.40	6.18	0.57	0.56
PANSS six weeks negative score	19.15	8.14	16.40	7.82	0.69	0.49
PANSS six weeks general psychopathology score	34.74	11.89	33.00	12.04	0.30	0.76
PANSS six weeks total score	67.30	23.94	60.80	25.58	0.55	0.58
Baseline serum testosterone level ng/dl	426.89	204.59	366.00	89.04	0.64	0.52
Baseline SHBG level nmol/L	37.10	17.61	50.02	23.04	-1.43	0.16
Baseline free testosterone index %	44.78	22.96	30.60	17.35	1.30	0.20

Baseline weight (kg)	55.50	8.04	63.60	17.03	-1.70	0.09
Six weeks weight (kg)	59.31	7.63	65.74	17.33	-1.38	0.17
Baseline body mass index (BMI)	19.57	2.54	23.96	7.30	-2.53	0.01*
Six weeks body mass index	20.88	2.35	24.78	7.47	-2.25	0.03*
Mean antipsychotic drug dose per day (CPZ equivalents)	515.76	165.42	535.40	102.19	-0.25	0.80
Days of antipsychotic drug exposure	42.08	8.70	41.40	7.40	0.16	0.87

SHBG – Sex hormone binding globulin; CPZ –Chlorpromazine; * p value ≤ 0.05

Table 5.14: Factors associated with sexual dysfunction at six weeks

Characteristic	Patients without sexual dysfunction N	Patients with sexual dysfunction n	Chi square value	p value
Marital status				
Married	4	5	15.14	0.001**
Others	23	0		
Religion				
Hindu	24	5		
Christian	2	0	0.61	0.73
Muslim	1	0		
Separate bedroom status				
No	13	2		
Yes	14	3	0.11	1.00
Residence				
Urban	2	0		
Rural	25	5	0.39	1.00
Literacy				
Literate	22	5		
Illiterate	5	0	1.09	0.56
Housing type				
Concrete	18	5		
Mud thatched	9	0	2.31	0.28
Unable to buy food				
Yes	1	0		
No	26	5	0.19	1.00

Debt				
Yes	17	4		
No	10	1	0.54	0.63
Substance use				
Nil	15	2		
Alcohol only	1	1		
Nicotine only	6	2	3.44	0.32
Both	5	0		
Baseline testosterone range				
Normal	20	5		
Below normal range	7	0	1.65	0.56
Baseline free testosterone index	17	1		
Normal	10	4	3.16	0.14
Below normal range				
Sexual misconception	12	2		
No	14	3	0.06	1.00
Yes				
Marital satisfaction	2	3		
No	2	2	0.09	1.00
Yes				
Antipsychotic drug	13	5		
Risperidone	11	0	4.60	0.20
Olanzapine	2	0		
Combination antipsychotics				

* $P < 0.05$; ** $P \leq 0.01$

V.5. SEXUAL DYSFUNCTION AT SIX MONTHS

V.5.A. PREVALENCE OF SEXUAL DYSFUNCTION AT SIX MONTHS

Follow up assessments at six months were done for 21 patients. 25 patients (54.34%) were lost for follow up. Fifty four patients have not yet completed their six months of treatment at the time of this analysis. The prevalence of sexual dysfunction with distress at the end of six months was 52.4%. Hypoactive sexual desire disorder constituted 52.4%, while male erectile disorder and orgasmic dysfunction 9.5% each

and premature ejaculation 4.8%. None had reported sexual aversion disorder or sexual pain disorder. (Table 5.15)

Table 5.15: Prevalence of sexual dysfunction with distress at six months

Type of sexual dysfunction	**Prevalence**
Hypoactive sexual desire disorder	52.4%
Male erectile disorder	9.5%
Premature ejaculation	4.8%
Orgasmic dysfunction	9.5%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall prevalence	52.4%

Prevalence of sexual dysfunction without distress at six months is summarized in table 5.16. The overall prevalence without distress was 42.9%

Table 5.16: Prevalence of sexual dysfunction without distress at six months

Type of sexual dysfunction	Prevalence
Hypoactive sexual desire disorder	42.9%
Male erectile disorder	0%
Premature ejaculation	0%
Orgasmic dysfunction	0%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall prevalence	42.9%

V.5.B. INCIDENCE OF SEXUAL DYSFUNCTION AT SIX MONTHS

Among the twenty one people who were followed up at six months, four had sexual dysfunction at baseline and hence were excluded from analysis. The overall incidence of sexual dysfunction at six months was 47.1%. The incident rates for hypoactive sexual desire disorder, male erectile disorder, orgasmic dysfunction and premature ejaculation were 47.1%, 11.8%, 11.8% and 5.9% respectively. (Table 5.17)

Table 5.17: Incidence of sexual dysfunction at six months

Type of sexual dysfunction	Incidence
Hypoactive sexual desire disorder	47.1%
Male erectile disorder	11.8%
Premature ejaculation	5.9%
Orgasmic dysfunction	11.8%
Sexual aversion disorder	0%
Sexual pain disorder	0%
Overall incidence at six months	47.1%

V.5.C. FACTORS ASSOCIATED WITH SEXUAL DYSFUNCTION AT SIX MONTHS:

The factors which were associated with sexual dysfunction at six months are age of the patient ($t = -2.92$; $p = 0.01$), marital status (chi square value = 4.73; $p = 0.01$), number of sexual partners ($t = -2.24$; $p = 0.04$), illness duration ($t = -2.24$; $p = 0.04$) and PANSS baseline general psychopathology score ($t = 2.13$; $p = 0.04$). (Tables 5.18 & 5.19)

Table 5.18: Factors associated with sexual dysfunction at six months

Characteristic	Patients without sexual dysfunction (n = 10)		Patients with sexual dysfunction (n = 7)		t value	p value
	Mean	SD	Mean	SD		
Age of the patient in years	27.00	4.88	37.86	10.27	-2.92	0.01*
Age of the spouse in years (n = 9)	27.33	5.13	32.00	6.48	-1.07	0.31
Duration of marriage in years (n = 9)	6.00	4.58	11.00	8.60	-0.92	0.38
Number of sexual partners	0.40	0.51	1.00	0.57	-2.24	0.04*
Years of schooling	9.10	4.81	11.29	3.63	-1.01	0.32
Number of people living in the house	3.80	1.87	3.57	0.97	0.29	0.77
Patient's monthly income INR	800.00	1932.18	5714.29	11025.94	-1.39	0.18
Illness duration in months	13.40	10.98	80.14	94.62	-2.24	0.04*
Age of onset of illness in years	26.00	5.31	31.00	5.59	-1.86	0.08
PANSS baseline positive score	23.50	3.44	20.00	8.54	1.17	0.25
PANSS baseline negative score	29.70	6.27	25.57	5.74	1.38	0.18
PANSS baseline general psychopathology score	52.40	5.81	46.14	6.12	2.13	0.04*
PANSS baseline total score	105.60	13.80	91.71	15.09	1.22	0.23
PANSS six weeks positive score	11.22	6.26	10.43	5.88	0.25	0.80
PANSS six weeks negative score	19.56	9.19	13.43	6.05	1.52	0.15
PANSS six weeks general psychopathology score	32.89	13.01	27.29	9.08	0.96	0.35
PANSS six weeks total score	63.67	25.94	51.14	20.46	1.04	0.31
PANSS six months positive score	9.90	6.15	8.14	1.95	0.72	0.48
PANSS six months negative score	17.90	9.44	12.14	5.24	1.45	0.16
PANSS six months general psychopathology score	29.70	16.50	22.29	2.87	1.16	0.26

PANSS six months total score	57.50	30.76	42.57	7.89	0.03	0.23
Baseline serum testosterone level ng/dl	382.90	162.18	418.00	138.62	-0.46	0.64
Baseline SHBG level nmol/L	30.70	11.43	45.15	23.05	-1.71	0.10
Baseline free testosterone index %	46.27	21.47	40.03	22.56	0.57	0.57
Six months serum testosterone level ng/dl	372.50	177.20	276.57	83.37	1.32	0.20
Six months SHBG level nmol/l	26.72	11.67	30.11	15.24	-0.52	0.61
Six months free testosterone index %	52.74	25.52	38.59	22.04	1.18	0.25
Baseline weight (kg)	59.10	8.77	60.42	15.54	-0.22	0.82
Six weeks weight (kg)	62.76	6.56	62.92	15.56	-0.02	0.97
Six months weight (kg)	64.80	7.25	65.28	15.51	-0.08	0.93
Baseline body mass index (BMI)	20.11	2.92	23.14	6.27	-1.34	0.19
Six weeks body mass index	21.34	2.31	24.07	6.21	-1.22	0.24
Six months body mass index	22.00	2.30	24.97	6.18	-1.33	0.20
Mean antipsychotic drug dose per day (CPZ equivalents)	615.00	396.60	509.5	113.3	0.72	0.48
Days of antipsychotic drug exposure	164.11	46.68	157.12	28.25	0.36	0.71

SHBG – Sex hormone binding globulin; CPZ –Chlorpromazine; * p value ≤ 0.05

Table 5.19: Factors associated with sexual dysfunction at six months

Characteristic	Patients without sexual dysfunction (n = 10)	Patients with sexual dysfunction (n = 7)	Chi square value	p value
Marital status				
Married	7	2	4.73	0.03*
Others	3	5		
Religion				
Hindu	9	7		
Christian	1	0	0.74	1.00
Muslim	0	0		
Literacy				
Literate	8	7	1.63	0.33
Illiterate	2	0		
Separate bedroom status				
No	6	2		
Yes	4	5	2.01	0.47
Residence				
Urban	1	1		
Rural	9	6	0.07	1.00
Unable to buy food				
Yes	1	0		
No	9	7	0.29	0.64
Debt				
No	3	3		
Yes	7	4	0.29	0.64
Substance use				
Nil	6	2		
Alcohol only	1	0		
Nicotine only	1	5	7.36	0.06
Both	2	0		
Baseline testosterone level				
Normal	8	7		
Below normal range	2	0	1.5	0.48
Baseline free testosterone index	6	3		
Normal range	4	4	0.48	0.63
Below normal range				

Six months testosterone level	6	4		
Normal range	4	3	0.01	1.00
Below normal range				
Six months free testosterone index	8	4		
Normal range	2	3	1.03	0.59
Below normal range				
	7	3		
Sexual misconception	3	4	1.25	0.35
No				
Yes				
	1	3		
Marital satisfaction	1	3	0.00	1.00
No				
Yes				
	3	5		
Antipsychotic drug	4	1	1.98	0.57
Risperidone	1	0		
Olanzapine	2	1		
Aripiprazole				
Combination antipsychotic				

* $P < 0.05$; ** $P \leq 0.01$

V.6. CHANGES IN CLINICAL CHARACTERISTICS AT SIX WEEKS AND AT SIX MONTHS

There was a reduction in total PANSS score by the end of six weeks. Mean reduction in PANSS total score was 39.07 (SD±21.86). Body weight and BMI increased at six weeks. Mean increases in weight and BMI were 3.2kg (SD±2.74; 5.58%) and 1.1 (SD± 0.098; 5.34%) respectively**.**

At six months, mean reduction in PANSS scores was 46.28 (SD±27.34). Mean increases in body weight and BMI were 4.59kg (SD±4.27; 7.74%) and 1.61 (SD±1.48; 7.57%). There was a reduction in serum testosterone levels by 89.95ng/dl (SD±218.48) at the end of six months. The prevalence of hypotestosteronism increased to 42.9% at six months follow up.

Among the forty one patients who were assessed at six weeks, twenty four were being prescribed Risperidone, fourteen were on Olanzapine and three were on a combination of antipsychotics.

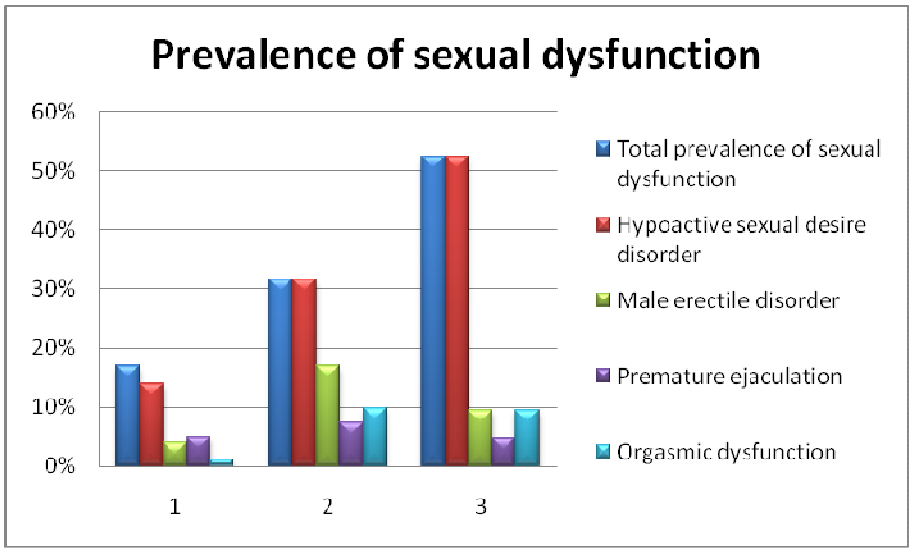
At six months assessment, nine patients were on Risperidone, seven were on Olanzapine, one was on Aripiprazole and remaining four were on a combination of antipsychotics.

Although eleven people among the twenty one had sexual dysfunction at six months, only three had reported this to their treating psychiatrists. Antipsychotic drug was changed for all three of them and their sexual functioning reportedly improved with medication change.

V.7. COMPARISON OF PREVALENCE OF SEXUAL DYSFUNCTION ACROSS BASELINE, SIX WEEKS AND SIX MONTHS FOLLOW UP

The following figure shows comparison of prevalence of various types of sexual dysfunction. Hypoactive sexual desire disorder is the most prevalent type of sexual dysfunction at anytime

Figure 5.2: Prevalence of types of sexual dysfunction (Baseline, Six weeks & Six months)

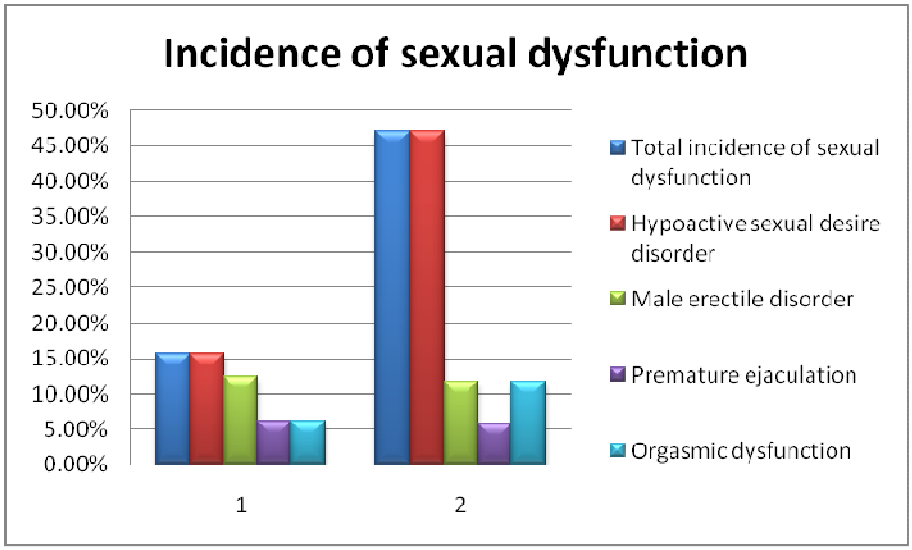


1 - Baseline; 2 - Six weeks; 3 - Six months

V.8. COMPARISON OF INCIDENCE OF SEXUAL DYSFUNCTION ACROSS SIX WEEKS AND SIX MONTHS

The following figure shows a comparison of incidence of sexual dysfunction at six weeks and six months. Highest incidence was observed for hypoactive sexual desire disorder across six weeks and six months.

Figure 5.3: Incidence of sexual dysfunction at six weeks and six months

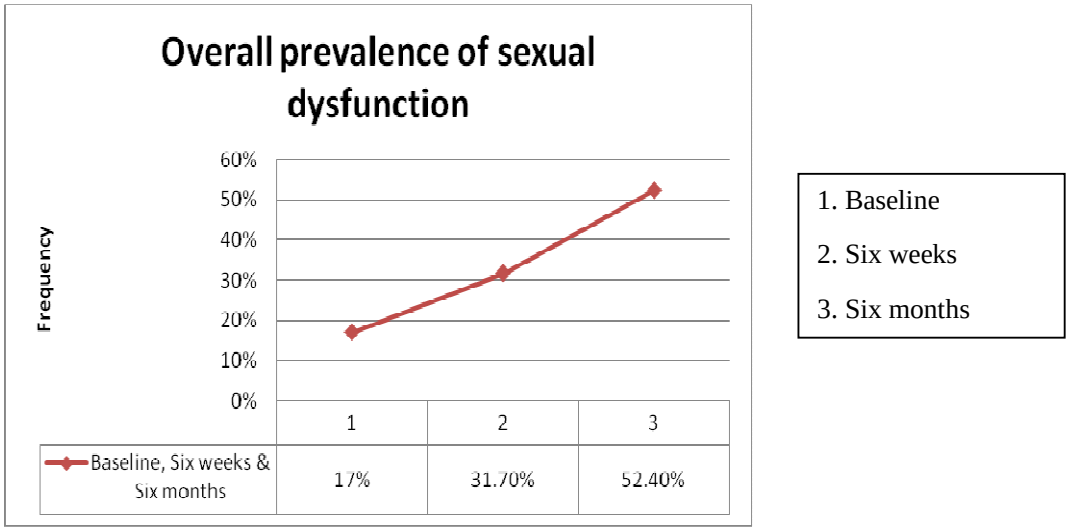


1 – Six weeks; 2 – Six months

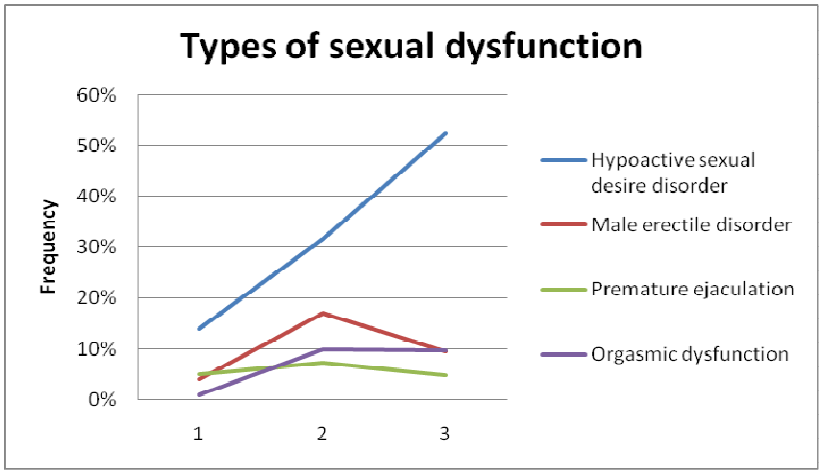
V.9. TRENDS IN SEXUAL DYSFUNCTION PREVALENCE ACROSS BASELINE, SIX WEEKS AND SIX MONTHS

The figure given below shows the trends of various types of sexual dysfunctions across baseline, six weeks and six months. The overall prevalence of sexual dysfunction increased from a baseline of 17% to 31.7% at six weeks and 52.4% at the end of six months. Hypoactive sexual desire disorder increased from a baseline of 14% to 52.4% at six months. Erectile dysfunction reached 9.5% at six months end as compared to a baseline prevalence of 4%. Orgasmic dysfunction increased from 1% baseline to 9.5% at six months follow up. Premature ejaculation reduced from 5% at baseline to 4.8% at six months.

Graph 5.1: Trends in prevalence of sexual dysfunction at baseline, six weeks and six months



Graph 5.2 : Trends in prevalence of types of sexual dysfunction at baseline, six weeks and six months



1. Baseline
2. Six weeks
3. Six months

VI. DISCUSSION

Sexual dysfunction in schizophrenia is widely prevalent. While antipsychotic drugs constitute a major cause for sexual dysfunction in this population, other factors like the illness itself may be contributory. Sexual side effects have been linked to depressive symptoms, poor quality of life and non adherence to prescribed treatment in previous literature. It has also been described as one of the most distressing side effects in this group of patients. Despite its wide prevalence and high incidence rates on treatment with antipsychotic medications, it is often not routinely assessed in clinical practice.

The existing literature in this area is sparse. The majority of studies are cross sectional in nature. The few available longitudinal studies were not specifically designed to assess sexual functioning and hence have methodological limitations. The other issues affecting quality of reported studies include small sample size, inclusion of specific subsets (married, institutionalized, patients in remission), and assessments using instruments which have not been proven to be psychometrically sound. Most instruments that assess sexual functioning have a tendency to focus on the relationship and psychological aspects of sexual functioning. A psychotic patient's ability to form relationships and report his/her sexual functioning has been questioned. These issues have more recently been addressed by specific questionnaires which focus on the physical aspects of sexual functioning. Attempts to explore the biological correlates of sexual dysfunction in this population have been inconclusive. Reproductive hormone assays (testosterone, prolactin and gonadotrophins levels) have also not correlated with sexual side effects while on antipsychotic medications.

There are very few reports on sexual dysfunction in psychotic illness from India. The Indian studies that have looked into antipsychotic induced sexual dysfunction have been cross sectional in nature (78) and included patients with bipolar illness(91)

Thus, there exists a need for well designed longitudinal studies, which will assess both the prevalence of sexual dysfunction in untreated patients with psychotic illness and treatment emergent sexual side effects. An ideal study should include both married and unmarried patients, use a validated instrument and assess changes in reproductive hormone levels.

This study aimed to assess sexual function in male patients with psychotic disorders. The main objectives were to determine the prevalence and risk factors for sexual dysfunction in antipsychotic naïve patients and to study the incidence and risk factors of sexual dysfunction in men treated with antipsychotic medication.

A prospective cohort design was used involving men with psychotic disorder (acute psychosis or schizophrenia) who were antipsychotic drug naïve or antipsychotic drug free for six months. Sociodemographic and clinical parameters and sexual functioning were assessed at baseline. Clinical parameters and sexual functioning were reassessed at follow up at six weeks and six months. Testosterone and serum sex hormone globulin levels were measured at baseline and repeated at six months.

VI.1. Socio-demographic and clinical profile

The mean age of the participants was 31 years and the duration of illness was about three years. The majority of the patients were single and almost half of them did not have a current partner. This is similar to earlier reports that a significant proportion of patients with schizophrenia do not have a current sexual partner(70)(60). 36% of the

participants were currently married. This finding is in contrast to earlier reports that marital rates in this region are between 50 and 70%. (92)(93) .

VI.2. Sexual dysfunction in drug naïve or drug free patients with psychosis: Prevalence and risk factors

The overall prevalence of sexual dysfunction at baseline (antipsychotic naïve or free for six months) was 17%. Hypoactive sexual desire disorder was the most prevalent type of sexual dysfunction accounting for 14% of the total. Premature ejaculation (5%), erectile dysfunction (4%) and orgasmic dysfunction (1%) were the other disorders reported. This finding is consistent with other studies which also reported decreased libido to be the commonest type of sexual dysfunction in antipsychotic naïve patients.(71)(94)

These rates are lower than that reported in some earlier studies. EUFEST assessed sexual functioning in patients with first episode psychosis and reported decreased libido in 30.8%, erectile dysfunction in 17.7% and orgasmic dysfunction in 15.0%.(71) Another report from Europe, which assessed patients who were part of the IC-SOHO observational study, reported the prevalence of sexual problems as 37%, which is again much higher than our findings. (72) The varying prevalence rates can be explained by the differences in sample selection, assessment instruments and diagnostic criteria used. (78) One could attempt to explain the difference in prevalence rates as a methodological limitation, that patients with psychosis are unable to describe their sexual difficulties due to severity of psychopathology. However, in our study, there were no statistically significant differences between the two groups in terms of psychopathology as measured by PANSS scores.

More than half (53%) of the participants in this study reported sexual difficulties at the baseline assessment that would fulfill criteria for sexual dysfunction except for the distress criterion. It could be assumed that the lack of distress was part of the illness per se as part of the negative syndrome. However statistical testing did not prove this assumption.

Older age, later age of onset of illness, greater number of sexual partners, marital status and more number of people living in the same house were associated with sexual dysfunction at baseline. However, the direction of association between marital status and sexual dysfunction is not clear. Testosterone levels and free testosterone index were not significantly associated with baseline sexual dysfunction in our study.

VI.3. Sexual dysfunction with antipsychotic treatment: Incidence, prevalence and risk factors:

Prevalence of sexual dysfunction increased to 31.7% at six weeks and 52.4% at six months as compared to 17% at baseline. This is in contrast to earlier reports that sexual dysfunction rates did not change significantly at the end of twelve months of antipsychotic treatment.(71) Another study reported that the rates of sexual dysfunction reduced at the end of six months(72). Hypoactive sexual desire disorder was the commonest type of dysfunction found with a prevalence of 31.7% and 52.4% respectively at six weeks and six months. All patients who reported sexual difficulties at six weeks and six months follow up had low sexual desire. This finding is similar to earlier reports that reduced sexual desire is the most common sexual side effect of antipsychotic medications.(71)(72)

The prevalence of erectile dysfunction increased to 17.1% at six weeks but at six months it had reduced to 9.5%. This however did not correlate with the reproductive hormone levels. Premature ejaculation showed a downward trend (4.8%) at the end of six months while orgasmic dysfunction increased to 9.5% at the same point of time. Antipsychotics (both typical and atypical) have been known to delay ejaculation time. The exact mechanism is not known, though serotoninergic and cholinergic pathways have been implicated. The findings of this study highlights that sexual side effects can occur as early as six weeks in the course of treatment.

Overall prevalence rates of sexual dysfunction among patients with schizophrenia on antipsychotic medications have been shown to vary widely. A review on sexuality by Kelly and Conley has reported that it may range from 50% to 80%. (31) A limitation to these estimates is that most of these studies are cross sectional in nature. A recent report from China on patients with a diagnosis of first episode psychosis found the prevalence rate to be 13.4%, which is similar to our finding. (95) Possible reasons for the difference in prevalence rates between Caucasians and Asians could be the conservative attitude towards sexuality and lower frequency of sexual behaviors found in Asian population(96).

This is probably the first study which has looked at incidence rates of sexual dysfunction in patients with schizophrenia on antipsychotic medications. The incidence of sexual dysfunction was 15.6% at six weeks and 47.1% at six months. All patients who developed sexual dysfunction at six weeks and six months reported hypoactive sexual desire disorder. In these individuals additionally, erectile dysfunction was seen in 12.5% and 11.8% at six weeks and six months respectively, incidence of orgasmic dysfunction rose from 6.2% at six weeks to 11.8% at six months and premature ejaculation reduced from 6.2% at six weeks to 5.9% at six months.

Thus the prevalence and incidence of sexual dysfunction consistently rose from baseline to six months indicating the importance of this highly prevalent antipsychotic adverse effect. However, it is unclear whether the incidence rates continue to rise or becomes static or falls after a point of time. This can only be proved by a well designed longitudinal study.

Older age and marital status were the factors that were found to be significantly associated with sexual dysfunction at six weeks and six months. Greater age of onset of illness which was associated at baseline, continued to be associated at six weeks, but was not associated at six months. These findings are consistent with the Chinese study mentioned earlier, in which age of patient, age of onset of illness and marital status were all statistically significant.(95) Duration of illness appeared to be a statistically significant risk factor for sexual dysfunction at six months. It can be hypothesized that earlier age of onset of psychotic illness interferes with the sexual maturation of an individual. As a result, the patient is not aware of his normal sexual functioning and hence reports lesser sexual difficulties. Likewise, later onset of illness following a period of normal sexual functioning makes a patient aware of his difficulties. This hypothesis however needs further testing.

Age constitutes an independent risk factor for sexual dysfunction even in normal subjects. This is well documented from the Massachusetts male aging study and similar studies.(11). Our study's finding of patient's age significantly associated with sexual dysfunction at all points of assessment (baseline, six weeks and six months) confirms the above.

Higher BMI at six weeks was associated with increased rates of sexual dysfunction. Body mass index has also been reported to be an independent risk factor

for sexual dysfunction in otherwise healthy persons.(11) Thus the same risk factors for sexual dysfunction operating in general population have its impact on patients with schizophrenia also.

Married subjects had statistically significant higher rates of sexual dysfunction as compared to others. This could be presumed to be due to higher reporting of distress in the context of dysfunction in this subset of population.

In our study, the type of antipsychotic used, mean antipsychotic dosage and duration of exposure were not associated with sexual dysfunction at six weeks and at six months. A similar results was obtained in the EUFEST study where the differences between the antipsychotic medications was found to be small for all sexual dysfunctions.(71) Another study from UK among first episode psychosis patients also did not report any significant difference in incidence rates between the prolactin sparing and raising antipsychotic medications(70). However there are several reports that state that prolactin sparing antipsychotic medications like Quetiapine, Aripiprazole etc have a better sexual side effect profile(97)(87). Although, our study findings are consistent with the aforementioned ones, caution needs to exercised, while interpreting this finding, as the number of patients followed up was small.

At six months of antipsychotic use, though the prevalence of sexual dysfunction was 52.4%, only 27.3% of these patients reported their sexual problems to the treating psychiatrist. Antipsychotics were switched in all these patients, which resulted in improvement in sexual functioning. This highlights the issue that patients with psychosis often do not report their sexual side effects(98) . Clinicians should be aware of this and be proactive in assessing for these side effects.

Hyperprolactinemia associated with antipsychotic treatment is well documented. Hyperprolactinemia appears to affect sexuality through inhibition of gonadal hormones(42)(44). 19% of the study sample had baseline hypotestosteronism and 42% had their baseline free testosterone index below the normal range. However these were not associated with baseline sexual dysfunction. Similarly, although a mean reduction of 89.95 ng/dl was noted in serum testosterone levels at six months from baseline and 42.9% having hypotestosteronism at six months; these parameters were not significantly associated with sexual dysfunction. Our findings are in concordance with two other studies which assessed gonadal hormones including testosterone but did not find significant associations with sexual dysfunction.(52)(75)

VI.4. LIMITATIONS

The following limitations merit acknowledgement in this study.

First of all, this study was conducted on patients with psychosis who might have had problems with reality testing. Diagnosis of sexual dysfunction was made on the patient's report. The reliability of patients' report when psychotic has been questioned. However this difficulty in inherent in this subset of population and any study design will face this problem. Objective measuring of sexual functioning is not only time consuming and resource intensive, but could result in ethical violations. Patient reports can be supplemented with spousal report, to improve reliability, but this will not be possible in patients who are unmarried or living separately.

Secondly an appropriate healthy control group was not used in this study. However as the study design was a longitudinal one, the same patients for whom baseline assessments were done will act as controls for the follow up assessments.

Thirdly there is a high dropout rate at six weeks and six months and moreover the study's follow up assessments are not yet completed at the time of this analysis. Hence the follow up analysis could be done only for small number of patients. This might interfere with interpreting the results. However as the study is ongoing, efforts will be made to account for this high number of drop outs like further increasing the sample size or planning home visits for those patients who have dropped out.

Fourthly testosterone levels were measured at two points at baseline and six months. However fluctuations in this hormone levels, both diurnal and day to day may exist.

VII. SUMMARY

Table 7.1: Summary

- Baseline prevalence of sexual dysfunction in male patients with psychotic disorders who were antipsychotic naïve or antipsychotic free for six months was 17%. Hypoactive sexual desire disorder was the commonest (14%) followed by premature ejaculation 5%, erectile dysfunction 4% and orgasmic dysfunction (1%).

- The incident rates of sexual dysfunction at six weeks and six months were 15.6% and 47.1% respectively.

- Age of the patient and marital status were the factors consistently associated with sexual dysfunction across baseline, six weeks and six months. Additional factors which were significant at varying periods of time include age of onset of illness, illness duration, number of sexual partners and body mass index.

- Factors such as PANSS scores, type of antipsychotic drug, mean antipsychotic dosage and duration of exposure and testosterone levels were not significantly associated with sexual dysfunction.

- 19% of the patients had baseline hypotestosteronism and this increased to 42% at six months following treatment with antipsychotic medications.

VIII. CONCLUSION

Our study findings confirm the high prevalence and incidence rates of sexual dysfunction in male patients with psychotic disorders. Higher rates of hypotestosteronism were observed in the treated population. Clinicians need to routinely assess for sexual dysfunction in these patients.

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Appendix 1: Consent form in English

CONSENT FORM

Title of study:

Sexual dysfunction in men with psychosis.

Institution:

Christian Medical College, Vellore

Nature and purpose of the study:

Sexual problems are common in men who experience psychosis. We would like to determine the nature of these problems and study the effect of medication on sexual functions.

Procedure to be followed:

A doctor from the Department of Psychiatry will conduct this study. He will collect information regarding various aspects of sexual functioning by administering some standard instruments. Some of these questions asked may deal with information of a very personal nature and you are free to either answer such questions or refuse. You will also be requested to do a blood test at each of these interviews. About 100 men will participate in this study.

Expected duration of involvement:

The assessment will be done in three separate sessions that will each last about half an hour.

Possible benefits of the study:

The information we obtain may help us find problems related to your sexual functioning. If further intervention is required or you desire help, you will be advised regarding the same. Others may also benefit from the overall conclusions at the end of the study.

Confidentiality:

The records and details obtained in this study will remain confidential at all times and will only be available to the doctor conducting the study. Your personal data will be collected and processed only for research purposes. You will not be referred to by name or identified in any report or publication.

Right to withdraw from the study:

You are free to leave the study at any time. Your decision to/ not to participate in this study will not affect your future medical or psychiatric care in our hospital. For further queries you may contact:

Dr. Dhananjayan R

Department of Psychiatry,

Christian Medical College,

Vellore-632002

Phone: 0416-228 4516,

Email: psych1@cmcvellore.ac.in

Consent:

I, ----------, have been informed about the study on sexual dysfunction in men with psychosis. The investigator has explained the details of this study to me. I am voluntarily entering the study and have agreed on my own free will to participate in the interviews.

Signature of the participant **Date:**

Signature of the investigator **Date:**

Assent:

I, …… being the …… of …… have been informed about the study on sexual dysfunction in men with psychosis. The investigator has explained the details of this study to me. I give assent for ……. to enter this study.

Signature of the relative **Date:**

Name of the relative

Nature of relationship

Signature of the investigator **Date:**

Appendix 2: Consent form in Tamil

ஒப்புதல் படிவம்

ஆய்வின் தலைப்பு:
மனச்சிதைவு நோயுற்றோரின் உடலுறவுப் பிரச்சனைகள்.

நிலையம்:
கிருத்துவ மருத்துவக் கல்லூரி, வேலூர்.

ஆய்வின் நோக்கம்:
மனச்சிதைவு நோயுற்ற ஆண்களுக்கு உடலுறவு பிரச்சனைகள் பொதுவாக காணப்படுகிறது. நாங்கள் இந்த உடலுறவு பிரச்சனைகள் எந்தவிதத்தில் இருக்கின்றன என்பதையும் மற்றும் மருந்துகளால் எந்தவித பிரச்சனைகள் ஏற்படுகின்றன என்பதையும் இந்த ஆய்வின் மூலம் தெரிந்துக்கொள்ள விரும்புகிறோம்.

பின்பற்ற இருக்கும் செயல்முறை:
மனநோய் மருத்துவப் பிரிவிலிருந்து ஒரு மருத்துவர் இந்த ஆய்வினை மேற்கொள்வார். அவர் பலவித உடலுறவு செயல்பாடுகள் பற்றிய தகவல்களை சில கேள்விச்சாதனங்கள் மூலம் சேகரிப்பார். தங்களின் தனிப்பட்ட விஷயங்கள் குறித்து சில கேள்விகள் கேட்கப்பட உள்ளது. நீங்கள் அந்தவித கேள்விகளுக்கு பதிலளிக்கவும் அல்லது மறுப்பு தெரிவிக்கவும் தங்களுக்கு முழு சுதந்திரம் உள்ளது. ஒவ்வொரு நேர்முக கலந்துரையாடலுக்குப் பின் ஒரு இரத்தப் பரிசோதனை செய்ய வேண்டி தாழ்மையடன் கேட்டுக்கொள்ளப்படும். சுமார் ஒரு நூறு ஆண்கள் இந்த ஆய்வில் கலந்துக்கொள்வார்கள்.

எதிர்பார்க்கப்படும் பங்கேற்பு காலம்:
இந்த ஆய்வின் நேர்முக கலந்துரையாடல் மூன்று முறை வெவ்வேறு காலங்களில் நடைபெறும். ஒவ்வொரு முறையும் கலந்துரையாடல் சுமார் அரைமணி நேரம் வரை ஆகலாம்.

இந்த ஆய்வின் மூலம் ஏற்படும் நன்மைகள்:
எங்களுக்கு கிடைக்கும் தகவல்கள் மூலம் தங்களின் உடலுறவு செயல்பாட்டில் உள்ள பிரச்சனைகளை நாங்கள் அறிந்துகொள்வதற்கு உதவியாக இருக்கம். மேற்கொண்டு இதற்கு சிகிச்சை தேவைப்பட்டால் அல்லது தாங்கள் உதவி வேண்டும் என்று விரும்பினால் அதன்படியே ஆலோசனை வழங்கப்படும். மேலும் இந்த ஆய்வின் முடிவில் தெரிய வரும் தகவல்களினால் மற்றவர்களும் பயன்பெற வாய்புகள் உள்ளது.

இரகசியக்காப்பு:
இந்த ஆய்வின் ஆவனங்கள் மற்றும் இந்த ஆய்வில் பெறப்படும் தகவல்கள் அனைத்தும் மிகவும் இரகசியமாக வைக்கப்படும். இந்த ஆய்வை மேற்கொள்ளும் மருத்துவரை தவிர மற்றவர்களுக்கு எப்பொழுதும் தெரியப்படமாட்டது. தங்களின் தனிப்பட்ட தகவல்கள் இந்த ஆய்விற்காக மட்டுமே பயன்படுத்தப்படும். தங்களின் பெயர் மற்றும் அடையாளம் எந்தவித வெளியீட்டிலும் தெரியபடுத்தமாட்டாது.

ஆய்விலிருந்து விலகிக்கொள்வதற்கான உரிமை:

இந்த ஆய்விலிருந்து விலகிக்கொள்வதற்கு எந்த நேரமும் தங்களுக்கு முழு சுதந்திரம் உண்டு. தாங்கள் இந்த ஆய்வில் பங்கேற்பதற்கும் அல்லது மறுப்பு தெரிவிப்பதற்கும் எடுக்கும் முடிவு இந்த மருத்துவமனையில் மேற்கொண்டு தொடர்ந்து மருத்துவ அல்லது மனநோய் சிகிச்சை பெறுவதை எந்த வகையிலும் பாதிக்காது. மேலும் சந்தேகங்களுக்கு கீழ்கண்ட முகவரியினை தொடர்புகொள்ளுங்கள்.

டாக்டர் : ர. தனஞ்செயன்
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ஒப்புதல்

..... என்கின்ற எனக்கு மனச்சிதைவு நோயுற்ற ஆண்களுக்கு ஏற்படும் உடலுறவு பிரச்சனைகள் குறித்த ஆய்வினை பற்றிய தகவல்கள் தெரிவிக்கப்பட்டது. இந்த ஆய்வின் விவரங்கள் பற்றி ஆய்வாளர் எனக்கு தெளிவாக எடுத்துக் கூறினார். நான் என் சொந்த விருப்பத்தில் இந்த ஆய்வில் கலந்துக்கொள்வதற்கு சம்மதம் தெரிவித்துக் கொள்கிறேன்.

கலந்துகொள்பவரின் கையொப்பம் : தேதி

ஆய்வாளரின் கையொப்பம் : தேதி

உறவினரின் ஒப்புதல்

..... என்பவரின் .....ஆகிய ..... என்கின்ற எனக்கு மனச்சிதைவு நோயுற்ற ஆண்களுக்கு ஏற்படும் உடலுறவு பிரச்சனைகள் குறித்த ஆய்வினை பற்றிய தகவல்கள் தெரிவிக்கப்பட்டது. இந்த ஆய்வின் விவரங்கள் பற்றி ஆய்வாளர் எனக்கு தெளிவாக எடுத்துக் கூறினார். ..... இந்த ஆய்வில் கலந்துக்கொள்வதற்கு அவரது சார்பாக நான் சம்மதம் தெரிவித்துக் கொள்கிறேன்.

உறவினரின் கையொப்பம் : தேதி

உறவுமுறையின் பெயர் :

ஆய்வாளரின் கையொப்பம் : தேதி

Appendix 3: Proforma for collecting sociodemographic and clinical data

PROFORMA

Name:

Hospital Number: Age (in years) of patient:
Age (in years) of spouse:

Marital status: Single/Married/Separated/Divorced/Widower

Duration of marriage:

Number of sexual partners:

Occupation: Patient:
Spouse:

Religion: Hindu/Christian/Muslim/Others

Number of Children:

Number of people staying in the same house:

Do you have a separate bedroom? Yes/No

Residence: 1) Urban 2) Rural

Years of Schooling:

Literacy: 1) Read and write 2) Read only 3) Illiterate

Type of house: 1) Concrete with more than 2 rooms 2) Concrete with 2 or less rooms 3) Mud thatched house 4) No house

House Ownership: 1) Own 2) Rented 3) Squatting

Unable to buy food in the last month: 1) No 2) Yes

Income of the family per month:

Patient income per month:

Are you in debt? 1) No 2) Yes
If yes how much?

Substance use? 1) No 2) Yes

Diagnosis:

Total duration of illness:

Duration of drug free period before current episode:

Age of onset of illness:

Number of psychotic episodes:

ECT: 1) No 2) Yes (details)

PANSS scores:

Subscales	Baseline	At six weeks	At six months
Positive			
Negative			
General Psychopathology			
Total			

IIEF scores:

Subscales	Baseline	At six weeks	At six months
Erectile function			
Orgasmic function			
Sexual desire			
Intercourse satisfaction			
Overall satisfaction			

Medical Illness: Yes/No
If yes give details

Biometric measurements:

	Baseline	At six weeks	At six months
Height			
Weight			
BMI			

Blood investigations:

Blood tests	Baseline	At six weeks	At six months
Serum testosterone			
Serum sex hormone binding globulin			
Fasting blood sugar			

Medications:

Name:

Duration:
Mean dose:

Name:

Duration:

Mean dose:

Name:

Duration:

Mean dose:

Name:

Duration:

Mean dose:

Extrapyramidal side effects:
Baseline:
At six weeks:
At six months:

Sexual Misconception: Yes/No
If yes details:

Marital satisfaction: Yes/No

Appendix 4: PANSS POSITIVE AND NEGATIVE SYNDROME SCALE

Item	Name	Baseline	Six weeks	Six months
P1	Delusions			
P2	Conceptual disorganization			
P3	Hallucinatory behavior			
P4	Excitement			
P5	Grandiosity			
P6	Suspiciousness/persecution			
P7	Hostility			
Total Positive				
N1	Blunted affect			
N2	Emotional withdrawal			
N3	Poor rapport			
N4	Passive/apathetic social withdrawal			
N5	Difficulty in abstract thinking			
N6	Lack of spontaneity &flow of conversation			
N7	Stereotyped thinking			
Total Negative				
G1	Somatic concern			
G2	Anxiety			
G3	Guilt feelings			
G4	Tension			
G5	Mannerisms and posturing			
G6	Depression			
G7	Motor retardation			
G8	Uncooperativeness			
G9	Unusual thought content			
G10	Disorientation			
G11	Poor attention			
G12	Lack of judgement & insight			
G13	Disturbance of volition			
G14	Poor impulse control			
G15	Preoccupation			
G16	Active social avoidance			
Total GP score				
Total score				

Appendix 5: IIEF

International Index of Erectile Function (IIEF) Questionnaire*

Name:_____ Date:_____

(Write the number that best describes your erectile function for the past 4 weeks in the spaces provided.)

Over the past four weeks:	0 = No sexual activity
1. How often were you able to get an erection during sexual activity? _____	1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration? _____	0 = No sexual activity 1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
3. When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner? _____	0 = Did not attempt intercourse 1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
4. During intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? _____	0 = Did not attempt intercourse 1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
5. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse? _____	0 = Did not attempt intercourse 1 = Extremely difficult 2 = Very difficult

3 = Difficult
4 = Slightly difficult
5 = Not difficult

6. How many times have you attempted sexual intercourse? _____

0 = No attempts
1 = One to two attempts
2 = Three to four attmepts
3 = Five to six attempts
4 = Seven to ten attempts
5 = Eleven or more attempts

7. When you attempted sexual intercourse, how often was it satisfactory for you? _____

0 = Did not attempt intercourse
1 = Almost never/never
2 = A few times (much less than half the ti me)
3 = Sometimes (about half the time)
4 = Most times (much more than half the ti me)
5 = Almost always/always

8. How much have you enjoyed sexual intercourse? _____

0 = No intercourse
1 = No enjoyment
2 = Not very enjoyable
3 = Fairly enjoyable
4 = Highy enjoyable
5 = Very highly enjoyable

9. When you had sexual stimulation or intercourse, how often did you ejaculate? _____

0 = No sexual stimulation/intercourse
1 = Almost never/never
2 = A few times (much less than half the ti me)
3 = Sometimes (about half the time)
4 = Most times (much more than half the ti me)
5 = Almost always/always

10. When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax? _____

0 = No sexual stimulation/intercourse
1 = Almost never/never
2 = A few times (much less than half the ti me)
3 = Sometimes (about half the time)
4 = Most times (much more than half the ti me)
5 = Almost always/always

11. How often have you felt sexual desire? _____

1 = Almost never/never
2 = A few times (much less than half the ti

	me) 3 = Sometimes (about half the time) 4 = Most times (much more than half the ti me) 5 = Almost always/always
12. How would you rate your sexual desire? _____	1 = Very low/none at all 2 = Low 3 = Moderate 4 = High 5 = Very high
13. How satisfied have you been with your overall sex life? _____	1 = Very dissatisfied 2 = Moderately dissatisfied 3 = About equally satisfied and dissatisfied 4 = Moderately satisfied 5 = Very satisfied
14. How satisfied have you been with your sexual relationship with your partner? _____	1 = Very dissatisfied 2 = Moderately dissatisfied 3 = About equally satisfied and dissatisfied 4 = Moderately satisfied 5 = Very satisfied
15. How would you rate your confidence that you could get and keep an erection? _____	1 = Very low 2 = Low 3 = Moderate 4 = High 5 = Very high

*RC Rosen, A Riley, G Wagner et al. The international index of erectile dysfunction (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology 1997 49: 822-30.

இந்தக் கேள்விகள் <u>கடந்த 4 வாரங்களில்</u> உங்களுடைய விறைப்புத் தொடர்பான பிரச்சினைகள் உங்கள் பாலியல் வாழ்க்கையில் ஏற்படுத்தியிருக்கும் விளைவுகளைப் பற்றிக் கேட்கின்றன. தயவு செய்து இந்தக் கேள்விகளுக்கு இயன்றவரை நேர்மையாகவும் தெளிவாகவும் பதிலளியுங்கள். தயவு செய்து ஒ வ்வொரு கேள்விக்கும் ஒரு கட்டத்தில் டிக் [✓] செய்து பதிலளியுங்கள். எந்த பதிலைத் தேர்ந்தெடுப்பது என்பதில் உங்களுக்குத் தயக்கம் எற்பட்டால், தயவு செய்து உங்களால் இயன்ற அளவு சிறப்பான பதிலைத் தேர்ந்தெடுக்கவும்.

இந்தக் கேள்விகளுக்கு பதிலளிப்பதில் பின்வரும் விளக்கங்கள் பொருந்தும்:

* **உடலுறவு**

இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.

** **பாலியல் செயல்பாடு**

இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, சுயமைதுனம் ஆகியவை அடங்கும்.

*** **விந்து வெளிப்படுதல்**

இது ஆணுறுப்பிலிருந்து விந்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.

**** **பாலியல் தூண்டல்**

மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

1. <u>கடந்த 4 வாரங்களில்</u> பாலியல் செயல்பாட்டின்போது** எத்தனை தடவை உங்களால் விறைப்பை வரவழைக்க முடிந்தது?
   தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

   பாலியல் *செயல்பாடு* எதுவும் இல்லை ..... ☐
   கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும்..... ☐
   பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்) ..... ☐
   சில தடவைகள் (சுமார் பாதி தடவைகள்) ..... ☐
   ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு)..... ☐
   கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை..... ☐

2. <u>கடந்த 4 வாரங்களில்</u> பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்தும் அளவிற்கான, பாலியல் தூண்டலோடு**** சேர்ந்த விறைப்பை நீங்கள் எத்தனை தட வைப் பெற்றீர்கள்?
   தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

   பாலியல் தூண்டல் இல்லை..... ☐
   கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும்..... ☐
   பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்) ..... ☐
   சில தடவைகள் (சுமார் பாதி தடவைகள்) ..... ☐
   ஒரு சில த டவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ..... ☐
   கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை ..... ☐

அடுத்த 3 கேள்விகளும் உடலுறவின்* போது உங்களுக்கு ஏற்பட்டிருக்கக் கூடிய விறைப்பு பற்றிக் கேட்கின்றன.

3. <u>கடந்த 4 வாரங்களில்</u> நீங்கள் உடலுறவு* கொள்ள முயன்றபோது எத்தனை தடவை உங்கள் மனைவியின் பெண்ணுறுப்பிற்குள் உங்கள் ஆணுறுப்பைப் புகுத்த (நுழைக்க) முடிந்தது?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

- உடலுறவு கொள்ள முயற்சிக்கவில்லை ☐
- கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ☐
- பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்) ☐
- சில தடவைகள் (சுமார் பாதி தடவைகள்) ☐
- ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ☐
- கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை ☐

4. <u>கடந்த 4 வாரங்களில்</u> உடலுறவு* கொண்டபோது, உங்கள் மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைச் செலுத்திய (நுழைத்த) பின் <u>**எத்தனை தடவை**</u> உங்கள் விறைப்பைத் தக்கவைத்துக் கொள்ள முடிந்தது?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

- உடலுறவு கொள்ள முயற்சிக்கவில்லை ☐
- கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ☐
- பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்) ☐
- சில தடவைகள் (சுமார் பாதி தடவைகள்) ☐
- ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ☐
- கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை ☐

5. <u>கடந்த 4 வாரங்களில்</u> உடலுறவு* கொண்டபோது, உடலுறவு முடியும் வரை விறைப்பைத் தக்கவைத்துக் கொள்வது <u>எவ்வளவு கடினமாக</u> இருந்தது?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

- உடலுறவு கொள்ள முயற்சிக்கவில்லை ☐
- *மிகமிகக் கடினமாக* ☐
- மிகவும் கடினமாக ☐
- கடினமாக ☐
- சிறிது கடினமாக ☐
- கடினமாக இல்லை ☐

* **உடலுறவு**: இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.
** **பாலியல் செயல்பாடு**: இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, சுயமைதுனம் ஆகியவை அடங்கும்.
*** **வித்து வெளிப்படுதல்**: இது ஆணுறுப்பிலிருந்து வித்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.
**** **பாலியல் தூண்டல்**: மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

6. <u>கடந்த 4 வாரங்களில்</u> எத்தனை தடவை நீங்கள் உடலுறவு* கொள்ள முயற்சித்தீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

முயற்சிக்கவில்லை ☐
1-2 தடவைகள் ☐
3-4 தடவைகள் ☐
5-6 தடவைகள் ☐
7-10 தடவைகள் ☐
11-க்கும் மேற்பட்ட தடவைகள் ☐

7. <u>கடந்த 4 வாரங்களில்</u> உடலுறவு* கொள்ள முயற்சித்தபோது, அது எத்தனை தடவை **<u>உங்களுக்குத்</u>** திருப்தியளிப்பதாக இருந்தது?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

உடலுறவு கொள்ள முயற்சிக்கவில்லை ☐
கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ☐
பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்) ☐
சில தடவைகள் (சுமார் பாதி தடவைகள்) ☐
ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ☐
கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை ☐

8. <u>கடந்த 4 வாரங்களில்</u> நீங்கள் உடலுறவில்* எவ்வளவு இன்பம் கண்டீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

உடலுறவு கொள்ளவில்லை ☐
மிக அதிக அளவு இன்பம் ☐
அதிக அளவு இன்பம் ☐
சுமாரான அளவு இன்பம் ☐
அதிக இன்பமாக இல்லை ☐
இன்பமாக இல்லை ☐

* **உடலுறவு**: இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.
** **பாலியல் செயல்பாடு**: இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, கயமைதனம் ஆகியவை அடங்கும்.
*** **விந்து வெளிப்படுதல்**: இது ஆணுறுப்பிலிருந்து விந்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.
**** **பாலியல் தூண்டல்**: மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

9. <u>கடந்த 4 வாரங்களில்</u> உங்களுக்குப் பாலியல் தூண்டல்**** ஏற்பட்டபோது <u>**அல்லது**</u>
நீங்கள் உடலுறவு* கொண்டபோது உங்களுக்கு எத்தனை தடவை விந்து வெளிப்பட்டது***?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

பாலியல் தூண்டலோ உடலுறவோ இல்லை ..... ☐
கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ..... ☐
பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்)..... ☐
சில தடவைகள் (சுமார் பாதி தடவைகள்)..... ☐
ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ..... ☐
கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை..... ☐

10. <u>கடந்த 4 வாரங்களில்</u> உங்களுக்குப் பாலியல் தூண்டல்**** ஏற்பட்டபோது <u>**அல்லது**</u>
நீங்கள் உடலுறவு* கொண்டபோது விந்து வெளிப்படுதலுடனோ*** வெளிப்படாமலோ
நீங்கள் எத்தனை தடவை உச்சநிலை உணர்வைப் பெற்றீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

பாலியல் தூண்டலோ உடலுறவோ இல்லை ..... ☐
கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ..... ☐
பெரும்பாலான தடவைகள் (பாதி தடவைகளுக்கும் மிக அதிகம்)..... ☐
சில தடவைகள் (சுமார் பாதி தடவைகள்)..... ☐
ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ..... ☐
கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை..... ☐

* **உடலுறவு**: இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.
** **பாலியல் செயல்பாடு**: இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, சுயமைதுனம் ஆகியவை அடங்கும்.
*** **விந்து வெளிப்படுதல்**: இது ஆணுறுப்பிலிருந்து விந்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.
**** **பாலியல் தூண்டல்**: மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

அடுத்த 2 கேள்விகளும் பாலியல் இச்சையைப் பற்றிக் கேட்கின்றன. பாலியல் செயல்பாட்டில் ஈடுபட விரும்புதல் (உதா. சுய மைதுனம் அல்லது உடலுறவு*), பாலுறவு பற்றி யோசித்தல் அல்லது உடலுறவில் ஈடுபடாததால் விரக்தி ஆகியவையும் உள்ளடங்கக் கூடிய உணர்வை நாம் பாலியல் இச்சை என்று விளக்கலாம்.

11. <u>கடந்த 4 வாரங்களில்</u> உங்களுக்கு எத்தனை தடவை <u>பாலியல் இச்சை</u> ஏற்பட்டதாக உணர்ந்தீர்கள்?

தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

கிட்டத்தட்ட எப்போதும் அல்லது எப்போதும் ..... ☐
பெரும்பாலான தடவைகள் (பாதி தட வைகளுக்கும் மிக அதிகம்) ..... ☐
சில தடவைகள் (சுமார் பாதி தடவைகள்) ..... ☐
ஒரு சில தடவைகள் (பாதி தடவைகளை விட மிகக் குறைவு) ..... ☐
கிட்டத்தட்ட ஒருபோதும் இல்லை அல்லது ஒருபோதும் இல்லை ..... ☐

12. <u>கடந்த 4 வாரங்களில்</u> உங்களுக்கு இருந்த <u>பாலியல் இச்சையின்</u> நிலையை நீங்கள் எப்படி மதிப்பிடுவீர்கள்?

தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

மிக அதிகம் ..... ☐
அதிகம் ..... ☐
மிதம் ..... ☐
குறைவு ..... ☐
மிகக் குறைவு அல்லது இல்லவே இல்லை ..... ☐

* **உடலுறவு**: இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.

** **பாலியல் செயல்பாடு**: இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, சுயமைதுனம் ஆகியவை அடங்கும்.

*** **விந்து வெளிப்படுதல்**: இது ஆணுறுப்பிலிருந்து விந்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.

**** **பாலியல் தூண்டல்**: மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

13. <u>கடந்த 4 வாரங்களில்</u> உங்களின் ஒட்டுமொத்த <u>பாலியல் வாழ்க்கையில்</u> நீங்கள் எந்த அளவு திருப்தி அடைந்திருக்கிறீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

மிகவும் திருப்தி ..... ☐
மிதமான திருப்தி ..... ☐
ஏறத்தாழ சமமான திருப்தி மற்றும் அதிருப்தி ..... ☐
மிதமான அதிருப்தி ..... ☐
மிகவும் அதிருப்தி ..... ☐

14. <u>கடந்த 4 வாரங்களில்</u> உங்கள் மனைவியுடனான <u>பாலியல் உறவில்</u> நீங்கள் எவ்வளவு திருப்தி அடைதிருக்கிறீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

மிகவும் திருப்தி ..... ☐
மிதமான திருப்தி ..... ☐
ஏறத்தாழ சமமான திருப்தி மற்றும் அதிருப்தி ..... ☐
மிதமான அதிருப்தி ..... ☐
மிகவும் அதிருப்தி ..... ☐

15. <u>கடந்த 4 வாரங்களில்</u> உங்களுக்கு விறைப்பு ஏற்பட்டு அது நீடிக்கும் என்ற <u>நம்பிக்கையை</u> நீங்கள் எவ்வாறு மதிப்பிடுவீர்கள்?
தயவு செய்து ஒரு கட்டத்தில் மட்டும் டிக் செய்யுங்கள்.

மிக அதிகம் ..... ☐
அதிகம் ..... ☐
மிதம் ..... ☐
குறைவு ..... ☐
மிகக் குறைவு ..... ☐

* **உடலுறவு:** இது மனைவியின் பெண்ணுறுப்பிற்குள் ஆணுறுப்பைப் புகுத்துதல் (நுழைத்தல்) என்று விளக்கப்படுகிறது.
** **பாலியல் செயல்பாடு:** இதில் உடலுறவு, வருடிக் கொடுத்தல், உடலுறவுக்கு முன் காமவிளையாட்டு, சுயமைதுனம் ஆகியவை அடங்கும்.
*** **விந்து வெளிப்படுதல்:** இது ஆணுறுப்பிலிருந்து விந்து வெளிப்படுதல் (அல்லது அதுபோன்ற உணர்வு) என்று விளக்கப்படுகிறது.
**** **பாலியல் தூண்டல்:** மனைவியுடன் காதல் விளையாட்டில் ஈடுபடுதல், காமத்தைத் தூண்டும் படங்களைப் பார்த்தல் போன்றவை இதில் அடங்கும்.

IIEF scoring sheet

INTERNATIONAL INDEX OF ERECTILE FUNCTION SCORES

Q.NO.	BASELINE	SIX WEEKS	SIX MONTHS
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
TOTAL SCORE			

Appendix 6: DSM IV-TR Additional questions for diagnosing sexual dysfunction

Additional questions for DSM-IV TR Diagnosis

Question IIa:

Have you developed an extreme aversion to, or do you avoid genital sexual contact with your partner? Is this happening regularly or is it persistent?

Yes/No

Question IIb:

Do you ejaculate with minimal sexual stimulation before, on, or shortly after penetration and before you wish it to happen? Is this recurrent or persistent?

Yes/No

Question IIc:

Do you experience genital pain associated with sexual intercourse? Is it recurrent and persistent?

Yes/No

Question III:

Do these sexual difficulties cause marked distress or interpersonal difficulty?

Yes/No

Appendix 7: DSM IV-TR Protocol for diagnosing various types of sexual dysfunction

DSM-IV TR algorithm for sexual dysfunction

Hypoactive Sexual Desire Disorder

A. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity. The judgment of deficiency or absence is made by the clinician, taking into account factors that affect sexual functioning, such as age and the context of the person's life.

IIEF Question 11 & 12 score ≤ 3

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

Sexual Aversion Disorder

A. Persistent or recurrent extreme aversion to, and avoidance of, all (or almost all) genital sexual contact with a sexual partner.

Question No. IIa - Yes

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

Male Erectile Disorder

A. Persistent or recurrent inability to attain, or to maintain until completion of the sexual activity, an adequate erection.

IIEF Question No. 1, 2, 3, 4, 5 score ≤ 3 & $15 \leq 2$

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

Male Orgasmic Disorder

A. Persistent or recurrent delay in, or absence of, orgasm following a normal sexual excitement phase during sexual activity that the clinician, taking into account the person's age, judges to be adequate in focus, intensity, and duration.

IIEF Question 9&10 score ≤ 3

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

Premature Ejaculation

A. Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it. The clinician must take into account factors that affect duration of the excitement phase, such as age, novelty of the sexual partner or situation, and recent frequency of sexual activity.

Question No. IIb - Yes

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

Dyspareunia

A. Recurrent or persistent genital pain associated with sexual intercourse

Question No. IIc - Yes

B. The disturbance causes marked distress or interpersonal difficulty.

Question III - Yes

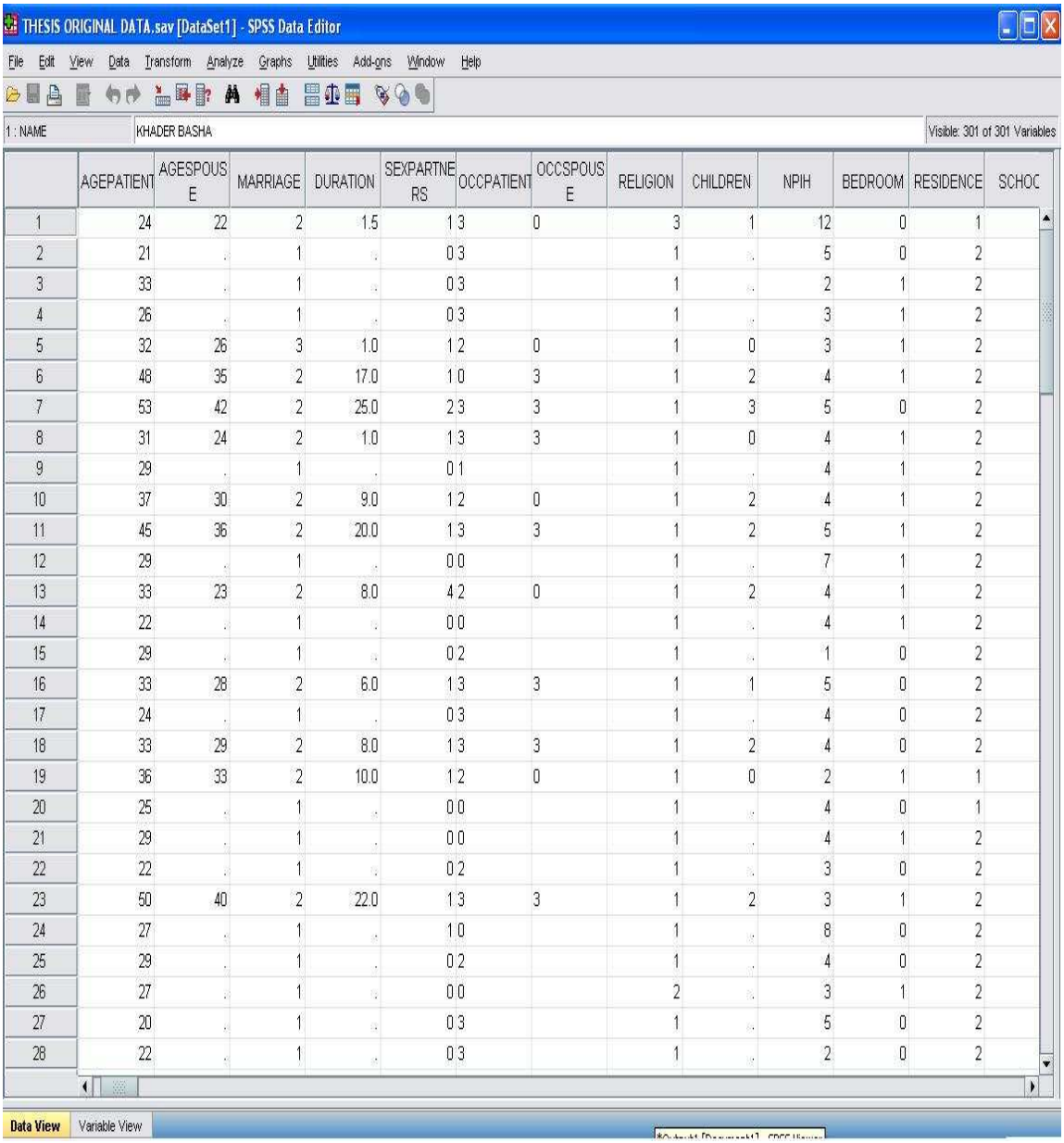
Appendix 8: UKU Scale

UKU SIDE EFFECT RATING SCALE

(NEUROLOGIC)

CATEGORY	SYMPTOM	BASELINE	SIX WEEKS	SIX MONTHS
2.1	Dystonia			
2.2	Rigidity			
2.3	Hypokinesia/akinesia			
2.4	Hyperkinesia			
2.5	Tremor			
2.6	Akathisia			
2.7	Epileptic seizures			
2.8	Paraesthesias			

Appendix 9: SPSS data sheet



THESIS ORIGINAL DATA.sav [DataSet1] - SPSS Data Editor

File Edit View Data Transform Analyze Graphs Utilities Add-ons Window Help

1 : NAME KHADER BASHA Visible: 301 of 301 Variables

	AGEPATIENT	AGESPOUSE	MARRIAGE	DURATION	SEXPARTNERS	OCCPATIENT	OCCSPOUSE	RELIGION	CHILDREN	NPIH	BEDROOM	RESIDENCE	SCHOC
1	24	22	2	1.5	1	3	0	3	1	12	0	1	
2	21	.	1	.	0	3		1	.	5	0	2	
3	33	.	1	.	0	3		1	.	2	1	2	
4	26	.	1	.	0	3		1	.	3	1	2	
5	32	26	3	1.0	1	2	0	1	0	3	1	2	
6	48	35	2	17.0	1	0	3	1	2	4	1	2	
7	53	42	2	25.0	2	3	3	1	3	5	0	2	
8	31	24	2	1.0	1	3	3	1	0	4	1	2	
9	29	.	1	.	0	1		1	.	4	1	2	
10	37	30	2	9.0	1	2	0	1	2	4	1	2	
11	45	36	2	20.0	1	3	3	1	2	5	1	2	
12	29	.	1	.	0	0		1	.	7	1	2	
13	33	23	2	8.0	4	2	0	1	2	4	1	2	
14	22	.	1	.	0	0		1	.	4	1	2	
15	29	.	1	.	0	2		1	.	1	0	2	
16	33	28	2	6.0	1	3	3	1	1	5	0	2	
17	24	.	1	.	0	3		1	.	4	0	2	
18	33	29	2	8.0	1	3	3	1	2	4	0	2	
19	36	33	2	10.0	1	2	0	1	0	2	1	1	
20	25	.	1	.	0	0		1	.	4	0	1	
21	29	.	1	.	0	0		1	.	4	1	2	
22	22	.	1	.	0	2		1	.	3	0	2	
23	50	40	2	22.0	1	3	3	1	2	3	1	2	
24	27	.	1	.	1	0		1	.	8	0	2	
25	29	.	1	.	0	2		1	.	4	0	2	
26	27	.	1	.	0	0		2	.	3	1	2	
27	20	.	1	.	0	3		1	.	5	0	2	
28	22	.	1	.	0	3		1	.	2	0	2	

Data View Variable View