# ASSESSMENT OF SEXUAL DYSFUNCTION AND ITS ASSOCIATIONS AMONG MALE PATIENTS DEPENDENT ON NATURAL OPIUM SEEKING TREATMENT FROM A TERTIARY CARE CENTRE



Thesis

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

## **DOCTOR OF MEDICINE (MD)**

(PSYCHIATRY)

JULY, 2020

**DR. DINESH KUMAR** 

AIIMS, JODHPUR

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## **ABBREVIATIONS**

ASEX	Arizona Sexual Experience Scale
BMT	Buprenorphine Maintenance Treatment
СІ	Confidence interval
CLIA	Chemiluminescence Immunoassay
COWS	Clinical Opioid Withdrawal Scale
DSM	Diagnostic and Statistical Manual for Mental Disorders
ED	Erectile Dysfunction
FSH	Follicular Stimulating Hormone
FTND	Fagerstrom Test for Nicotine Dependence
FTND-ST	Fagerstrom Test for Nicotine Dependence – Smokeless Tobacco
GnRH	Gonadotropin-Releasing Hormone
ICD	International Classification of Diseases
HEF	International Index of Erectile Function
IQR	Interquartile Range
LH	Luteinizing Hormone
MMT	Methadone Maintenance Treatment
NMHS	National Mental Health Survey
OUD	Opioids Use disorder
OR	Odd Ratio
RAS	Relationship Assessment Scale
SD	Sexual Dysfunction
SKAQ-II	Sex Knowledge and Attitude Questionnaire
SODQ	Severity of Opioid Dependence Questionnaire
SQoL-M	Sexual Quality of Life Questionnaire- male
ТТ	Total Testosterone
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

#### SUMMARY

Background: Natural opioids have been utilized for ages in socio-cultural contexts in nations like India. According to reports, opium is utilized in northwest India to alleviate pain, treat health issues, for enjoyment, and to strengthen social ties. It is commonly believed in community that opium use is associated with increased performance in physical, mental and sexual domains. Several studies have shown that opioids can improve mood or sexual performance by lowering or decreasing anxiety, but persistent usage can cause various sexual problems. According to the literature, opium negatively affects the endocrine system it binds to opioid receptors in the hypothalamus, and pituitary affecting the gonadal processes decreasing the release of gonadotropinreleasing hormone (GnRH) at the level of the hypothalamus, which causes a decrease in the pituitary's production of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) as well as a subsequent decline in the production of gonadal steroids (hypogonadism) and it has a direct effect on the testicles, which reduces the release of testosterone. The majority of earlier studies have assessed sexual dysfunction either in patients using synthetic opioids such as heroin or therapeutic opioids such as Methadone, Buprenorphine, and tramadol. Natural opium use is common in this region of India, and there is limited data among this population regarding the effect of natural opium on sexual functioning. Because the effect of natural opium on gonadal steroid production and its association with sexual dysfunction remains unclear, this study examined the association of sexual dysfunction with the hormonal level of Total testosterone, LH, FSH and Prolactin. Hence, this study is helpful to know the association between natural opium use and sexual functioning and also to fill the existing gap in this important area.

**Aim:** To evaluate the sexual dysfunction and its associations in male patients dependent on natural opium

**Methodology:** A total 107 participants who fulfilled the selection criteria were recruited and explained about the study in detail, and written informed consent was taken. After that socio-demographic and clinical profile sheet was filled. The severity of opioid and tobacco dependence was measured by the Severity of Opioid Dependence Questionnaire (SODQ), Fagerström Test for Nicotine Dependence (FTND) and FTND-smokeless tobacco (ST) respectively. Thereafter assessment for sexual dysfunction was carried out if the patient had a withdrawal score <5, based on an assessment on the clinical opiate withdrawal scale (COWS). Sexual knowledge was checked by Sex Knowledge and Attitude Questionnaire (SKAQ)-II and sexual functioning was assessed by using the International Index of Erectile Function (IIEF) and Arizona Sexual quality of life was assessed by Relationship Assessment Scale and Sexual Quality of life Questionnaire-male (SQoL-M) respectively. Hormone profile (Total Testosterone, FSH, LH, Prolactin) assay was done by the process of Chemiluminescence immunoassay (CLIA) for which morning sample was drawn.

**Results:** All the study participants were males belonging to Hindu religion. Mean age of the patients was  $35.34 \pm 6.65$ , with mean years of education was  $10.86 \pm 4.18$  and with a mean Family income of around 29000 rupees per month. Among the total participants, 67 patients used Amal and other 40 used Doda. Nearly 23% had a family history of substance use. Prevalence of sexual dysfunction was around 47% and 91% by using ASEX and IIEF respectively. Around 22% of cases were found to have low Testosterone and around 16% of case were found to have low LH. Hyperprolactinemia

and low FSH was found in around 11% and 3% cases respectively. Significant difference in the age, occupation and SODQ total score were present between sexual dysfunction and non-sexual dysfunction group. There was no significant difference between the groups in other socio-demographic variables and clinical variables. Also, there was significant difference in both groups in all subdomains of the ASEX scale, in domains of Sexual desire and Overall satisfaction on IIEF scale, in the Knowledge part on SKAQ scale, SQoL-M scale and serum testosterone level. On Spearman's correlation, age was found to be significantly correlated with dysfunction in all domains of the ASEX scale and total ASEX scale score along with the dysfunction in the domain of the IIEF scale like sexual desire and overall satisfaction, knowledge part of SKAQ-II scale and total score of SQoL-M. Age of Opioid initiation was found significantly correlated with the total score of the ASEX scale along with other domains except for the domain of ASEX arousal, the domain of the IIEF scale like sexual desire, and overall satisfaction. The total score of SODQ was significantly correlated with the total score of the ASEX scale, all individual domains and all domains of the IIEF scale except for the orgasmic function, total score of RAS scale, SQoL-M and knowledge part of the SKAQ-II scale. A total score of SQoL-M had a significant correlation with a total score of ASEX, all domains of this scale except the arousal domain; other domains of IIEF scale (erectile function, sexual desire, and overall satisfaction). The knowledge part of SKAQ-II was found to have significant correlation with the total score of ASEX, all domains of this scale except the arousal domain; other domains of IIEF scale (erectile function, sexual desire, and overall satisfaction). The attitude part of SKAQ-II was found to have significant correlation with total score of ASEX, and its desire and satisfaction with orgasm domains. Serum level of testosterone was found to have significant correlation with only the ability to reach orgasm domain of ASEX scale. By using binary logistic regression, total score of SODQ (OR = 1.124, 95 % C.I. 1.124-1.060, p = <0.001) and Testosterone (OR: 0.997, 95 % C.I. 0.997-0.995. p = 0.022) were found to be significant predictor for sexual dysfunction.

**Conclusion:** In this study, nearly half of the patients had sexual dysfunction and desire/drive was the most frequently affected domain. Total score of SODQ and Testosterone were found to be significant predictor for sexual dysfunction. Hence, the clinicians should routinely enquire about it and attempt to address the same during treatment.

#### INTRODUCTION

The term opioid has come to refer to any natural, semi-synthetic, or synthetic drug that interacts with opioid receptors as full or partial agonist. Opium, the first chemical in this pharmacological category, is produced from poppies, the common name for Papaver somniferum, one of the numerous species in the Papaveraceae family with solitary leaves and capsulated fruits. The main difference between an opiate and an opioid is that opiates are naturally made and opioids are both synthetically and naturally made. All opiates are classified under the opioids category, but not all opioids are opiates. Opioids act on the opioid receptors mu, delta, and kappa in the human body to suppress respiration, heighten pleasure, and block pain impulses from the neurological system. Other then natural opium, the opioid family also includes a range of synthetic or pharmaceutical opioids such as methadone, pethidine, tramadol, and fentanyl. (1)

Natural opioids have been utilized for ages in socio-cultural contexts in nations like India. According to reports, opium is utilized in northwest India to alleviate pain, treat health issues, for enjoyment, and to strengthen social ties. (2) As a result, although progressively being undermined by the implementation of tight laws, societal acceptance of natural opioids has been widespread in the Indian cultural setting. Instead, stronger and easier-to-obtain prescription opiates are taking their place. (3)

In the past, opium was frequently used in battle to stop bleeding in Rajput soldiers in Rajasthan. It was also utilized ceremonially in several regions of India on important occasions, festivals, and village social gatherings. (4) In Rajasthan, the use of opium is customary and firmly woven into the "socio-cultural fabric." Even though 90% of the users consumed a significant amount of opium, they stayed within the bounds of acceptable conduct and were seen as usual. Opium was served to visitors at ceremonies

for marriages, funerals, and other events in the same manner as food and beverages. The elders, family chiefs, and shamans all received gifts of opium. However, parents regularly intervened with authorities to discourage and advise their young sons and daughters against associating with opium users. Long-time opium users in the community were met with a mix of acceptance and rejection. (2)

Opium is readily available in Rajasthan since it is also grown legally throughout the country, including in the cities of Kota, Baran, Jhalawar, Chittorgarh, Udaipur, and Bhilwara, as well as through illegal trafficking. (2, 5, 6) It is commonly believed in community that opium use is associated with increased performance in physical, mental and sexual domains. People also believe that it's use is safe and it will further prevent uses of other illicit substances.

Opium is generally known as Amal in the local dialect and is accessible in two forms; the nugget form is known as Amal (exudate from poppy pod) and generates 9.5-14.2% morphine, whilst the powered form is known as Doda (poppy husk) and yields 0.1-0.3% morphine. The poorer population mostly consumes Doda because it is cheaper than Amal. However, consumption of the cheaper quality of opium is not good for health as it is often adulterated with jaggery, sugar, and even sometimes burnt rubber granules. In addition to codeine, papaverine, thebaine, and other naturally occurring opiates, the medication morphine, which is generated from the natural juice of the opium poppy, is thought to be the most effective analgesic painkiller on the market. It is also known to provide relaxation and pleasure. All opioids, including morphine, heroin, and prescription analgesics, have a very high potential for misuse because of these characteristics. (7)

According to the World Drug Report 2022, over 284 million persons aged between 15 to 64 years were took drugs globally in 2020, a 26% rise over the previous decade. Young people are taking more drugs, with rates of consumption in many nations being greater than in earlier generations.

According to the World Drug Report 2020, opioid consumption was prevalent in 61.3 million persons, accounting for 1.2% of the world's population aged 15-64 years, with men being the majority (80%). The report has also claimed India to be having most number of opiate users in the world. The trend is anticipated to rise with an increase in illegal trade. The information provided by the United Nations Office on Drugs and Crime (UNODC) has given data regarding various form of opioids in India as:

- 5200 kg opium (4<sup>th</sup> highest globally)
- 700 kg morphine (3<sup>rd</sup> highest)
- 3750 kg heroin (5<sup>th</sup> highest)

The report, which was released on June 27, 2022, did not provide specific information about the number of opioid users in India but did note that the country is one of the biggest markets on the planet for the drug and is particularly vulnerable to supply growth given its geographic location between the Golden Triangle and Golden Crescent. Additionally, there are indications that illegal trades coming from Afghanistan may be intensifying, possibly moving eastward in addition to southwards and westward along the traditional route.

According to prevalence measurements, heroin, prescription opioids for non-medical use (25 of the reporting countries), opium (16 of the reporting countries), and tramadol (11 of the reporting countries) were the most commonly used opioids. (8)

As per the Magnitute of substance use in India 2019 survey, around 2.1% of the country's population, or 2.26 crore people, in India, use opioids, including heroin or its impure form (smack or brown sugar), opium or its variations (such as poppy husk known as Doda/phukki), and other prescription opioids. Heroin, prescription opioids, and opium are the most frequently used narcotics in India, in that order. Out of the entire 77 lakhs of such problem opioid users, 3.1 lakhs were found in Rajasthan. (9)

According to the National Mental Health Survey (NMHS) of India, for 2015–16, 0.6% of adults over 18 were diagnosed with an illicit substance use disorder, including opioid, cannabis, stimulant, inhalant, and prescription drug use. According to the survey, India has a significant "treatment gap", or the proportion of individuals who need therapy but are not getting it. According to NMHS, the treatment gap was more severe for alcohol use disorders (86%) than other drug use disorders (73%). (10)

Lakshmi Narayana and Singh (2009) surveyed 45 rural villages in the Rajasthan districts of Barmer, Jaisalmer, and Bikaner. In Barmer, Jaisalmer, and Bikaner, the addiction rates were 8.4%, 7.9%, and 6.9%, respectively. In Rajasthan, the incidence of natural opium consumption ranged from 6.4 to 8.9%. The rate of addiction with age and peaked (at 42%) in the 40–50 years of age range. The bulk were uneducated men who worked as farmers (>80%). Poor socioeconomic position and low literacy rates were the main causes of addiction, and key worries were health decline, rising opium prices, and the possibility that their kids may start using as well. (5)

The Eleventh Revision of the International Classification of Diseases and Health Problems (ICD-11) describes harmful use and dependence as: 6C43.1 Harmful pattern of use of opioids: "A pattern of use of opioids that has caused damage to a person's physical or mental health or has resulted in behavior leading to harm to the health of others".

**ICD-11: 6C43.2 Opioid dependence:** "Opioid dependence is a disorder of regulation of opioid use arising from repeated or continuous use of opioids. The characteristic feature is a strong internal drive to use opioids, which is manifested by impaired ability to control use, increasing priority given to use over other activities and persistence of use despite harm or negative consequences. These experiences are often accompanied by a subjective sensation of urge or craving to use opioids. Physiological features of dependence may also be present, including tolerance to the effects of opioids, withdrawal symptoms following cessation or reduction in use of opioids, or repeated use of opioids or pharmacologically similar substances to prevent or alleviate withdrawal symptoms. The features of dependence are usually evident over a period of at least 12 months but the diagnosis may be made if opioid use is continuous (daily or almost daily) for at least 3 months." (11)

Opioid-naive individuals are often aware of the sedative effects of opioids. It is believed that opioids' anticholinergic action causes opioid-induced sedation and sleepiness. Although tolerance to these adverse effects frequently develops over time, dosage introduction and fast dose escalation may cause drowsiness, impairing compliance and/or lowering the quality of life. (12) Opioids are frequently thought to improve sleep, although there is not much data to back this up. Opioids cause more sleep-waking transitions, less overall sleep time, sleep efficiency, delta sleep, and REM sleep. (13) Constipation is a typical issue that affects 40% to 95% of individuals using opioid medications. It can even happen after taking only one dosage of morphine. Constipation

is sometimes brushed off as a minor side effect, but its long-term effects can cause severe morbidity or death or negatively impact patients' quality of life. (13) Opioids are widely recognized for inhibiting the voiding reflex, reducing detrusor tone and contraction force, and the feeling of fullness and the need to urinate. (14) Opioid side effects on the cardiovascular system are uncommon. The production of histamine, which results in vasodilation and hypotension, has been linked to morphine. Chronic opioid medication, particularly when methadone and buprenorphine are used, can occasionally cause cardiovascular adverse effects, including QTc prolongation. (15)

People use to take opium for various issues related to sexual functioning such as to control their pre-sex performance anxiety, to improve their sexual performance, and to self-treat their sexual problems. (16) Specifically, opioids have been used as an aphrodisiac, to prolong erections and postpone ejaculation. (17,18) Several studies have shown that these drugs can improve mood or sexual performance by lowering or decreasing anxiety, but persistent usage can cause problems with erection, orgasm, and even ejaculation. (19) Although the link between opiate usage and sexual dysfunction is complicated, those who abuse them have both short- and long-term sexual dysfunction. Sexual dysfunction is a common and clinically important side effect of heroin abuse and opioid substitution therapy, among other possible negative effects. Due to the potential for non-adherence to treatment and high dropout rates, this region is frequently disregarded and hence unexplored in normal clinical care of opioid users.

In the community, sexual dysfunction (SD) is fairly prevalent. More than 40% of women and 30% of men in a large epidemiological population study in the United States were found to have some form of SD, with decreased sexual desire in women (22%) and premature ejaculation in males (21%) being the most prevalent. (20)

Using the ASEX and IIEF scale, Rao TSS et al., (2015) conducted a door-to-door survey among 1529 participants (742 men; 787 females) to evaluate the prevalence of sexual disorders and their associations with various sociodemographic factors in the chosen rural region. One (or more) sexual disorders were identified in 21.15 per cent of the male participants. Men were found to have a prevalence of 15.77% for erectile dysfunction, 2.56% for male hypoactive sexual desire disorder (HSDD), and 8.76% for premature ejaculation. (21)

In a meta-analysis conducted by Yee A et al., (2014) 52% of male patients receiving methadone and buprenorphine therapy experienced sexual dysfunction. (22) According to a recent systemic review by Sarkar S et al., (2021) prevalence rates for sexual dysfunction varied from 40 to 90% for research involving opioid dependence. (23)

Among comparison to the general population, SD was more prevalent in those who were dependent on heroin or receiving methadone maintenance therapy (MMT) or buprenorphine maintenance therapy (BMT). SD rates have varied between 14 and 81% (MMT), 34 and 85% (heroin addicts), and 36 to 83% (others). (16)

The person who has been using opioids for a long time reported a higher rate of erectile dysfunction (ED). In the literature, the prevalence of ED in the young population was reported in a range of 21-52%. (24,25) Rate of ED was highest in methadone, followed by heroin and buprenorphine group. (19,24,25)

#### Phases of Sexual functioning in male:

Most definitions are based on the four-phase model of Masters and Johnson from a psychiatric standpoint. (26)

- 1. **Sexual desire:** it comprises of the enticing or motivating elements of the sexual reaction. This phase includes cravings, fantasies, and desires related to sexuality.
- 2. **Sexual excitement:** a subjective feeling a personal experience of sexual pleasure and related physiologic alterations. Men's penile erection and women's vaginal lubrication are both parts of this phase.
- 3. **Orgasm or climax**: is the height of arousal marked by ejaculation in males and rhythmic genital muscle spasms in both sexes.
- 4. **Resolution:** it is characterized by an overall feeling of comfort and well-being

#### **Sexual Dysfunction:**

As per ICD-11, "Sexual Dysfunctions are syndromes that comprise the various ways in which adult people may have difficulty experiencing personally satisfying, non-coercive sexual activities. Sexual response is a complex interaction of psychological, interpersonal, social, cultural, and physiological processes, and these factors either alone or in combination may affect the different stages of the sexual response. To make the diagnosis of sexual dysfunction, the dysfunction must occur frequently, present for at least several months, and associated with clinically significant distress/impairment." (11)

In ICD-11 sexual dysfunction was further classified in following categories:

**HA00 Hypoactive sexual desire dysfunction:** It is characterized by the lack of or noticeably diminished drive or desire to participate in sexual activity, as shown by any of the following: Diminished or missing erotic response desire; reduced or absent spontaneous desire (sexual thoughts or fantasies); or difficulty to maintain interest in

sexual activity after it has begun. The pattern of reduced or absent spontaneous or responsive desire, or the inability to maintain desire or interest in sexual activity, has happened intermittently or consistently over a period of at least several months and is linked with clinically substantial suffering. (11)

**HA01 Sexual arousal dysfunctions:** Problems with the physiological or subjective components of sexual arousal are examples of sexual arousal dysfunctions.

• **HA01.1 Male erectile dysfunction**: Male erectile dysfunction is characterized by inability or marked reduction in the ability in men to attain or sustain a penile erection of sufficient duration or rigidity to allow for sexual activity. The pattern of erectile difficulty occurs despite the desire for sexual activity and adequate sexual stimulation, has occurred episodically or persistently over a period at least several months, and is associated with clinically significant distress.

**HA02 Orgasmic dysfunctions:** refers to challenges associated with the individual orgasmic experience.

**HA03 Ejaculatory dysfunctions:** ejaculatory latencies that are seen as being too short (Male early ejaculation) or too protracted (ejaculatory issues in males) (Male delayed ejaculation).

• **HA03.0 Male early ejaculation:** characterized by ejaculation that happens without any or little apparent control prior to the start of vaginal penetration or other significant sexual stimulation, or within a very short time after. Early ejaculation is a trend that has happened repeatedly for at least a few months and is connected to clinically severe discomfort.

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• HA03.1 Male delayed ejaculation: it is associated with failure to ejaculate or an excessively long interval between ejaculations, even when there is sufficient sexual excitement and a desire to ejaculate. The pattern of delayed ejaculation is linked to clinically substantial distress and has happened intermittently or consistently for at least many months.

**Opioid induced Sexual dysfunction:** In ICD-11, each sexual dysfunction category was further specified:

## HA40.2 Associated with use of psychoactive substance or medication Other associative categories with sexual dysfunction:

- HA40.3 Associated with lack of knowledge or experience
- HA40.4 Associated with relationship factors
- HA40.5 Associated with cultural factors (11)

#### Assessment of SD in males:

Any patient with a sexual dysfunction has to be thoroughly assessed, including the kind of sexual dysfunction, causes contributing to or perpetuating the sexual dysfunction, and other relevant information. A complete history taking, focused physical examination, laboratory testing, including an assessment of the hormonal profile, assessment using validated scales, and proper consultation with the specialists are all necessary for a good evaluation. (27)

In general, these group of patients do not mention their sexual concerns to physicians, and professionals too either forget to ask such questions or are uncomfortable discussing and handling sexual difficulties. Therefore, it is important to assess and identify SD in clinical practice in order to effectively manage it and boost patient compliance because the presence of SD after quitting opiates may result in relapse and treatment dropout.

The majority of sexual dysfunction instances go undiagnosed because of ignorance, despite the fact that it is a fairly frequent problem among people. The patient learned information about sexual function via publications, newspapers, acquaintances, and material on the roadside. The patient may have misconstrued this information, which might have exacerbated pre-existing worry about sexual function. (28)

Adolescent sexual practices are influenced by their understanding of sex, attitudes, and sources of influence. (29) Sexual knowledge includes information about sex-related myths and misunderstandings as well as sexuality, reproduction, pregnancy, masturbation, abortion, fertility, methods of contraceptives, and sexually transmitted diseases. (30) A person's attitude toward sexuality or sexual behavior is referred to as their sexual attitude, and it can be either liberal or conservative. (31) Although young people are becoming more knowledgeable and aware of sexual and reproductive health, much of it is still superficial and contaminated with myths, misunderstandings, and a sense of invulnerability. (30)

A good sexual life is essential to adult wellbeing. Although sexual dysfunction seldom poses a life-threatening hazard, it commonly leads to people avoiding intimate relationships, which decreases their quality of life. Inadequate research has been done on sexual quality of life. (32)

According to Hendrick, "the measuring of a person's feelings and ideas about their marriage or comparable intimate connection" is what relationship satisfaction is all about. (33) Couples who are dissatisfied in their relationships have the potential to develop several serious psychological, social, and physical health issues. (34)

#### Physiology of opioid-endocrine interactions:

Male hypogonadism defined as a clinical disease that develops when the hypothalamicpituitary-gonadal axis is disrupted, preventing the testes from producing physiological amounts of testosterone (androgen deficiency). (35)

Many things can alter the hypothalamic-pituitary-gonadal axis. One of them is the presence of opioids. When hypogonadism results from opioid usage, known as opioid-associated androgen deficiency. (36)

Opium negatively affects the endocrine system in several ways. Opioids can bind to opioid receptors in the hypothalamus, pituitary, and testis, affecting the gonadal processes. Opioids work by decreasing the release of gonadotropin-releasing hormone (GnRH) at the level of the hypothalamus, which causes a decrease in the pituitary's production of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) as well as a subsequent decline in the production of gonadal steroids, or hypogonadism. Opioids can also have a direct effect on the testicles, which reduces the release of testosterone. Studies have shown that opioids also boost the pituitary's production of prolactin. (37) A reduction in testosterone production may result from increased prolactin levels in the blood and negative regulation of LH release. (38)

Most research has been on androgen hormones because of their association with several symptomatic side effects of opioid use. Many men who use prescribed or illegal opioids have a variety of negative side effects, such as depression, reduced energy, and sexual dysfunction (such as erectile dysfunction, diminished libido, etc.). Hypogonadism,

most likely hypogonadotropic hypogonadism, has been linked to several undesirable side effects. (39)

Although the link between opioid usage and sexual dysfunction is complicated, people who abuse opioids do have short- and long-term sexual dysfunction. A few patients may not genuinely have sexual dysfunction but may believe it to be so due to inadequate information and a negative outlook on sex. Additionally, in certain people, sexual issues may be related to cultural traditions and beliefs. It might also be useful for sexual education and psychoeducation.

The majority of earlier studies have assessed sexual dysfunction either in patients using synthetic opioids such as heroin or therapeutic opioids such as Methadone, Buprenorphine, and tramadol. Natural opium use is common in this region of India, and there is limited data among this population regarding the effect of natural opium on sexual functioning. Because the effect of natural opium on gonadal steroid production and its association with sexual dysfunction remains unclear, this study examined the association of sexual dysfunction with the hormonal level of Total testosterone, LH, FSH and Prolactin. Hence, this study is helpful to know the association between natural opium use and sexual functioning and also to fill the existing gap in this important area.

### **REVIEW OF LITERATURE**

Opioids have been associated with impairment in sexual functioning. The neurovascular, endocrine, and neurological systems work together to control the complicated bio-psycho-social process of sexual functioning. In addition to biological variables, psychosocial factors such as societal and religious beliefs, personal experience, ethnicity and socio-demographic situations, as well as the psychological status of the individual or couple, are crucial for a person's proper sexual functioning. Interpersonal interactions are also an aspect of sexual activity, with each partner bringing their own attitudes, wants, and reactions to the relationship. Sexual dysfunction might result from a malfunction in any of these areas.

The majority of earlier studies have assessed sexual dysfunction in patients using synthetic opioids such as heroin and therapeutic opioids such as Methadone, Buprenorphine, and tramadol. There is scarcity of literature about sexual dysfunction in patients using natural opium in western countries as well as in India.

#### Literature on reasons to start and continuing opioids:

A cross-sectional observational research was done by **Parmer A et al.**, (**2017**) on 100 individuals who used opium or poppy husk. The respondents' ages ranged from 18 to 65. The results indicated that 97% of people consumed poppy husk orally daily. Natural opiates were most frequently consumed out of curiosity and experimentation, while treatment was most frequently sought because one could not obtain opiates. Low rates of medical, family, social, psychological, and legal difficulties coexisted with World Health Organization Quality of Life Instrument, Short Form scores that ranged from 40 to 50 in various areas. (40)

According to **Chekuri V et al.**, (**2012**) the prevalence of premature ejaculation was nearly three times higher than what was recorded in the general population. Most patients thought heroin was beneficial for preventing early ejaculation (PE). Therefore, sexual dysfunction may be a risk factor for relapsing into heroin abuse. Most doctors refrain from asking sexually explicit inquiries about their patients. However, treating sexual issues in opiate-dependent people may be crucial in preventing relapse. (41)

**Lakshmi Narayana and Singh (2009)** performed a survey in 45 rural villages in the Rajasthan districts of Barmer, Jaisalmer, and Bikaner. In Rajasthan, the incidence of natural opium consumption ranged from 6.4 to 8.9%. Low socioeconomic level and low literacy rates were the primary causes of addiction. (5)

# Literature on prevalence and pattern of Sexual dysfunction in patients with Opioid dependence:

Research on 192 males on methadone maintenance therapy was undertaken by **Motazedian S et al., (2020)** to determine the impact of methadone use over time on erectile dysfunction. They have included demographic questions, questions about methadone usage, and questions about common erectile dysfunction. Thirty-seven men had mild erectile dysfunction, 78 had mild to moderate erectile dysfunction, 48 had serious erectile dysfunction, and 16 had severe erectile dysfunction. The results show that age and length of use are the most important risk factors for erectile dysfunction in men using methadone. Small sample size, lack of a control group, various confounding factors, and use of self-reporting scales were only a few of the study's drawbacks. It is advisable to do additional study, especially longitudinal research that examines biomarkers like hormone levels. (42)

A case control research was undertaken by **Hashim MA et al.**, (2019) to compare male tramadol hydrochloride users (n-30) with heroin use disorder patients (n-30) and control subjects (n-30) in terms of their sexual function and its relationship to free testosterone levels, luteinizing hormone, and follicle stimulating hormone. Sexual dysfunction was assessed using the International Index of Erectile Function. An enzyme-linked immunosorbent assay was performed to measure the levels of free testosterone, follicular stimulating hormone, and luteinizing hormone in a morning blood sample. They found that individuals with opiates use disorders had lower levels of luteinizing hormone and free testosterone than control subjects, with heroin addiction patients getting much lower levels than tramadol users. In contrast to control subjects, opioid-dependent persons (Tramadol and heroin abusers) were more likely to experience sexual dysfunction, with erectile dysfunction being the most severely affected domain. The small sample size was one of the limitation. (43)

**Yee A et al.**, (2016) conducted a cross sectional study to assess sexual dysfunction in individuals (age more than 18 years) on methadone maintenance therapy (MMT) and buprenorphine maintenance therapy (BMT). The World Health Organization Quality of Life Instrument, Short Form Scale, the Opiate Treatment Index, the Malay version of the International Index of Erectile Function 15 (Mal-IIEF-15), and the Mini International Neuropsychiatric Interview were all employed in this study. A total 67 individuals were receiving BMT, and 171 patients were receiving MMT. Those in the MMT group who had a sexual partner performed considerably worse than patients in the BMT group in the domains of overall pleasure and sexual desire. On the other hand, MMT patients who did not have a sexual partner performed considerably worse in orgasmic function. The category of social ties was strongly associated with intercourse satisfaction and overall satisfaction. (44)

A study done by **Ajo R et al., (2016)** assessed sexual dysfunction in patients with chronic use of opioids. It was a descriptive cross-sectional study and included 750 patients who presented with non-cancer pain. They have used medical records, Female Sexual Function Index and the International Index of Erectile Function scale to assess erectile function. Sexual dysfunction was reported in 33% of patients. (45)

**Yee A et al.**, (2014) conducted a meta-analysis to assess the prevalence and odds ratio of sexual dysfunction among male patients receiving methadone and buprenorphine therapies. They carefully evaluated heterogeneity, publication bias, and odds ratio. This meta-analysis found a total of 1,570 individuals from 16 eligible trials. They discovered that the prevalence of sexual dysfunction among methadone users was estimated to be 52% (95% confidence interval [CI], 0.39-0.65) based on pooled metaanalytical data. Only four studies evaluated the two groups' levels of sexual dysfunction, with the methadone group having a considerably higher cumulative odds ratio (OR = 4.01, 95% CI, 1.52-1.55, P = 0.0049). Evidence suggested that methadone users were more likely than buprenorphine users to experience sexual dysfunction. Patients receiving methadone therapy were encouraged to switch to Buprenorphine if they were experiencing sexual problems. (22)

In a sample of males receiving methadone maintenance treatment for opioid dependence, **Brown R et al. (2005)** conducted a research to determine the prevalence and forms of sexual dysfunction. They also discussed potential risk factors for sexual dysfunction. Utilizing the Sexual History Form and the Beck Depression Inventory-II, they included 92 opioid-dependent males. Total 40% of the males in this survey indicated some sexual dysfunction. Erectile dysfunction, libido dysfunction, and overall

dysfunction worsened with patients' advancing years. Increased orgasm dysfunction was correlated with a higher methadone dosage. (46)

**Pacheco Palha and M Esteves (2002)** studied the influence of heroin use on sexual behavior in 61 males and 40 female patients attending a drug abuse program using Sexuality Experience Scale and compared it with 102 age-matched healthy control. According to this survey, 67% of women and 75% of men said that their sexual desire had declined as a result of drug abuse. Around 62% of males and 60% of women had unfavorable effects on the orgasm. In the first six months, 21% of men and 28% of women said their sexuality had improved. This can encourage individuals to continue abusing drugs in the first month after becoming addicted. For 42.6% of men and 45% of women, sexual dysfunction was a factor in their decision to give up drugs. (47)

#### **Indian Literature:**

A systematic review of Indian research on sexual dysfunction in population with drug use disorders was conducted by **Sarkar S et al.**, (2021). To find papers over the previous 20 years that documented sexual dysfunction in people with various substance use disorders, electronic search engines were utilized to locate the studies. Most of these occurred in people with alcohol dependence, while opioid dependence was less common. Although several case-control cross-sectional studies were also found, singlegroup cross-sectional research designs predominated. In research on alcohol dependence and opioid dependence, the proportion of subjects with sexual dysfunction ranged from 22.2% to 76% and 40% to 90%, respectively. Numerous sexual dysfunctions, such as erectile dysfunction, inadequate erection, lack of desire, and low satisfaction, were discovered. Majority of the research did not include attempts to address bias and confounders. The author claimed that physicians could attempt to recognize and treat sexual dysfunction in individuals with drug use disorders while they are receiving treatment. (23)

**Mattoo SK et al., (2020)** done a study on prevalence and correlates of sexual dysfunction in men on Buprenorphine and naltrexone based substitution therapy. They included 40 men which were on treatment for six months. Sexual dysfunction was assessed by Arizona Sexual Experience Scale and International Index of Erectile Function. Prevalence of sexual dysfunction was 40%. The IIEF reported intercourse dissatisfaction in 95%, hypoactive sexual desire in 92.5% and erectile dysfunction in 77.5%. (48)

**Zhao S et al.**, (2017) conducted a review to assess whether opioid use was a risk factor for erectile dysfunction. This meta-analysis included 8,829 men (mean age = 41.6 years) from 10 studies and it was found that opioids use was significantly associated with an increased risk of ED (relative risk = 1.96, 95% CI=1.66–2.32, P < .001). (49)

A cross-sectional study was carried out by **Sethi MS et al.**, (**2017**) to determine the prevalence of sexual dysfunction in individuals with opioid dependence. The International Index of Erectile Function was used to evaluate 109 de-addiction clinic male applicants with age from 18 to 55 years for erectile dysfunction. They discovered that heroin was the opioid that was utilized the most (81.7%). Reduced orgasmic function (57.8%), erectile dysfunction (56.4%), decreased overall pleasure (52.2%), and decreased intercourse satisfaction (46.7%) were the most prevalent sexual dysfunctions. (50)

In order to evaluate sexual dysfunction in male individuals seeking therapy for opioid use, **Aggarwal N et al., (2016)** conducted a comparative cross-sectional observational study. Total 120 controls and 60 opioid dependent male patients with age ranges from 21 to 50 years were enrolled. Compared to the control group (15.8%-41.7%), cases (53.3%-81.7%) had considerably higher rates of sexual dysfunction. (51)

Using the Arizona Sexual Experience Questionnaire, International Index of Erectile Function, and Changes in Sexual Functioning Questionnaire Short-Form, **Venkatesh K et al.**, (2014) examined the incidence of sexual dysfunction in males seeking treatment for opioid dependency. Sexual dysfunction was found to affect 48% (by ASEX), 92% (by IIEF), and 90% of people by Changes in Sexual Functioning Questionnaire Short-Form scale. (52)

According to a review by **Grover S et al., (2014),** SD rates are greater in heroin addicts, those using MMT, or people receiving BMT than they are in the general population. SD rates for heroin users have ranged from 34 to 85%, for MMT, 14 to 80%, for BMT, and for naltrexone maintenance, from 36 to 80%. (16)

In order to evaluate sexual dysfunction in opioid-dependent males on buprenorphine and naltrexone maintenance treatment, **Ramdurg S et al.**, (2011) performed a research. They used the International Index of Erectile Function and the Brief Male Sexual Functioning Inventory on 60 patients. Premature ejaculation was observed in 83% of buprenorphine users and 87% of naltrexone users; erectile dysfunction in 43% of buprenorphine users and 67% of naltrexone users, and a loss or drop in sexual desire in 33% of buprenorphine users and 47% of naltrexone users. (53)

#### Literature on knowledge, attitude, behaviors towards sex:

Lahari S et al., (2021) conducted a research to examine sexual knowledge, attitudes, practices, and the sources of influence among young adult (18–25) girls (n = 374, 50.4%) and boys (n = 368, 49.6%) in the rural Srikakulam district. The SKAQ-II and the Sexual Behavior and Sources of Influence scale were used for the assessment. It was shown that the young adult lacked a strong understanding of sexual issues and attitudes. Low levels of sexual activity were seen with both oneself and others and with media. The majority of information was discovered to be gathered online, which was also thought to be the most trustworthy source. They came to the conclusion that Indian college students still lack sexual literacy. (54)

In a study done by **Dutt S and Manjula M (2017)** the researchers looked at sexual knowledge, attitudes, behaviors, and sources of influence as well as the connections between these variables in young people. The sample was chosen (n = 300) from universities using the snowball approach from the community and using the purposive sampling method. The SKAQ-II, the sociodemographic data sheet, and the sexual behavior and sources of influence scale were the instruments employed. Additionally, they discovered that people had low sexual knowledge, and that attitudes and sexual knowledge were positively correlated. Low levels of sexual behavior were seen with both oneself and others and with media. The majority of information was discovered to be gathered online, which was also thought to be the most trustworthy source. (29)

**Kumar P et al., (2020)** used a Google document with a structured questionnaire that was divided into four key elements to perform a cross-sectional study to evaluate the knowledge and attitudes of 752 undergraduate medical students. Information on the students' demographics were taken and the SKAQ-II was used. On a scale measuring

participants' attitudes about sex, the mean score is 25.47 + 5.04. Participants generally have a conservative view regarding sex. The sex knowledge and attitude scores of female participants are statistically considerably higher (p=0.038 and p0.001, respectively). Participants lack specific sex knowledge and exhibit conservative attitudes. Participants who are female, more educated, and from metropolitan areas had more liberal attitudes and sex knowledge. (55)

#### Literature on sexual quality of life and relationship assessment in Opioid users:

A study to assess erectile dysfunction and quality of life (QoL) in males on methadone or buprenorphine therapy was done by **Lugoboni F et al.**, (2017). They showed that the quality of life in erectile dysfunction patients was poor and was associated with factors including age, education, employment, opioid dosage, and the degree of psychopathology. (56)

**Xia Y et al.**, (2013) conducted a study to evaluate the impact of sexual dysfunction on patients' lives and treatment while they were on methadone maintenance therapy. Five of the participants' partners, three practitioners, and 13 males and 14 female MMT patients participated in face-to-face, in-depth interviews for this study. Patients and their spouses were questioned individually about how they felt about the patient's sexual function throughout MMT and how SD affected their personal/family lives and their treatment. Libido inhibition and diminished sexual pleasure were the primary issues that people with SD reported. The patient's sexual life had a worse quality and their close relations were harmed by SD. The way that different genders handled SD differed. Men typically had tendency to reject, run away from, or alienate their relationships. Women often masked their sexual tiredness, put up with sexual activity, and sought to appease their spouses. Sexual dysfunction made it difficult for patients to rebuild

healthy interpersonal relationships and weakened the effectiveness of maintenance therapy. Clinicians responses to patients' SD and SD-related issues were insufficient. (57)

In a cross-sectional research, **Vallejo-Medina P and Sierra JC** (**2013**) compared the sexual functioning ratings of drug users' group with non-users' group. It examined the connection between sexual function and drug abstinence. 905 men participated in this research (549 met the substance dependence criteria and 356 were controls). The Changes in Sexual Functioning Questionnaire Drugs version was used to evaluate each of them. Pleasure, desire, arousal, and orgasm were all just moderately affected. However, preferences for substances varied. The two most severely affected areas were pleasure and orgasm. All substances seemed to affect sexual function in these domains. There was no correlation between drug abstinence and an improvement in sexual functioning than the control group and had, on average, abstained from substances for one year. The findings go counter to claims that drug usage only briefly affects sexual function. Additionally, they contend that quitting drug usage alone does not improve one's sexual function. (58)

Sexual dysfunction in patients on methadone maintenance treatment may result from concurrent psychological issues rather than being brought on by opiates, according to a **study** by **Spring WD et al.**, (**1992**). Patients on methadone experiencing sexual dysfunction should be evaluated by a psychiatrist. (59)

#### Literature on hormonal profile and SD in patients with Opioid dependence:

To evaluate the effects of opioid use on pituitary function, **De Vries F et al.**, (2020) carried out a systematic review and meta-analysis. The two most often used opioids were morphine and methadone. Hypogonadism was prevalent in 63% of people (95% CI: 55%-70%, 15 trials, 3250 patients, 99.5% men). Five out of the seven studies revealed high prolactin levels. (60)

**Siege JA and Ortman HA (2020)** conducted a systematic evaluation of the effects of methadone on the hypothalamus-pituitary gonadal axis hormones and sexual functioning in men and women. They discovered sexual dysfunction, hormonal alterations brought on by methadone, and disturbances of the hypothalamus-pituitary gonadal axis. Variability in the findings may be influenced by differences in methadone dosage and duration of treatment. (61)

A cross-sectional research was undertaken in **Cepeda MS et al.**, (2015) to evaluate the impact of opioids on testosterone levels. Participants who said they had used prescription opioids over the last 30 days (n = 320) had their testosterone levels compared to those who had not (n = 4909). Odd ratio (OR) 5 1.40, 95% confidence interval (CI): Participants using opioids had higher chances of having low testosterone levels than those who weren't (1.07–1.84). In all categories, the chances of having low testosterone levels considerably increased with the number and age of comorbidities after adjusting for opioid use. Participants over 70 had an OR of 5.17, 95% CI, compared to those between 17 and 45. (1.16–2.50). Participants with more than two comorbidities had an OR of 5.69 (95% CI) compared to those without comorbidities (1.24–2.30). Age and medical factors should be taken into account when evaluating how opioids affect testosterone. (62)
A systemic review and meta-analysis by **Bawor M et al.**, (2015) comprised 17 (10 cross-sectional and 7 cohort studies) research with 2769 individuals (800 opioid users and 1969 controls). In compared to the control group, they discovered that males who took opioids have considerably lower testosterone levels. (63)

**Zhang M et al.**, (2014) performed a cross-sectional study that included interviews with 293 males who are actively on MMT. Long-term heroin use was highly related to sexual dysfunction across all five IIEF-15 categories (erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction). With the start of MMT, the level of sexual dysfunction was shown to be less severe. The individuals' erectile dysfunction, lack of sexual desire, inability to climax, and lack of satisfaction during the intercourse were all strongly linked with their advancing age. Sexual dysfunction was not observed to be correlated to methadone dosage or methadone treatment duration. Even though plasma testosterone levels were considerably decreased after methadone therapy, multivariate analysis findings showed that reduced testosterone levels were not the primary factor in sexual dysfunction. There was no link between sexual function and reported depressed state. Although heroin-dependent males in our study reported significant levels of sexual dysfunction both before and after MMT was started, MMT seems to be associated with better sexual function in the study group. (64)

**Trajanovska AS et al., (2013)** evaluated 20 male drug addicts who had been receiving high-dosage oral methadone 60–120 mg/day for more than 3 years and compared them to a group of 20 male heroin addicts using street heroin. Methadone maintenance patients have plasma prolactin levels that are significantly lower than those of street heroin users. (65)

Male heroin addicts on MMT were studied by **Chen W et al.**, (**2012**) for the prevalence of ED. Using monthly assessments of psychological disorders and erectile dysfunction, 74 men were included in the research. TT, FSH, LH, prolactin, and 17-estradiol levels were measured in the serum at baseline, the 3-month follow-up. At the baseline, 1, 2, and 3 month follow-ups, respectively, 75.7%, 88.7%, 80.8%, and 80.9% of the patients reported experiencing erectile dysfunction which means there were no significant variations in the prevalence of ED throughout the treatment. (15)

In order to determine the prevalence of impaired gonadal function in both men and women taking opioids for chronic pain, as well as the link between symptoms and hormonal evaluations of gonadal function, Wong D et al., (2011) conducted a cohort study of patients in a multidisciplinary pain clinic. A total of 65 females (47 opioid users and 18 non-opioid analgesic controls) and 32 men (26 opioid users and six controls) were enrolled in the study. They found that male opioid users (20/26; P=0.04)had lower free testosterone levels than female opioid users. Men with aberrant hormone levels did not experience sexual dysfunction more frequently than men with normal hormone levels, and opioid users did not experience sexual dysfunction more frequently than non-users of opioids. There was no correlation between the incidence of female sex dysfunction among opioid users (32/47) and controls (13/18; p=0.75) or any aberrant hormone levels. While male opioid users had more prolactin and decreased free testosterone, female opioid users reported lower amounts of this hormone. The incidence of sexual dysfunction did not coincide with hormone levels in opioid-using males or females. Even if there is no connection between aberrant hormone levels and the signs of sexual dysfunction, low levels of free testosterone are frequently caused by opiate use in males. Thus, reduced Free testosterone levels should be examined in all guys. However, there was no correlation between this and signs of sexual dysfunction.

Free testosterone levels were less among female opioid users. Measuring free testosterone or other hormones was therefore not regarded to be important in women. (66)

Fifty-seven male opiate users who sought treatment at a hospital for buprenorphine therapy participated in a study by **Cioe PA et al., (2010)** to determine the prevalence of ED. They discovered that 34% of individuals had ED, and 17% of ED patients had low total testosterone levels, although there was no statistically significant link between total testosterone and ED. Men who used opioids had a higher incidence of erectile dysfunction, although low total testosterone is unlikely to cause it. (67)

To determine the relationship between plasma testosterone and sexual function in men receiving buprenorphine maintenance for opioid dependence, **Bliesener N et al.**, (2005) did a research. They enrolled 54 patients, of whom 17 were taking buprenorphine sublingually, 37 were taking high oral doses of methadone, and 51 normal blood donors were used as a comparison. When compared to patients using methadone, people taking buprenorphine had much lower rates of sexual dysfunction and significantly greater testosterone levels. (68)

In research on hypogonadism in men consuming sustained-action oral opioids, **Daniell HW (2002)** included 54 case with OUD and 27 healthy controls in the same age range. LH, FSH, Estradiol (E2), total testosterone, and free testosterone levels were assessed for hypogonadism. Compared to control groups, they discovered that opioid users had low hormone levels. In 56%, 74%, and 74% of cases, respectively, free testosterone, total testosterone, and estradiol levels were found to be below normal. (69) According to Mirin SM et al., (1980) decreased libido and poor sexual performance are common consequences of chronic use, even though opiate addicts frequently connect the drug experience with sexual orgasm. Early clinical research revealed that opiates may impede the release of sex hormones. (70)

#### **Rationale of Index study:**

From the review, it is obvious that opioids use is associated with sexual dysfunction in various domains. But in the Indian population, there has been a dearth of studies examining the association of sexual dysfunction and opioid abuse. Most of the western and Indian studies on this topic were in context of synthetic opioid use and few on combined use of natural opium and synthetic opioids. Studies on effect of natural opium use on various harmones and its association with sexual functioning has not been studied. This study aims to fill this gap of knowledge and contribute to better treatment outcomes in a more holistic manner in patients of natural opium use.

### AIM AND OBJECTIVES

**AIM:** To evaluate the sexual dysfunction and its associations in male patients dependent on natural opium

#### **OBJECTIVES**

**Primary objective:** To estimate the prevalence and pattern of sexual dysfunction in patients dependent on natural opium seeking treatment under the Department of Psychiatry.

#### Secondary objectives:

- 1. To assess the knowledge, attitude, and behavior towards the sexuality and it's association with sexual dysfunction of patients dependent on natural opium
- 2. To assess the relationship satisfaction and sexual quality of life of patients and it's association with sexual dysfunction of patients dependent on natural opium
- 3. To assess the hormonal profile (Total Testosterone, LH, FSH, and Prolactin) and it's association with sexual dysfunction of patients dependent on natural opium
- 4. To determine the association of sexual dysfunction with demographic and clinical variables of patients dependent on natural opium

## MATERIALS AND METHODS

#### **Study setting:**

Patients who took treatment under the Department of Psychiatry of All India Institute

of Medical Sciences, Jodhpur, Rajasthan.

Study design: Cross-sectional study

#### **Study participants:**

Patients of age between 20 to 50 years dependent on natural opium had taken treatment under the Department of Psychiatry

#### **Inclusion criteria:**

- Male Patients dependent on natural opium (current users) who fulfilled the criteria of opioid dependence as per International Classification of Diseases, Eleventh Revision (ICD-11)
- 2. COWS score <5
- 3. Either married or in a relationship for at least 6 months
- 4. Patients of age between 20 to 50 years
- 5. Able to read and write in Hindi or English

#### **Exclusion criteria:**

- Presence of co-morbid psychiatric disorders, other substance dependence except for tobacco
- 2. Presence of current dependence on synthetic/pharmaceutical opioids
- 3. Current treatment with androgen replacement therapy
- Known case of chronic medical disorders, endocrinal disorder, and neurological disorder
- 5. History of head injury and trauma or surgery in the pelvic area

Sampling Method: Non-probability sampling

**Sample size:** After obtaining Ethical approval from Institutional Ethics Committee, a total 107 patients were enrolled who have fulfilled the selection criteria.

By using the formula for sample size calculation for Prevalence study (http://sampsize.sourceforge.net/iface/)

#### Estimated sample size: n=107

(Precision= 5.00 %, Prevalence of Sexual Dysfunction= 40.00 %, Population size (patients of opioid use seeking treatment from Psychiatry OPD=150)

**Study duration:** After obtained Ethical approval from Institutional Ethics Committee, the study was conducted from 01/01/2021 to 30/06/2022

**Methodology:** All the participants who fulfilled the selection criteria were explained about the study in detail (Appendix 1 or 3), and written informed consent (Appendix 2 or 4) was taken from them. After that socio-demographic and clinical profile sheet (Appendix 5 and 6) was filled. The severity of opioid and tobacco dependence was measured by the Severity of Opioid Dependence Questionnaire (SODQ) (71) , Fagerström Test for Nicotine Dependence (FTND) and FTND-smokeless tobacco(ST) (72) respectively. Thereafter assessment for sexual dysfunction was carried out if the patient had a withdrawal score <5, based on an assessment on the clinical opiate withdrawal scale (COWS)(73). Sexual knowledge was checked by Sex Knowledge and Attitude Questionnaire (SKAQ)-II (31) and sexual functioning was assessed by using the International Index of Erectile Function (IIEF) (74) and Arizona Sexual Experience Scale (ASEX). (75) After that Relationship satisfaction assessment and Sexual quality of life was assessed by Relationship Assessment Scale and Sexual Quality of life

Questionnaire-male (SQoL-M) respectively. (33, 75) Hormone profile (Total Testosterone, FSH, LH, Prolactin) assay was done by the process of Chemiluminescence immunoassay (CLIA) for which morning sample was drawn. By Using the ASEX scale study participants were divided into two groups on the basis of sexual dysfunction present (group-1) and absent (group-2).

## Methodology: Flow chart of the study

Patients using natural opium who attended the OPD and IPD services of the Department of Psychiatry of All India Institute of Medical Sciences, Jodhpur T Patients who fulfilled the selection criteria Explained about study detail and took informed written consent Socio-demographic details and clinical profile SOD-Q, FTND and FTND-ST (to assesses the severity of opioid and nicotine dependence respectively) Ţ When COWS score < 5Ţ Sexual knowledge was checked by the Sex Knowledge and Attitude Questionnaire (SKAQ)-II Sexual function assessment was done by (International Index of Erectile Function (IIEF) and Arizona Sexual Experience Scale (ASEX) Relationship satisfaction assessment was done by Relationship Assessment Scale Sexual quality of life was assessed by Sexual Quality of Life Questionnaire-male (SQoL-M) Ţ Hormone profile (S. Total Testosterone, FSH, LH, Prolactin) Ţ

Data collection and statistical analysis

#### **Measures and Tools of Assessments:**

- 1. **Socio-demographic variables:** Name, age, gender, marital status/stable sexual relation, religion, locality, type of family, education, occupation, family income, and socioeconomic status.
- 2. **Clinical variables:** Age of onset, reason of starting, duration of use, duration of dependence pattern, form and amount of opiate use, high-risk behavior, previous abstinent attempt, last date of consumption, withdrawal scores at the baseline and before sexual dysfunction assessment, presence of other medical comorbidities, and tobacco dependence.
- Severity of Opioid Dependence Questionnaire (SOD-Q): This9-item instrument was developed to measure the severity of opiate dependence. It is a self-administered questionnaire which consists of five main sections of questions corresponding to (1) Quantity and pattern of opiate use (usual route of administration, e.g.); (2) Physical symptoms of withdrawal (presence of symptoms on waking before first dose is taken); (3) Affective symptoms of withdrawal, including craving (mood states on waking before first dose is taken); (4) Withdrawal-relief drug taking (extent to which drugs are used to avoid or relieve withdrawal symptoms); and (5) Rapidity of reinstatement of withdrawal symptoms after a period of abstinence. A sixth related section, the "Opiate Subjective Dependence Questionnaire," can also be used; it consists of five questions assessing the subjects' own perception of dependence. (71)
- 4. **Clinical Opioid Withdrawal Scale (COWS):** 11 item scale administered by clinician, helps in determining severity of opioid withdrawal and assess the level of dependence on opioids. (73)

- 5. Fagerström Test for Nicotine Dependence (FTND) and Fagerström Test for Nicotine Dependence- smokeless tobacco (FTND-ST): These are standard instrument for assessing the intensity of physical addiction to nicotine. In scoring of these test, yes/no items are scored from 0 to 1 and multiple-choice items are scored from 0 to 2 and 0 to 3. The items are summed to yield a total score of 0-10. The higher the total Fagerström score, the more intense is the patient's physical dependence on nicotine. (72)
- 6. Sex Knowledge and Attitude Questionnaire (SKAQ)-II: SKAQ is a 55- item questionnaire split into two parts: a 35-item knowledge-part with dichotomous choice of responses and a 20-item attitude-part storable on 3-point Likert scale. Higher scores indicated a better knowledge and a liberal attitude. Its test-retest reliability was established and discriminant validity demonstrated. (31)
- 7. International Index of Erectile Function (IIEF): The IIEF is a 15-item self-administered instrument with well-established cross-cultural validity for the following domains of sexual function: Erectile Function (6 items), Orgasmic Function (2 items), Sexual Desire (2 items), Intercourse Satisfaction (3 items), and Overall Satisfaction (2 items). The Index correlates positively with the clinical interviews of sexual function and is considered to be the gold standard in evaluating erectile function. It marks the sexual dysfunction as present when the total score of the items is <25 for erectile function; <13 for intercourse satisfaction. (74)</p>
- 8. Arizona Sexual Experience Scale (ASEX): The ASEX is a 5-item selfadministered inventory with one question each for the evaluation of five dimensions of sexual functioning in both genders regardless of sexual orientation

or relationship with a sexual partner. Consistent with the domains of sexual function described in the Diagnostic and Statistical Manual of Mental Disorders-IV, and currently used inventories of sexual function, it covers drive, arousal, penile erection/vaginal lubrication, ability to reach orgasm, and satisfaction from orgasm. Rated on a 6-point Likert scale, scores for each domain as well as the total scale are taken into account. The clinical sexual dysfunction is defined as a score of >19 for the whole scale, >5 for any domain, or  $\geq$ 4 for any three domains. (75)

- 9. Sexual Quality of Life Questionnaire- male (SQoL-M): This 11 item scale made for sexual dysfunction like premature ejaculation(PE) and erectile dysfunction(ED). Psychometric validation done with a Cronbach's alpha of 0.82 in all groups. SQOL-M showed excellent test–retest reliability: the infraclass correlation coefficient was 0.77 for men with PE, and 0.79 for men with ED. Convergent validity was also good. (76)
- 10. **Relationship Assessment Scale:** A seven-item questionnaire intended to assess general relationship satisfaction Each question is answered on a 5-point scale by respondents, ranging from 1 (poor satisfaction) to 5. (high satisfaction). It comprises of seven items, each of which is assessed on a Likert scale of 1 to 5. It can be used with anyone who is in a close relationship, including married people, people who live together, people who are engaged, and people who are just dating. According to research, the scale correlates with various indicators of love, sexual attitudes, self-disclosure, commitment, and relationship investment. It has been determined that the instrument's psychometric qualities are suitable. (33)

**Principle of Diasorin liaison XL:** A sandwich chemiluminescence immunoassay was utilised to measure LH, FSH, and prolactin in quantitative terms. These magnetic nanoparticles (solid phase) are coated with a particular mouse monoclonal antibody, and a different monoclonal antibody is connected to an isolumino derivative (Soluminol-antibody conjugate). The solid phase monoclonal antibody binds to LH, FSH, and prolactin found in calibrators, samples, or controls during incubation. Then, the antibody conjugate reacts with the LH, FSH, and prolactin already bound to the solid phase. Following incubation, a wash cycle was used to get clear of the unbound material. Afterwards, the starter reagent was added and a flash chemiluminescence reaction was thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, was measured by a photomultiplier as relative light units (RLU) and was taken as indicative of LH, FSH and prolactin concentration present in calibrators, samples, or controls. In each kit, approximately 90 samples can be run at a time, out of which 6 were used for calibration. Reference ranges of the kit for LH, FSH and Prolactin in the male sex are 1.3-11.8 mIU/mL, 2.8-6.8 mIU/mL and 87-392 mIU/L respectively.

The ADVIA Centaur Testosterone assay is a competitive immunoassay using direct chemiluminescent technology. The system automatically performs the following actions: Mix the 15  $\mu$ L of sample and 50  $\mu$ L of Releasing Agent in a sample cell and thereafter rinses the reagent probe with 100  $\mu$ L of Probe Wash then mix 50  $\mu$ L of Lite Reagent and 300  $\mu$ L of Solid Phase and incubates for 5.0 minutes at 37°C and after that separates, aspirates, and washes the sample cell with reagent water and then dispenses 300  $\mu$ L each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction finally reports results according to the selected option, as described in the system operating instructions or in the online help system

The number of relative light units (RLUs) identified by the device and the quantity of testosterone contained in the patient sample are inversely correlated. Reference ranges of the kit for testosterone in the male sex are 241- 827 ng/dL.

Statistical analysis: Data was entered and analyzed using SPSS (Statistical Package for the Social Science) version 21. For categorical variables frequencies and percentages was calculated and mean and standard deviations was calculated for continuous variables. The normality of data was assessed using the Shapiro–Wilk test. The relationship between two categorical variables has been determined using either the Chisquare test or Fisher exact test (if more than 20% of cells have less than 5 frequency). Comparison of further subgroups (with or without sexual dysfunction as per ASEX) on various Socio-demographic and clinical parameters and association between opium use, sexual dysfunction, and hormonal levels was done by using the Mann U Whitney test for non-normal data. Bivariate correlation analysis has been done to look for an association between two continuous variables for which Spearman's coefficient has been used in view of non-normal data. It was performed among the various continuous sociodemographic and clinical variables and individual domains of ASEX, IIEF scale and total scores of ASEX, IIEF, SKAQ-II, SQOL-M and RAS.

Binary Logistic regression analysis was performed to find the predictors of sexual dysfunction with Age, SODQ score, Testosterone, SKAQ Knowledge, SKAQ attitude and SQoL-M. P value less than 0.05 was deemed significant.

#### **Ethical considerations:**

Data collection was started after obtaining ethical clearance (AIIMS/IEC/2021/3387) from institute's Ethics Committee. Informed written consent was obtained from the

study participants in the language they understand. Participants were provided verbal as well as written communication about the purpose of the study, contacts of persons concerned, respondent's right to discontinue the interview at any time they so deemed without affecting the appropriate treatment. There were no potential risks for the patients participating in the study. Standard treatment protocol and appropriate referral system was followed for study participants.

## **OBSERVATION & RESULTS**

#### **Descriptive Analysis:**

#### Table 1: Socio-demographic variables (n=107)

Socio-demographic variable	Frequency (%)		
Marital Status			
Single	2 (1.9)		
Married	105 (98.1)		
Occupation			
Cleric/farmer/shop owner	48 (44.5)		
Skilled	34 (31.8)		
Semi/unskilled	21 (19.6)		
Unemployed	4 (3.7)		
Family type:			
Nuclear	25 (23.4)		
Extended	37 (34.6)		
Joint	45 (42.1)		
Locality:			
Urban	38 (27.1)		
Rural	69 (64.5)		
	Mean ± SD	Median (IQR)	
Age (Years)	35.34 ± 6.65	35 (9)	
Education (Years)	$10.86 \pm 4.18$	10 (6)	
Family Income/month (Rupees)	29289.71±39474.13	20000 (20000)	

n= number of participants; %= percentage of participants of a particular variable; SD= Standard Deviation; IQR= Interquartile Range

In this study, majority of the patients were married and employed. Nearly half of the patients were belonging to category of clerks/farmers/shop owners and belonged to a Joint family. 64.5% of patients were from rural backgrounds. The mean age of the patients was seen to be  $35.34 \pm 6.65$ , and the mean education in years was  $10.86 \pm 4.18$  with a mean monthly family income of  $29289.71 \pm 39474.13$ . (Table 1)

Clinical variable	Frequency (%)
Types of Opium:	
Amal (opium exudate/ milk)	67 (62.6)
Doda (poppy husk)	40 (37.38)
High-risk behaviors:	
Absent	106 (99.1)
Present	1 (0.9)
Nicotine use pattern:	
Occasional	0 (0)
Dependent	81 (75.7)
Abstinent	1 (0.93)
Never Used	25 (23.36)
Past history of other substance use:	
No	95 (88.8)
Yes	12(11.2)
Family history of substance use:	
No	82 (76.6)
Yes	25 (23.4)

Table 2.1: Clinical variables (categorical) (n=107)

n = number of participants; % = percentage of participants of a particular variable

Among the natural opium, around 63% of patients were consuming Amal/afeem, and rest 37% were consuming doda (husk/Popy). High-risk behavior was found only in one patient. Around 76% of cases had nicotine use in one form or other, mainly in dependent pattern. Nearly 23% had a family history of substance use. (Table 2.1)

Clinical variables	$\mathbf{Mean} \pm \mathbf{SD}$	Median (IQR)
	27.29.6.42	25 (9.75)
Age of optum initiation	27.38±0.43	25 (8.75)
(Years)		
Duration of opium use	$7.54 \pm 4.74$	5 (7)
(Years)		
Duration of opium	7.35±4.55	5 (5.75)
dependence (Years)		
SODQ Total score	47.42±11.02	42 (14.25)
FTND score (n=37)	5.98±1.70	5 (2)
FTND ST score (n=59)	5.94±1.79	5 (3)
COWS score	$1.11 \pm 1.28$	1 (2.50)

 Table 2.2: Clinical variables (continuous) (n=107)

n= number of participants; SD= Standard Deviation; IQR= Interquartile Range; SODQ= Severity of Opioid Dependence Questionnaire; FTND= Fagerstrom Test for Nicotine Dependence; FTND-ST= Fagerstrom Test for Nicotine Dependence – Smokeless Tobacco; COWS= Clinical Opioid Withdrawal Scale

The mean age for initiation of opium was around 28 years, with average duration of both opium use and dependence being nearly same, around 7.5 years, indicating early dependence. The mean FTND and FTND-ST score was around 6 which indicates moderate nicotine dependence. The average COWS score was around 1 indicating no withdrawal. (Table 2.2)

Scales	Mean ± SD	Median (IQR)
ASEX total Score	15.79 ±5.38	15 (8)
Desire/drive	$3.43 \pm 1.36$	3 (1)
Arousal	$3.12\pm1.79$	3 (2)
Erection	$3.17 \pm 1.21$	3 (2)
Ability to reach orgasm	$3.03 \pm 1.52$	3 (2)
Satisfaction with orgasm	$3.02 \pm 1.43$	3 (2)
IIEF		
Erectile function	$19.43 \pm 4.96$	20 (6)
Orgasmic function	$6.20\pm2.34$	7 (1)
Sexual Desire	$6.20\pm2.01$	6 (3)
Intercourse satisfaction	$8.81\pm3.14$	9 (4)
Overall satisfaction	$6.56\pm2.51$	8 (4)

Table 3.1: Mean score of sexual functioning as per ASEX and IIEF (n=107)

n= number of participants; SD= Standard Deviation; IQR= Interquartile Range; ASEX= Arizona Sexual Experience Scale; IIEF= International Index of Erectile Function

The mean total score on ASEX was  $15.79 \pm 5.38$ . The mean score of IIEF was found to be low than the cutoff value for sexual dysfunction in all subdomains of this scale. (Table 3.1)

Scales	Mean ± SD	Median (IQR)
SKAQ-II		
Knowledge-part	$18.59 \pm 4.53$	44 (6)
Attitude-part	$5.97 \pm 2.16$	32 (7)
RAS	$23.73 \pm 10.01$	24 (10)
SQoL-M	$41.05 \pm 22.25$	36 (33)

Table 3.2: Mean score of SKAQ-II, RAS and SQoL-M (n=107)

n= number of participants; SD= Standard Deviation; IQR= Interquartile Range; SKAQ-II= Sex Knowledge and Attitude Questionnaire; RAS= Relationship Assessment Scale; SQoL-M= Sexual Quality of Life Questionnaire- male

The mean total score of knowledge and attitude part of SKAQ-II was  $18.59 \pm 4.54$  and  $5.97 \pm 2.16$  respectively. Mean SQoL-M total score was  $41.05 \pm 22.25$  and mean RAS scores was  $23.73 \pm 10.01$ . (Table 3.2)

Hormones	Mean ± SD	Median (IQR)
Testosterone	427.48 ± 225.45	423.65 (493.12)
Prolactin	$369.92 \pm 569.82$	212.5 (232.5)
FSH	$4.65 \pm 3.14$	4.12 (4.97)
LH	$3.52\pm2.25$	3.95 (4.97)

 Table 3.3: Hormonal profile (n=107)

n= number of participants; SD= Standard Deviation; IQR= Interquartile Range; FSH= Follicular Stimulating hormone; LH= Luteinizing hormone

The mean score of Testosterone, Prolactin, LH, and FSH were  $427.48 \pm 225.45$  ng/dL,  $369.92 \pm 569.82$  mIU/L,  $4.65 \pm 3.14$  mIU/mL, and  $3.52 \pm 2.25$  mIU/mL respectively. (Table 3.2)

Table 4.1: Prevalence of sexual dysfunction as per Arizona Sexual Experience Scale

(ASEX) (n=107)

Criteria A: ASEX score >19	Frequency (%)
Yes	30 (28.0)
No	77 (72.0)
Criteria B: ASEX score $\geq 4$ in 3 or more domains but global	Frequency (%)
score $\leq 19$	
Yes	6 (5.6)
No	101 (94.4)
Criteria C: ASEX score≥5 in one or more domains but global	Frequency (%)
score $\leq 19$	
Yes	13 (12.1)
No	94 (87.9)
Criteria D: Sexual dysfunction (Summation of all criteria)	Frequency (%)
Yes	50 (46.7)
No	57 (53.3)

n= number of participants; %= percentage of participants of a particular variable; ASEX= Arizona Sexual Experience Scale

In this study, prevalence of sexual dysfunction was around 28%, 6%, 12% and 47% respectively as per four different ASEX criteria to assess sexual dysfunction. Criteria D, which is the sum of all other ASEX criteria, found that nearly half of the patients have sexual dysfunction. (Table 4.1)

 Table 4.2: Pattern of sexual dysfunction on ASEX (as per cutoff score four or more in each domain) (n= 107)

Sexual dysfunction domains	Frequency (%)
Desire/drive	50 (46.7)
Arousal	38 (35.5)
Erection	41 (38.3)
Ability to reach orgasm	42 (39.3)
Satisfaction with orgasm	31 (29.0)

n= number of participants; %= percentage of participants of a particular variable; ASEX= Arizona Sexual Experience Scale

In this study, prevalence of sexual dysfunction as per ASEX was around 47%. On ASEX, the most commonly affected domain was desire/drive (47%) and followed by domains of ability of reach orgasm (39%), erection (38%), and arousal (36%) and the least affected was satisfaction with orgasm. (Table 4.2)

Table 5: Prevalence and pattern of sexual dysfunction as per IIEF (n=107)

Sexual dysfunction domains	Frequency (%)
Erectile function	96 (89.7)
Orgasmic function	97 (90.7)
Sexual desire	92 (86.0)
Intercourse satisfaction	92 (86.0)
Overall satisfaction	79 (73.8)
Sexual dysfunction in at least one domain as per IIEF	97 (90.7)

n= number of participants; %= percentage of participants of a particular variable; IIEF= International Index of Erectile Function

In this study, the proportion of those with sexual dysfunction as per IIEF was around 91%. The most commonly affected domain was orgasmic function (90.7%) and erectile function (89.7%), followed by equal percentage in both intercourse satisfaction and sexual desire (86%). (Table 5)

Hormones	Category (as per hormone level)	Frequency (%)
Testosterone	Low (<241 ng/dL)	24 (22.4)
	Normal (241-827 ng/dL)	80 (74.8)
	High (>827 ng/dL)	3 (2.8)
Prolactin	Low (<87 mIU/L)	4 (3.7)
	Normal (87-392 mIU/L)	91 (85.0)
	High (>392 mIU/L)	12 (11.2)
LH	Low (<1.5 mIU/mL)	17 (15.9)
	Normal (1.5-9.3 mIU/mL)	86 (80.4)
	High (>9.3 mIU/mL)	4 (3.7)
FSH	Low (<1.3 mIU/mL)	3 (2.8)
	Normal (1.3-11.8 mIU/mL)	100 (93.5)
	High (>11.8 mIU/mL)	4 (3.7)

Table 6: Hormonal levels (n=107)

n= number of participants; %= percentage of participants of a particular variable; LH= Luteinizing hormone; FSH= Follicular Stimulating hormone

In this study, 23% patients were found to have low Testosterone, and around 16% were found to have low LH. Hyperprolactinemia and low FSH was found in around 11% and 3% cases respectively. (Table 6)

#### **Inferential statistics**

Socio-demographic	Sexual Dysfunction		Chi-square/	р
variables	Group-1: Present n= 50 (%)	Group-2: Absent n= 57(%)	Fischer exact ( <sup>#</sup> )	
Marital Status:				
Single	0	2 (3.2)	_#	0.181
Married	50 (100)	55 (96.5)		
Occupation:				
Cleric/farmer/shop	32 (64.0)	16 (28.1)	_#	0.003
owner				
Skilled	11 (22.0)	23 (40.4)		
Semi/unskilled	6 (12.0)	15 (26.3)		
Unemployed	1 (2.0)	3 (5.3)		
Family type:				
Nuclear	13 (26.0)	12 (21.1)	0.460	0.795
Extended	16 (32.0)	21 (36.8)		
Joint	21 (42.0)	24 (42.1)		
Locality:				
Urban	14 (28.0)	24 (42.1)	2.314	0.128
Rural	36 (72.0)	33 (57.9)		

 Table 7.1: Comparison of socio-demographic variables (categorical) between two

 groups

p= level of significance; %= percentage of participants of a particular variable in that particular group; n= number of participants; ASEX= Arizona Sexual Experience Scale

There was a significant difference in the occupation of both groups, and most common occupation was Cleric/farmer/shop owners in sexual dysfunction group in comparison to skilled work in non-sexual dysfunction group. But there was no significant difference between the groups in regards to marital status, family type and locality, and most of the were married, belongs to joint family and rural background in both groups. (Table

Clinical variable	Sexual Dysfunction		Chi-square/	р
	Group-1: Present	Group-2:	Fischer exact	
	n=50 (%)	n = 57(%)	(*)	
Types of Opium:			0.015	0.902
Amal	31 (62.0)	36 (63.2)		
Doda	19(38.0)	21 (36.8)		
Nicotine use pattern:			_#	0.601
Never Used	11 (22.0)	14 (24.6)		
Dependent	39 (78.0)	42 (73.7)		
Abstinent	0	1 (1.8)		
Past history of other			_#	0.107
substance use:				
No	47 (94.0)	48 (84.2)		
Yes	3 (6.0)	9 (15.8)		
Family history of			_#	< 0.001
substance use:				
No	47 (94.0)	35 (61.0)		
Yes	3 (6.0)	22 (38.6)		

Table 7.2: Comparison of clinical variables (categorical) of two groups

#= Fischer exact test; %= percentage of participants; *p*= level of significance; n= number of participants; ASEX= Arizona Sexual Experience Scale

The group-2 was found to have more of positive family history of substance use which was statistically significant. No significant difference was found in regards to other clinical variable. (Table 7.2)

Socio-demographic	Mean rank of	Mean rank of	U	р
variables	Sexual	Sexual Non-sexual		
	dysfunction	dysfunction		
	(SD) group	(Non-SD) group		
	( <b>n=50</b> )	( <b>n=57</b> )		
Age (Years)	60.67	48.15	1071.50	0.037
Education (years)	49.85	57.64	1632.50	0.190
Family Income	53.11	54.78	1469.50	0.779
(Rupees/month)				

Table 8.1 Comparison of socio-demographic variables (continuous) of two groups

n= number of participants U= Mann Whitney Test statistic value; SD= Sexual dysfunction; Non-SD= Non-sexual dysfunction, p= level of significance

In this study, Mean rank score of age was more in group-1 as compared to group-2 and was statistically significant (p value 0.037). No significant difference was found in education and income. (Table 8.1)

Clinical variables	Mean rank of	Mean rank of	U	р
	Sexual	Non-sexual		
	dysfunction(SD)	dysfunction		
	group (n=50)	(Non-SD) group		
		( <b>n=57</b> )		
Age of opioid	58.29	50.24	1210.55	0.179
initiation (Years)				
Duration of opioid	59.84	48.88	1133	0.67
use (Years)				
Duration of opioid	59.53	49.15	2801.5	0.083
dependence (Years)				
SODQ Total score	72.5	37.33	497.5	< 0.001
FTND score	20.86	16.27	124	0.213
FTND-ST score	31.96	28.34	379	0.410
COWS score	55.07	53.06	1371.5	0.722

Table 8.2 Comparison of the clinical variables (continuous) of two groups

n= number of participants U= Mann Whitney Test statistic value; SD= Sexual dysfunction; Non-SD= Non-sexual dysfunction, p= level of significance; SODQ= Severity of Opioid Dependence Questionnaire; FTND= Fagerstrom Test for Nicotine Dependence; FTND-ST= Fagerstrom Test for Nicotine Dependence–Smokeless Tobacco; COWS= Clinical Opioid Withdrawal Scale

In this study, SODQ scale mean rank score was more in group-1 as compared to group-2 and the difference was found significant (p value <0.001). But no statistical difference was found in regards to other clinical variables. (Table 8.2)

Variables	Mean rank of	Mean rank of	U	р
	Sexual	Non-sexual		
	dysfunction(SD)	dysfunction		
	group (n=50)	(Non-SD)		
		group (n=57)		
ASEX domains				
Desire/drive	76.53	34.24	298	< 0.001
Arousal	75.03	35.55	373.5	< 0.001
Erection	74.48	36.04	401.5	< 0.001
Ability to reach orgasm	71.50	38.65	550.0	< 0.001
Satisfaction with	71.40	38.74	555	< 0.001
orgasm				
IIEF domains				
Erectile function	60.24	48.53	1113	0.051
Orgasmic function	48.18	59.11	1716	0.057
Sexual desire	38.88	67.26	2181	< 0.001
Intercourse satisfaction	59.23	49.41	1163.5	0.100
Overall satisfaction	35.19	70.50	2365.5	< 0.001
SKAQ-II Subdomains				
SKAQ Knowledge	47.35	59.83	1757.50	0.037
SKAQ attitude	57.96	49.49	1650.5	0.158
RAS	53.49	54.45	1450	0.873
SQoL-M	42.61	63.99	1994.5	< 0.001
Testosterone	46.82	60.30	1066	0.025
Prolactin	56.82	51.53	1284	0.379
FSH	53.67	54.29	1441.5	0.918
LH	54.62	53.46	1394.0	0.87

Table 8.3: Comparison of variables (ASEX, IIEF, SKAQ-II, SQoL-M, RAS and Hormones) between two groups

n= number of participants U= Mann Whitney Test statistic value; SD= Sexual dysfunction; Non-SD= Non-sexual dysfunction, *p*= level of significance; ASEX= Arizona Sexual Experience Scale; IIEF= International Index of Erectile Function; SKAQ-II= Sex Knowledge and Attitude Questionnaire; RAS= Relationship Assessment Scale; SQoL-M= Sexual Quality of Life Questionnaire- male; LH= Luteinizing hormone; FSH= Follicular Stimulating hormone As shown in table 8.3, mean rank score in every domain of the ASEX was more in group-1 in comparision to group-2 and the difference was statistically significant (p - <0.001).

However, the IIEF scale domains of sexual desire and overall satisfaction had lower mean rank score in group-1 as compared to group-2 and the difference was statistically significant ( $p - \langle 0.001 \rangle$ ).

In the knowledge part of SKAQ scale, a significant difference less mean rank score was found in group-1 as compared to group-2 which indicates that group-1 had poor sexual knowledge.

On SQoL-M scale, less mean rank score was found in group-1 as compared to group-2 and the difference was found to be statistically significant ( $p - \langle 0.001 \rangle$ ) which means group-1 had poor sexual quality of life compared to group-2.

In the serum hormonal level assessment, less mean rank score of serum Testosterone was found in group-1 in comparision to group-2 and the difference was found to be statistically significant (p = 0.025) which means group-1 had low testosterone compare to group-2. (Table 8.3)

	Age	Education	Income	Age of opioid	Duration opioid	SODQ total	FTND	FTND-ST
				Initiation	dependence			
ASEX Desire/drive	0.238*	0.007	0.006	0.206*	0.178	0.425**	0.137	0.366**
ASEX Arousal	0.240*	-0.123	0.000	0.166	0.242*	0.482**	0.200	0.138
ASEX Erection	0.288**	-0.098	-0.042	0.296**	0.092	0.579**	0.293	-0.085
ASEX Ability to reach orgasm	0.310**	-0.031	0.078	0.240*	0.260**	0.590**	0.400*	-0.038
ASEX Satisfaction with orgasm	0.334**	-0.103	0.049	0.323**	0.130	0.558**	0.209	0.083
ASEX Total score	0.351**	-0.071	0.036	0.297**	0.219*	0.642**	0.329*	0.117
IIEF Erectile function	0.208*	0.058	-0.010	0.132	0.071	0.481**	0.122	0.084
IIEF Orgasmic function	0.074	0.220*	0.003	0.018	0.047	-0.084	-0.155	0.064
IIEF Sexual desire	-0.314**	0.241*	0.144	-0.299**	-0.110	-0.682**	-0.178	-0.051
IIEF Intercourse satisfaction	0.096	0.072	0.019	0.022	-0.040	0.312**	-0.009	0.018
IIEF Overall satisfaction	-0.397**	0.211*	0.131	-0.386**	-0.162	-0.685**	-0.261	-0.057
SQoL-M	-0.206*	0.077	0.120	-0.142	-0.077	-0.305**	-0.006	-0.146
SKAQ-II Knowledge	-0.265**	0.245*	0.107	-0.183	-0.082	-0.333**	0.035	-0.062
SKAQ-II Attitude	-0.096	0.010	0.080	-0.040	-0.037	-0.136	0.146	-0.172
RAS_TOTAL	0.077	-0.108	0.114	-0.043	0.106	-0.190*	-0.211	-0.115
Testosterone	0.166	-0.100	0.122	0.110	-0.070	-0.025	-0.226	-0.058
FSH	-0.035	-0.216*	-0.102	0.003	-0.201*	0.083	-0.058	0.025
Prolactin	-0.015	0.000	-0.073	-0.011	-0.016	0.027	0.197	-0.047
LH	-0.015	-0.138	-0.028	0.050	-0.100	0.020	-0.289	-0.061

Table 9.1 Spearman's correlation of sociodemographic and clinical variables with ASEX, IIEF, SQoL-M, SKAQ-II, RAS and Hormones

SODQ= Severity of Opioid Dependence Questionnaire; FTND= Fagerstrom Test for Nicotine Dependence; FTND-ST= Fagerstrom Test for Nicotine Dependence– Smokeless Tobacco; ASEX= Arizona Sexual Experience Scale; IIEF= International Index of Erectile Function; SKAQ-II= Sex Knowledge and Attitude Questionnaire; RAS= Relationship Assessment Scale; SQoL-M= Sexual Quality of Life Questionnaire- male; LH= Luteinizing hormone; FSH= Follicular Stimulating hormone; \*= p value less than 0.05 \*\*= p value less than 0.01

	SQoL-M	SKAQ-II Knowledge	SKAQ-II Attitude	RAS	Testosterone	FSH	Prolactin	LH
ASEX Desire/drive	-0.296**	-0.327**	-0.297**	-0.067	-0.175	0.080	0.082	0.028
ASEX Arousal	-0.172	-0.240*	-0.224*	-0.009	-0.081	0.017	0.071	0.017
ASEX Erection	-0.368**	-0.320**	-0.225*	-0.181	-0.070	-0.022	0.063	0.113
ASEX Ability to reach orgasm	-0.262**	-0.340**	-0.144	-0.011	-0.200*	-0.091	0.119	-0.154
ASEX Satisfaction with orgasm	-0.447**	-0.320**	-0.267**	-0.090	0.037	0.050	0102	0.073
ASEX Total score	-0.393**	-0.373**	-0.278**	-0.077	-0.117	0.004	0.060	0.005
IIEF Erectile function	-0.283**	-0.228*	-0.104	-0.120	0.040	-0.056	-0.133	0.073
IIEF Orgasmic function	-0.013	0.110	0.105	0.012	0.062	-0.104	-0.123	-0.095
IIEF Sexual desire	0.418**	0.277**	0.116	0.104	0.001	-0.025	-0.052	-0.021
IIEF Intercourse satisfaction	0.011	-0.077	0.062	0.159	0.007	-0.024	-0.074	-0.109
IIEF Overall satisfaction	0.366**	0.247*	0.084	0.125	0.042	-0.046	-0.056	-0.038

#### Table 9.2 Spearman's correlation between ASEX and IIEF with SQoL-M, SKAQ-II, RAS and Hormones

ASEX= Arizona Sexual Experience Scale; IIEF= International Index of Erectile Function; SKAQ-II= Sex Knowledge and Attitude Questionnaire; RAS= Relationship Assessment Scale; SQoL-M= Sexual Quality of Life Questionnaire- male; LH= Luteinizing hormone; FSH= Follicular Stimulating hormone \*= p value less than 0.05 \*\*= p value less than 0.01

#### Table 9.3 Spearman's correlation between hormones

	FSH	LH	Prolactin	Testosterone
FSH	1.000	0.539**	-0.108	0.180
LH	0.539**	1.000	-0.300**	0.178
Prolactin	-0.108	-0.300**	1.000	-0.277**
Testosterone	0.180	0.178	-0.277**	1.000

LH= Luteinizing hormone; FSH= Follicular Stimulating hormone; \*\*= p value less than 0.01

## Correlation of sociodemographic and clinical variables with ASEX, IIEF, SQoL-M, SKAQ-II, RAS and Hormones:

Age was found significantly correlated with dysfunction in all domains of the ASEX scale and total ASEX score along with the dysfunction in the sexual desire and overall satisfaction domain of the IIEF scale, knowledge part of SKAQ-II scale and total score of SQoL-M. Education was found significantly correlated with orgasmic function, sexual desire, overall satisfaction domains of the IIEF scale and knowledge part of the SKAQ-II scale. Age of opioid initiation was significantly correlated with the total score of the ASEX scale along with its domains like erection, satisfaction with orgasm, desire/drive, ability to reach orgasm; and the sexual desire, and overall satisfaction domains of the IIEF scale. Duration of Opioid Dependence was found to be significantly correlated with ability to reach orgasm and arousal domains of ASEX and ASEX total score. The total score of SODQ was significantly correlated with the total score of the ASEX and all of its individual domains; all domains of the IIEF scale except the orgasmic function, SQoL-M and knowledge part of the SKAQ-II scale. This means that sexual dysfunction was high in patients who had higher SODQ total score. Total score of FTND- smokeless tobacco was found to be significantly correlated with desire/ drive domain of ASEX Scale. (Table 9.1)

# Correlation between ASEX and IIEF with SQoL-M, SKAQ-II, RAS and Hormones:

A total score of SQoL-M had a significant correlation (<0.01) with a total score of ASEX, dysfunction in all domains of ASEX scale except the arousal domain; dysfunction in erectile function, sexual desire, and overall satisfaction domains of IIEF scale. The knowledge part of SKAQ-II was found to have a significant correlation with

the total score and all domains of ASEX, and in the erectile function, sexual desire, and overall satisfaction domains of IIEF scale. The attitude part of SKAQ-II was found to have significant correlation with total score of ASEX, and with its desire and satisfaction with orgasm domains. Serum level of testosterone was found to have significant correlation only with ability to reach orgasm domain of ASEX scale. (Table 9.2)

**Correlation between hormones:** FSH and LH were found significantly (<0.01) correlated each other. LH and Prolactin also showed negative correlation with significant *p* value (<0.01), which means that with the increase in LH value the Prolactin value will decrease. Similarly, testosterone and prolactin were also negatively correlated with significant p value (<0.01).

Table 1	0.1:	Binary	Logistic	regression:	Model	Summary
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Observed Sexual	Predicted Sexu	Percentage	
Dysfunction	No Yes		Correct
No	47	10	82.5
Yes	13	37	74.0

The specificity (true negative rate) and sensitivity (true positive rate) for this model were around 82.5 % and 74.0 % respectively. (Table 10.1)

Variables	Observed	n	Odds	95% C.I.	with df= 1
	value	P	Ratio	Lower	Upper
Age	0.047	0.234	1.048	1.048	.970
SODQ score	0.117	<0.001	1.124	1.124	1.060
Testosterone	-0.003	0.022	0.997	.997	.995
SKAQ Knowledge	0.011	0.870	1.011	1.011	.885
SQoL-M	-0.008	0.461	0.992	.992	.971

 Table 10.2: Correlation of sexual dysfunction with independent clinical and

 outcome variables by using binary logistic regression

SODQ= Severity of Opioid Dependence Questionnaire; SKAQ-II= Sex Knowledge and Attitude Questionnaire; SQoL-M= Sexual Quality of Life Questionnaire- male

Binary logistic regression shows that the total score of SODQ (Odds ratio = 1.124, 95 % C.I. 1.124-1.060, p= <0.001) and Testosterone (odd ratio: 0.997, 95 % C.I. 0.997-0.995. p= 0.022) were significant predictors of sexual dysfunction. One-unit increase in SODQ score value increases the odds of sexual dysfunction by approximately 12.4% and one-unit decrease in Testosterone value may increases the odds of sexual dysfunction by approximately by 0.3%. (Table 10.2)

#### DISCUSSION

The purpose of this study was to evaluate the sexual dysfunction, it's pattern and associations with knowledge, attitude, and behavior towards the sexuality, relationship satisfaction and sexual quality of life of patients, hormonal profile and patient's demographic and clinical variable among male patient's dependent on natural opium.

The present study was one of the few Indian studies which assess sexual dysfunction in patients dependent on natural opium during the active phase of dependence rather than during withdrawal phase or during treatment.

#### Sexual dysfunction and its pattern in patients dependent on natural opium

According to the published research, persons with opioid use have frequently experienced SD. (22) As measured by the ASEX scale and the IIEF respectively, 46.2% and 90.7% of study participants were found to have SD in current study. As compared to this, SD was detected in about 21.15% of the population in India who were otherwise healthy, which is significantly less than the rates seen in opioid-dependent individuals. (21)

The rate of SD was higher in current study as compared to the study done by Sethi (50) on opioid-dependent (mostly heroin users) individuals where the prevalence of SD (assessed on IIEF scale) was ranged from 46.7% to 59.6%. Our study result is similar to the results of a study done by Venkatesh (52) on opioid dependence where the prevalence of SD was ranged from 48% to 92% on ASEX and IIEF. Similar to our study, an another Indian study by Aggarwal (51) have found SD ranged from 53.3% to 81.7% where majority of participants using natural opium before switching to synthetic opiates like smack. Among the synthetic opioids user, SD was documented in patients who were methadone users with a pooled prevalence of 52% (95% confidence interval

[CI] 0.12-0.38). (22) Another study by Mattoo (48) found that SD rates were 40% and 92.5% on ASEX and IIEF scales respectively in patients who have received buprenorphine-naloxone substitution therapy and our study results were similar to this study. This variation in prevalence of SD can be explained by various factors such as socio-cultural difference, gender difference, different forms, dose and duration of opioids use, other confounding factors, different methodology and different assessment tools.

It is challenging to draw a judgement on the real prevalence of sexual dysfunction with opioid addiction due to the incomparability across different scales. Due to its briefness, self-rating, availability of a Hindi language version, and usage in India to evaluate sexual dysfunction, the ASEX test has gained popularity. (75) On the other hand, IIEF was used since it is regarded as the gold standard for evaluating erectile function in particular. Thus the IIEF scale is an assessment of EF that has been standardized, however it does not assess men's overall sexual dysfunction as a whole domain. (74)

In current study, the assessment of various domains of sexual functioning on IIEF scale showed that orgasmic dysfunction (90.7%) and ED (89.7%) were the most prevalent sexual dysfunctions followed by intercourse dissatisfaction and hypoactive sexual desire (86%), with overall dissatisfaction being the least prevalent (73.8%). Similar results were obtained in a study by Sethi (50) which revealed that orgasmic dysfunction (57.8%) was the participants' main complaint. Our study result is also in line with the findings of Palha and Esteves, who investigated sexual dysfunction in 101 heroin addicts in Portugal and discovered that 60% of the men in their study had difficulties achieving orgasms (47), as well as a study by Venkatesh (52) which found that the dysfunction ranged from 41 to 86% for desire/drive, 29 to 78% for arousal, 36 to 45% for erectile dysfunction, and 21 to 76% for achieving an orgasm. It is conceivable that
the most frequent complaint among patients with opioid dependence who sought treatment for de-addiction was orgasmic dysfunction.

According to ASEX assessment, the desire/drive (47%) was the most frequently affected domain, followed by the ability to reach orgasm (39%), erection (38%), and arousal (36%) and the least affected was satisfaction with orgasm. Similar findings were found by Mattoo (48) where the most prevalent dysfunctions were hypoactive sexual desire (92.5%) and intercourse dissatisfaction (95%), followed by erectile dysfunction (77.5%), and orgasmic dysfunction (67.5%). According to a meta-analysis conducted by Yee (22) which included trials on both buprenorphine- and methadone-based substitution, hypoactive sexual desire was the dysfunction that occurred most frequently, at 51% (95% CI, 0.27-0.74). The opioid-induced suppression of testosterone levels may have been the root cause of the hypoactive sexual desire. This suppression was mediated by the inhibition of the production of gonadotropin-releasing hormone in the hypothalamus, which also has a direct impact on the reduction of testicular testosterone secretion. The result that patients with opioid dependence have a significant prevalence of sexual dysfunction shows that opioid usage is linked to sexual dysfunction across a variety of domains. These results are significant in light of the fact that some individuals begin using opioids to improve their sexual performance, despite the fact that opioid dependence is linked to sexual dysfunction.

# Association of sexual dysfunctions and Hormones (testosterone, FSH, LH and prolactin) in patients dependent on natural opium

In this study, the hormonal assay showed that 22.4% subjects were found to have low testosterone. Only 2.8% cases had low FSH levels, whereas 15.9% had low LH levels and 11.2% had hyperprolactinemia. In the current study, Prolactin correlated

negatively with Testosterone & LH whereas FSH and LH were positively correlated with each other.

The results of present study were consistent with the studies done in methadone users by Brown (46) and Daniell (70) where the prevalence of low testosterone was found to be 8.7% and 74%, respectively. Another comparative study on opioid dependence conducted by Cepeda (62) indicated that the proportions of males with and without opioid use (with multiple co-morbidities) had low testosterone were 61.4% and 54.4%, respectively.

In present study, only testosterone levels significantly differed between the two groups. In comparison to this, the LH and free testosterone levels were found to be significantly lower in patients with heroin and tramadol use disorders compared to healthy controls in a study by Hashim (43). In current study, only the ability to attain orgasm domain of the ASEX scale was found to significantly correlate with testosterone levels. Whereas in the study done by Hashim (43) there was no statistically significant association was found between the levels of sex hormones in the heroin use disorder group or the tramadol use disorder group with any of the sexual function domains. Study done by Brown (46) also found that plasma levels of testosterone or prolactin were not correlated to any of the subscales of sexual dysfunction or overall dysfunction. Another study on the association between sexual hormones and erectile function conducted by Muezzinoglu (77) found that only Prolactin levels exhibited a statistically significant correlation with lower libido, whereas testosterone levels were not shown to be significantly correlated with it, although Testosterone and FSH, as well as LH and FSH, showed statistically significant correlations. It can be hypothesized that reduced testosterone levels caused by opiate use is a key factor in opioid induced sexual dysfunction. Currently available

data support a reduction in testosterone levels brought on by opiate use. According to a meta-analysis and systematic review by Bawor (63) patients who use opioids for medical reasons, medication-assisted addiction treatment, or as a drug of abuse have significantly lower testosterone levels than non-users. Methadone, a commonly used substitute for opioid therapy, did not differ from other types of opioids. Hence, regardless of the indication for use, all opioids may reduce testosterone levels. The pulsatile release of gonadotropin-releasing hormone, the secretion of folliclestimulating hormone and luteinizing hormone, as well as opioids' direct effects on testicular tissue, are all possible causes for this. Finally, testosterone synthesis may be suppressed. (50)

In this study, testosterone was discovered to be a significant predictor of sexual dysfunction. Similar results were found in a study by Cepeda (62) who discovered that people who used opioids had a higher likelihood of having low testosterone levels than those who weren't exposed to opioids. (odds ratio (OR) 1.40, 95% confidence interval (CI)) (1.07–1.84).

#### Association of SD with Sex knowledge and attitude and behavior:

SKAQ mean scores found in our study for sexual knowledge and attitude were 18.59 and 5.97 respectively. In comparison to this, in a study by Sai Lahari and Abhinaya (54) on Knowledge, attitude, & behaviors towards sex and sources of influences among youth in rural areas showed mean scores for sexual knowledge and attitude to be 18.52 and 36.79 respectively. Similarly, Dutt and Manjula (29) in a study in healthy urban college youth found the scores to be 16.31 and 36.79 respectively and Kumar (56) found the scores to be 20.63 and 25.47 respectively. All these studies concluded that the participants had a poor knowledge but liberal attitudes towards sexuality. In

comparison, in our study the scores seem to indicate that the participants had both poor knowledge as well as conservative attitudes towards sexuality based on low SKAQ-II mean scores. In current study, people with SD had significantly lower scores in the Knowledge domain of SKAQ-II which indicates that sexual dysfunction is associated with poor sexual knowledge.

#### Association of SD and sexual quality of life and relationship assessment

In the present study people with SD were found to have significantly lower SQoL-M scores than people with no SD indicating a significant impact of opioid use on the sexual quality of life. This is consistent with the available literature. Naem (78) found a poor sexual quality of life in tramadol dependent individuals in their study. Similarly, in a study by Chawla (79) also found that sexual quality of life was significantly poor among patients seeking treatment for opioid dependence. Carlos (55) discovered that although a significant percentage of the sample gave importance to sex (71.7%), only 24.7% of them were satisfied with their sexual activity in their study on the relationship between sexual dysfunction and quality of life in chronic heroin-dependent people receiving methadone maintenance treatment. This is important because a significant number of people initiate opioid use with perception of potential improvement in existing sexual dysfunction or increase in their baseline sexual functioning. However, sexual dysfunction and associated reduction of sexual quality of life is associated with opioids use and people need to be educated about it to improve their overall quality of life.

In the present study no significant difference was seen in RAS scores between people with SD and no SD.

#### Association of SD and clinical variables

Total 25% of patients in the current study had positive family history, which is comparable to the findings of other studies. Vanderbroek (80) claim drug use in families tends to cluster, which may be due to shared genetic or environmental variables that affect the emergence of drug diseases.

In present study Mean SODQ total score was 47.42 and a significant difference was found in SODQ total score between both groups, which suggest that sexual dysfunction is associated with total SODQ score. In a study done by Venkatesh (52), 39% participants had a SODQ score of more than 30, and the average SODQ score of 28.78 suggested that our patients had a severe OUD. Our study results also supported by the previous Indian study by Aggarwal (51) where they found that SD (on both AESX & IIEF) more in the cases which had higher severity of dependence scale scores. This can be hypothesized that SD is more prevalent in individuals with severe opioid dependence. However, in a different research by Mattoo (48) in patients receiving buprenorphine and naloxone in combination, SODQ total score showed no significant difference between the SD and non-SD groups.

Present study was conducted on patients dependent on natural opium use and the study findings suggest that SD is comparable to synthetic opioids.

In present study no significant difference was found between two group in the form age of opioid initiation, duration of opioid use, amount and type of opioid. Although in one study done by Sethi (50) clamied that the prevalence of all domains of SD doubled with more than a year of opioid use, which was determined to be statistically significant, indicating that long-term opioid use increased the prevalence of SD. Nearly all of the patient had taken opium on the day of assessment and low mean clinical opioid withdrawal rating scale (COWS) score  $1.11\pm1.28$  suggested that none of our patients were in withdrawal phase. When the patient would have suffered withdrawal symptoms, the patient's participation in the research can have an impact on the evaluation of sexual dysfunction because of lack of interest due to his physical problems. In several individuals, opiate withdrawal has been linked to regained sexual desire and early ejaculation. (53)

The prevalence of co-occurring nicotine dependency in present study was found to be 75.7% which is comparable to the previous studies done by Sethi (50) and Venkatesh (52). Despite the high proportion of co-dependence on tobacco, it does not showed significant difference between two groups.

In the present study, high risk sexual behavior was found in only one patient, which is contrast to the previous studies whre high-risk sexual behavior have a high prevalence. (81–83) This may be due to the natural opium consumption which is culturally accepted in western Rajasthan. According to a research by Wong (84) 24.1% of truck drivers reported having sexual issues, including sexual impotence (3.1%), premature ejaculation (3.6%), and a lack of interest in sex (16.2%). They had an association with their risky sexual practices (OR 8.7, 95% CI 3.6-20.8). Sexual dysfunction, poor mental health, and risky sexual conduct are widespread issues. (84)

#### Association of SD and socio-demographic factors

In this study, a significant difference was found in mean age between two groups which indicates with the advancing age chances of sexual dysfunction would be more may be due to more duration of opioid dependence and severity of dependence and age related physical changes. Age is one of the consistently observed correlates of sexual dysfunction in opioid-dependent subjects across various studies. (53, 57, 68, 84, 85)

In the present study most of the cases (96.7%) were employed (Unskilled worker/semiskilled (19.6), skilled worker (31.8%), farmer/clerk/shop owner (48%), and only 3.7% were unemployed. In the present study sexual dysfunction was more in the cleric/farmer/shop owner group of occupation which can be explained by the fact that most of the patients were coming from rural background working as farmer. Although unemployment could be a psychosocial risk factor for SD and can be a factor determining the type and amount of opium consumption.

### CONCLUSION

In the current study, nearly half of the patients had SD which is almost similar to the previous studies conducted on patients dependent on synthetic opioids, hence patients who are using natural opium should also be actively screened for SD and psychoeducated for the same.

In present study findings regarding the various domains of sexual functioning suggest that desire/drive (47%) was the most frequently affected domain, followed by the ability to reach orgasm (39%), erection (38%), and arousal (36%) and the least affected was satisfaction with orgasm, hence natural opium has effects on various domains of sexual functioning.

SODQ score and total testosterone were found to be predictor for SD, hence severity of opioid dependence and serum testosterone level can directly affect the sexual functioning. SD significantly associated with SQoL-M and sexual knowledge of patients dependent on natural opium. Hence, SD would be more with poor sexual knowledge and associated with poor sexual quality of life. As reported in literature many subjects use opioids with a thought that it would improve their sexual functioning although evidence suggests that in the long run opioid use leads to disturbance in various domains of sexual functioning.

The findings of the present study and the existing literature seem to favor the conclusion that sexual dysfunction is highly prevalent in opioid-dependent patients. There is a need to increase the awareness of clinicians about this association as SD in patients with substance use may leads to poor compliance, dropout and ultimately poor treatment outcome. Hence, the clinicians should routinely enquire about and attempt to address the same.

#### Strengths of the study:

- The present study is one of the first Indian studies on patients dependent on natural opium which assessed prevalence and patterns of sexual dysfunctions.
- Sexual dysfunction was assessed by validated scales such as ASEX and IIEF and had assessed various domains that can affect SD
- Assessed hormonal profile and it's association with SD in patients dependent on natural opium
- Assessed the impact of opium on SD during the active phase when withdrawal symptoms were absent

#### Limitations of the study:

- Control were not included in the study for comparison due to the financial limitation
- It was a cross-sectional study, hence can not comment upon the course of sexual functioning with time and limits any causal inferences
- All participants were males which further curbs the generalizability of our study
- Sample drawn from a tertiary care center hence the results cannot be generalized to all the patients with OUD or on opioid users in the community
- Information from the sexual partner was not available, therefore some clinical details about sexual functioning was missed.

#### **Future directions:**

- Studies in community is required to assess belief system about the effect of natural opium use on sexual functioning
- Multicentric studies should be planned to see larger effect.
- Longitudinal studies should be conducated to see the effect in long run and also to see the effect of treatment on SD

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#### ANNEXURES

#### **ANNEXURE-1 ETHICAL CLEARANCE CERTIFICATES**



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर (6) का का

All India Institute of Medical Sciences, Jodhpur

संस्थागत नैतिकता समिति Institutional Ethics Committee

No. AIIMS/IEC/2021/ 3552-

Date: 12/03/2021

#### ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2021/3387

Project title: "Assessment of sexual dysfunction and its associations among male patients dependent on natural opium seeking treatment from a tertiary care centre"

Nature of Project: Submitted as: Student Name: Guide: Co-Guide: Research Project Submitted for Expedited Review M.D. Dissertation Dr. Dinesh Kumar Dr. Navratan Suthar Dr. Mukesh Kumar Swami, Dr. Naresh Nebhinani & Dr. Prasenjit Mitra

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- · Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- · Any unethical principle or practices are revealed or suspected
- · Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the Pl may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma Membe

Member secretary Institutional Ethics Committee AllMS.Jodhout

Basni Phase-2, Jodhpur, Rajasthan-342005; Website: www.aiimsjodhpur.edu.in; Phone: 0291-2740741 Extn. 3109 E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com



No.: AIIMS/RES/2021/6636

Dated: 23/10/21

To Dr. Navratan Suthar Assistant Professor, Department of Psychiatry, AIIMS, Jodhpur.

Subject: Request to change thesis Co-Guide: Reg.

Dear Dr. Suthar,

This is in reference to your letter no. AIIMS/JDH/PSY/2021/472&473 dated 18/10/2021. 1 am directed to inform you that Dean (Research) accorded his permission to appoint Dr. Dhannveer Yadav as a co-guide in place of Dr. Prasenjit Mitra for following students as per your request, if he is eligible for ship as per institutional guidelines. Details as follows:

Sr.	Name of Student	Session	Thesis Title
1.	Dr. Dinesh Kumar	July-2020	Assessment of sexual dysfunction and its association among male patients dependent on natural opium seeking treatment from a tertiary care Centre
2.	Dr. Raghvendra S. Singh	Jan-2020	Assessment of Neurocognitive Functions in Patients Dependent on Natural Opium

10hor

Dr. Jaykaran Charan Sub Dean (Research) Sub Dean (Research)

Copy for Information to: -

- Dr. Naresh Nebhinani, Additional Professor & Head, Dept. of Psychiatry Blachemistry of Ministry Of Jedhpur
  - 2. Dr. Dharmveer Yaday, Associate Professor, Dept. of Biochemistry, AllMS, Jodhpur
  - 3. Concerned PG Student
  - 4. Member Secretary, IEC, AlIMS, Jodhpur

Bassi Phase-2, Jodhpar, Rajasthan-342005, Websites www.niinsjodhpar.edu.in, Phene: 0201-2740741 Este. 3109 Email: dearresearchigainsjodhpar.edu.in, reservcheeftigainrojodhpar.edu.in

#### **ANNEXURE-2 PATIENT INFORMATION SHEET**

Name of the patient:

#### **Patient ID.:**

Aim of the study: Assessment of sexual dysfunction and its associations among male patients dependent on natural opium seeking treatment from a tertiary care centre

- 1. **Aim of the study:**To evaluate the sexual dysfunction and its correlates in male patients dependent on natural opium.
- 2. **Study site:**Patients seeking treatment under Department of Psychiatry, All India Institute of Medical Sciences, Jodhpur, Rajasthan.
- 3. Study procedure: All the participants who will fulfill the selection criteria's will be explained about the study in detail (Appendix 1 or 3), and a written informed consent (Appendix 2 or 4) will be taken from them. After that sociodemographic and clinical profile sheet (Appendix 5 and 6) will be filled. The severity of opioid and tobacco dependence will be measured by the Severity of Opioid Dependence Questionnaire (SODQ) and Fagerström Test for Nicotine Dependence (FTND)<sup>31</sup>respectively.Thereafter assessment for sexual dysfunction will be carried out if patient will have withdrawal score <5, based on assessment on clinical opiate withdrawal scale (COWS). Sexual knowledge will be checked by Sex Knowledge and Attitude Questionnaire (SKAQ)-II and sexual functioning will be assessed by using International Index of Erectile Function (IIEF) and Arizona Sexual Experience Scale (ASEX). After that Relationship satisfaction assessment and Sexual quality of life will be assessed by Relationship Assessment Scale and Sexual Quality of Life Questionnairemale (SQoL-M) respectively. To assess hypogonadism, hormone profile (Total Testosterone, FSH, LH, Prolactin) assay will be done by process of Chemiluminescence immunoassay (CLIA) and morning sample will be drawn.
- 4. Likely benefit:Study will help in identifying patient-specific characteristic, clinical and hormonal profile which can be used to tailor treatment for opioid dependence and sexual dysfunction. Patientswill also become aware about sexual knowledge, attitude and behavior.
- **5. Confidentiality:** All the data collected from each study participant will be kept highly confidential.

**6. Risk:** Enrollment in above study poses no substantial risk to any of the study participant and if any point of time participant wants to withdraw himself, he can do so voluntarily at any point of time during the study.

For further information and questions, the following personnel can be contacted:

Dr. Dinesh Kumar, Junior Resident, Department of Psychiatry, All India Institute of Medical Sciences, Jodhpur, Rajasthan. Ph: 8209419580

# ANNEXURE-3 रोगीसूचनापत्र

रोगीकानाम:

रोगीआईडी:

अध्ययन का उद्देश्य: "तृतीयक देखभाल केंद्र से उपचार लेने वाले प्राकृतिक अफीम पर निर्भर पुरुष रोगियों मै सेक्स रोग एवं उसके सहसबंधों का मूल्यांकन करना"

1.अध्ययन का उद्देश्य: पुरुष अफीम पर निर्भर प्राकृतिक अफीम में यौन रोग और उसके सहसंबंधों का मूल्यांकन करना।

2.अध्ययन स्थल: मनोचिकित्सा विभाग, अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान में उपचार के लिए आने वाले रोगी।

3.अध्ययन प्रक्रिया: वे सभी प्रतिभागी जो चयन मानदंडों को पूरा करेंगे, उन्हें अध्ययन के बारे में विस्तार से बताया जाएगा (परिशिष्ट 1 या 3), और लिखित सूचना (परिशिष्ट 2 या 4) उनसे ली जाएगी।उसके बाद सामाजिक-जनसांख्यिकीय और नैदानिक प्रोफ़ाइल शीट (परिशिष्ट 5 और 6) को भरना होगा। ओपिओयड और तंबाकू पर निर्भरता की गंभीरता को ओपियॉइड डिपेंडेंस प्रश्नावली (एसओडीक्यू)की गंभीरता और क्रमशः निकोटीन डिपेंडेंस (एफटीएनडी) और धुम्रहित तम्बाको के लिए फेजरस्ट्रॉम टेस्ट द्वारा मापा जाएगा। इसके बाद यौन रोग के लिए मूल्यांकन किया जाएगा, यदि रोगी के पास निकासी स्कोर होगा<5, नैदानिक अफीम निकासी पैमाने (COWS) पर मूल्यांकन के आधार पर. यौन ज्ञान की जाँच सेक्स ज्ञान और मनोवृत्ति प्रश्नावली (SKAQ -II) और यौन द्वारा की जाएगी।इरेक्टाइल फंक्शन (IIEF) के इंटरनेशनल इंडेक्स औरएरिज़ोना सेक्सुअल एक्सपीरियं संस्केल (ASEX). का उपयोग करके कामकाज का आकलन किया जाएगा। उसके बाद रिलेशनशिप संतुष्टि स्केल और जीवन की यौन गुणवत्ता का आकलन रिलेशनशिप एसेसमेंट स्केल और सेक्शुअल क्रालिटी ऑफ़ लाइफ प्रश्नावली-पुरुष द्वारा किया जाएगा। (SQoL-M) क्रमशः हाइपोगोनैडिज़्म का आकलन करने के लिए, रासायनिक प्रोफ़ाइल (टोटलटेस्टोस्टेरोन, FSH, LH, प्रोलैक्टिन) परख Chemiluminescence immunoassay (CLIA) की प्रक्रिया द्वारा किया जाएगा और सुबह का नमूना तैयार किया जाएगा।

4.संभावित लाभ: अध्ययन से रोगी-विशिष्ट विशेषता, नैदानिक और हार्मोनल प्रोफ़ाइल की पहचान करने में मदद मिलेगी, जिसका उपयोग ओपियोड निर्भरता और यौन रोग के लिए दर्जी उपचार के लिए किया जा सकता है।यौनज्ञान, दृष्टिकोण और व्यवहार के बारे में रोगी भी जागरूक हो जाएंगे।

 गोपनीयताः प्रत्येक अध्ययन प्रति भागी से एकत्र किए गए सभी डेटा को अत्यधिक गोपनीय रखा जाएगा।

6.जोखिम:उपरोक्त अध्ययन में नामांकन से अध्ययन के किसी भी प्रतिभागी को कोईभारी जोखिम नहीं होता है और यदि कोई भी प्रति भागी स्वयं को वापस लेना चाहता है,तो वह अध्ययन के दौरान किसी भी समय स्वेच्छा से ऐसा कर सकता है।

अधिक जानकारी और प्रश्नों के लिए, निम्नलिखित कर्मियों से संपर्क किया जा सकता है:

डाँ।दिनेशकुमार, जूनियररेजिडेंट, मनोरोगविभाग, अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर,राजस्थान। Ph: 8209419580

#### **ANNEXURE-4 INFORMED CONSENT FORM**

#### All India Institute of Medical Sciences Jodhpur, Rajasthan

Title of Thesis/Dissertation: Assessment of sexual dysfunction and its associations among male patients dependent on natural opium seeking treatment from a tertiary care centre

Name of PG Student: Dr. Dinesh Kumar, Tel. No.: 8209519580

Patient/Volunteer Identification No. :

I, \_\_\_\_\_ S/o or D/o \_\_\_\_\_

R/o\_\_\_\_\_

give my full, free, voluntary consent to be a part of "Assessment of sexual dysfunction and its associations among male patients dependent on natural opium seeking treatment from a tertiary care centre", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from All India Institute of Medical Sciences, Jodhpur. I give permission for these individuals to have access to my records.

Date: \_\_\_\_\_

Dlago		
FIACE.		

Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date:		
Date:		
Date.		

Place: \_\_\_\_\_

1. Witness-1

Si	gnature	
Name:		 
Address:		 

Signature of PG Student

2. Witness-2

Signature	
Name:	
Address:	

# ANNEXURE-5 INFORMED CONSENT FORM (HINDI)

# <u>स्चितसहमतिपत्र</u>

प्रोटोकॉल /अध्ययनसं\_

इस अध्ययन लिए रोगी आयीडी\_

अध्ययनकाशीर्षक: "तृतीयक देखभाल केंद्र से उपचार लेने वाले प्राकृतिक अफीम पर निर्भर पुरुष रोगियों मै सेक्स रोग एवं उसके सहसबंधों का मूल्यांकन करना"

अन्वेषक: डॉ. दिनेशकुमारतेल।नं .: 8209519580

इस सूचना पत्र की सामग्री दिनांक को प्रदान की गयी थी।मैंने सावधानीपूर्वक पढ़ लिया है / मुझे मेरी भाषा में विस्तार से समझा दिए गया है और मैंने पूरी जानकारी को अच्छी तरह समझ लिया है।मैं पुष्टि करता हूँ की मुझे प्रश्न पूछने का अवसर दिया गया है।अध्ययन का प्रकार और प्रयोजनत था इसके संभावित जोखिम/ लाभ और अध्ययन पूरा होने की अनुमानित अवधित था अध्ययन के अन्य सम्बंधित विवरण मुझे विस्तार से समझा दिए गए है ।मुझे बताया गया है की मेरी भागीदारी स्वेच्छानुसार है और मैं कोई कारण बताये बिना किसी भी समय अध्ययन से बाहर होने के लिए पूरी तरह स्वतंत्र हूँ और इसका मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा। मुझे पता है की इस अनुसन्धान में मेरी भागीदारी के बारे में जमा गयी जानकारी और मेरे चिकित्सा नोट्स एम्स के जिम्मेदार व्यक्तियों द्वारा देखे जायेंगे

उपराक्त अध्ययन म भाग लन क लिए सहमत हू।
----------------------------------------

दिनांक -				
स्थान				
हस्ताक्षर	/अंगूठेकानिशान			
रोगीकान 	11म 			.पुत्र/ पुत्री/ जीवनसाथी
पूरापता यह प्रमा	णित किया जाता है की	 गे उपरोक्त स्वीकृति मेरी उ		
प्रधान अ	ान्वेषक के हस्ताक्षर	दिनांक	स्था	न
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डाकका	पूरापता			
गवाह2	गवाहकानाम			
	डाककापूरापता			

#### ANNEXURE-6 SOCIO-DEMOGRAPHIC DATA SHEET

Name:.....Age: .... Years Sex: M/F

Education years: .....

Marital status: 0) single and in a relationship1) married

**Occupation:** 0) professional 1) clerical, shop owner/farm 3) skill worker 4) semiskilled / unskilled worker 5) unemployed 6) house wife/house hold 7) retired 8) student 9) not known

Family Income (per capita): ..... (INR)

**Religion:** 0) Hindu 1) Muslim 2) Sikh 3) Christian 4) others 5) not known

Family type: 0) nuclear 1) extended 2) joint 3) others 4) not known

Locality: 0) urban 1) rural 2) town/suburban

# ANNEXURE-7 CLINICAL HISTORY SHEET

Patient id:	
Name of patient:	
Psychiatric diagnosis:	
Physical diagnosis:	
Age of initiation of opium use: years	Duration of opiumuse:years
Duration ofdependence:years	Effective duration of use:years
Duration of Abstinence:	Usual dose:
Last intake of opium:High riskb	ehavior:

Tobacco use and pattern:

- Past history of substance use:
- Family history of substance use:
- Premorbid Personality:
- Mental status examination:
- Level of motivation to quit:
- Current treatment

# **ANNEXURE-8 SEVERITY OF OPIOID DEPENDENCE**

# **QUESTIONNARE (SODQ)**

APPENDIX 1	
1. Which opiate(s) do you usually take? (ple	ase circle as appropriate)
	Amount per day
Heroin	
Morphine	
Methadone (Dolophine)	
Meperidine (Demerol)	
Dilaudid	
Paregoric	
Codeine	
Percodan	
Other	
Please answer each question by circling one re	sponse
only	aponoc
For the rest of the questions please think of a typica	l recent
period of opiate use	10001
period of optime use.	
2. Do you usually inject/fix?	
YES NO	
V V.	
Go straight to	Q.3
→(a) How many times do you fix during a t	ypical day?
0 1 2 3 4 5 6 7 8 9	10 or more
⇒(b) What would be the fewest injections yo	ou would have during a
typical day?	
0 1 2 3 4 5 6 7 8 9	10 or more
(c) What would be the greatest number of	injections you would
have during a typical day?	
0 1 2 3 4 5 6 7 8 9	10 or more
2 Do you usually smake stister)	Contraction of the State
J. Do you usually shoke optales?	
IES NO	
V V	
	.4
Not Hand in the straight to Q	
(a) How many times do you smoke during	a typical day?
(a) How many times do you smoke during 0 1-2 3-4 5-6 7-8 9-10 11-	<i>a typical day?</i> 12 13-14 15-16 17 or more
<ul> <li>(a) How many times do you smoke during</li> <li>0 1-2 3-4 5-6 7-8 9-10 11-</li> <li>→(b) What would be the fewest smokes you</li> </ul>	a typical day? 12 13-14 15-16 17 or more would have during a typical day?
(a) How many times do you smoke during 0 1-2 3-4 5-6 7-8 9-10 11- (b) What would be the fewest smokes you 0 1-2 3-4 5-6 7-8 9-10 11-	a typical day? 12 13-14 15-16 17 or more would have during a typical day? 12 13-14 15-16 17 or more
<ul> <li>(a) How many times do you smoke during 0 1-2 3-4 5-6 7-8 9-10 11-</li> <li>(b) What would be the fewest smokes you 0 1-2 3-4 5-6 7-8 9-10 11-</li> <li>(c) What would the greatest number of smokes</li> </ul>	a typical day? 12 13-14 15-16 17 or more would have during a typical day? 12 13-14 15-16 17 or more okes you would have during
<ul> <li>(a) How many times do you smoke during 0 1-2 3-4 5-6 7-8 9-10 11-</li> <li>(b) What would be the fewest smokes you 0 1-2 3-4 5-6 7-8 9-10 11-</li> <li>(c) What would the greatest number of smu a typical day?</li> </ul>	a typical day? 12 13-14 15-16 17 or more would have during a typical day? 12 13-14 15-16 17 or more okes you would have during

4. Do	you usu	ally	tak	e li	qui	d o	r pil	ls?				
	YES			1	NO							
	1				V							
	<u>v</u>				•	$\rightarrow$	Go s	trai	ight	to	0.5	
$\rightarrow$ (a)	How m	anv	tim	les d	to 1	iou	tak	e it/	the	n di	uring	a typical day?
	0	1	2	3	4	5	6	7	8	9	10	or more
<del>)</del> (₽)	What a a typic	voul al d	ld be ay?	the	e fe	wes	st tin	nes	you	u wo	uld t	take it/them during
	0	1	2	3	4	5	6	7	8	9	10	or more
<del>)</del> (c)	What v a typic	voul al d	ld be ay?	the	e m	ost	tim	es y	ou	wou	ld ta	ke it/them during
	0	1	2	3	4	5	6	7	8	9	10	or more

5. Does the amount of opiate you take vary from day to day? Not at all Varies a little Varies a lot

6. Do you find you need higher doses than you did 6 months ago for the same effect? No Slightly Higher Much Higher

7. On waking, and before my first dose of opiates:

(a)	My body aches or f	eels stiff:			
.,	Never or almost never	Sometimes	Often	Always or nearly always	
(b)	I get stomach cram	bs:		,	
.,	Never or almost never	Sometimes	Often	Always or nearly always	
(c)	I feel sick:				
.,	Never or almost never	Sometimes	Often	Always or nearly always	
(d)	I notice my heart p	ounding:	<b>8</b> 0		
• • •	Never or almost never	Sometimes	Often	Always or nearly always	
(e)	I have hot and cold	l flushes:			
	Never or almost never	Sometimes	Often	Always or nearly always	
(f)	I feel miserable or a	lepressed:			
	Never or almost never	Sometimes	Often	Always or nearly always	
(g)	I feel tense:	- 1020	1000000000		
	Never or almost never	Sometimes	Often	Always or nearly always	
(h)	I feel irritable or an	igry:			
	Never or almost never	Sometimes	Often	Always or nearly always	
(i)	I feel restless and u	nable to relax:			
	Never or almost never	Sometimes	Often	Always or nearly always	
(j)	I have a strong cra	ving:			
	Never or almost never	Sometimes	Often	Always or nearly always	
8. (a)	I try to save some o	pointes to use on	waking:		
()	Never or almost never	Sometimes	Often	Always or nearly always	
(b)	I like to take my fin	rst dose of opiate	es within 2	hours	
,	of waking up:				
			And the second sec	contraction and a second distribution of the second s	

Never or almost Sometimes Often Always or nearly never (c) In the morning, I use opiates to stop myself feeling sick: Never or almost Sometimes Often Always or nearly

never

always

494 Gay Sutherland

- (d) The first thing I think of doing when I wake up is to take some opiates: Never or almost Sometimes Often Always or nearly never always
- (e) When I wake up I take opiates to stop myself aching or feeling stiff: Never or almost Sometimes Often Always or nearly never always
- (f) The first thing I do after I wake up is to take some opiates: Never or almost Sometimes Often Always or nearly never always



#### **APPENDIX 2**

Please answer each question by circling one response only Please think of your opiate use during a typical recent period of drug taking for these questions:

(a)	Did you think your opiate	e use was out of a	control?			
(-)	Never or almost	Sometimes	Often	Always or nearly always		
	Dild	. f. (an Jaco) an	aha way man	annious or morniad?		
(b)	Did the prospect of missing a fix (or aose) make you very anxious of worried?					
	Never or almost	Sometimes	Often	Always or nearly		
	never			always		
(c)	Did you worry about your opiate use?					
(•)	Not at all	A little	Quite a lot	A great deal		
(4)	Did you wish you could stop?					
(4)	Never or almost never	Sometimes	Often	Always or nearly always		
(e)	How difficult would you find it to stop or go without?					
(•)	Impossible	Very	Quite	Not difficult		
		difficult	difficult			

Thank you very much for your help

# ANNEXURE-9 FAGERSTROM TEST FOR NICOTINEDEPENDENCE(FTND) AND FTND SMOKELESS TOBACCO (FTND-ST)

# Fagerstrom Nicotine Dependence Scale

Questions	Answers	Points
How soon after you wake up do smoke your first	Within 5 min	3
ugarette :	6 - 30 min	2
	31 – 60 min	1
	After 60 min	0
Do you find it difficult to refrain from smoking in places	Yes	1
in a cinema, etc.?	No	0
Which cigarette would you hate to give up most?	The first one in the morning	1
	All others	0
How many cigarettes do you smoke per day?	10 or less	0
	11 - 20	1
	21 – 30	2
	31 or more	3
Do you smoke more frequently during the first hours	Yes	1
alter awakening man during the rest of the day?	No	0
Do you smoke if you are so ill that you are in bed	Yes	1
nives of and way :	No	0
		Total =

Scoring Instructions: Add up responses to all items. A score of 5 or more indicates a significant dependence, while a score of 4 or less shows a low to moderate dependence.

# Fagerstrom Nicotine Dependence Scale-Smokeless Tobacco (FTND-ST)

Questions	Answers	Points
How soon after you wake up do you place your first dia?	Within 5 min	3
	6 - 30 min	2
	31 – 60 min	1
	After 60 min	0
How often do you intentionally swallow tobacco juice?	Always	2
	Sometimes	1
	Never	0
Which chew would you hate to give up most?	The first one in the morning	1
	All others	0
How many cans/pouches per week do you use?	More than 3	2
	2- 3	1
	1	0
Do you chew more frequently during the first hours after awakening than during the rest of the day?	Yes	1
and awarening that withing the rest of the way:	No	0
Do you chew if you are so ill that you are in bed	Yes	1
	No	0
		Total =

Scoring Instructions: Add up responses to all items. A score of 5 or more indicates a significant dependence, while a score of 4 or less shows a low to moderate dependence.

# ANNEXURE-10 CLINICAL OPIOID WITHDRAWAL SCORE (COWS)

Resting Pulse Rate: (record beats per	Sweating: over past <sup>1</sup> / <sub>2</sub> hour not			
minute) Measured after patient is sitting	accounted for by room temperature or			
or lying for one minute	patient activity.			
0 pulse rate 80 or below	0 no report of chills or flushing			
1 pulse rate 81-100	1 subjective report of chills or flushing			
2 pulse rate 101-120	2 flushed or observable moistness on face			
4 pulse rate greater than 120	3 beads of sweat on brow or face			
	4 sweat streaming off face			
Restlessness Observation during	Pupil size			
assessment	0 pupils pinned or normal size for room			
0 able to sit still	light			
1 reports difficulty sitting still, but is able	1 pupils possibly larger than normal for			
to do so	room light			
3 frequent shifting or extraneous	2 pupils moderately dilated			
movements of legs/arms	5 pupils so dilated that only the rim of the			
5 Unable to sit still for more than a few	iris is visible			
seconds				
seconds Bone or Joint aches If patient was	Runny nose or tearing Not accounted			
seconds Bone or Joint aches If patient was having pain	Runny nose or tearing Not accounted for by cold			
seconds <b>Bone or Joint aches</b> If patient was having pain previously, only the additional	Runny nose or tearing Not accounted for by cold symptoms or allergies			
seconds <b>Bone or Joint aches</b> If patient was having pain previously, only the additional component attributed to opiates	Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present			
seconds <b>Bone or Joint aches</b> If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored	Runny nose or tearing Not accountedfor by coldsymptoms or allergies0 not present1 nasal stuffiness or unusually moist eyes			
seconds <b>Bone or Joint aches</b> If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present	Runny nose or tearing Not accountedfor by coldsymptoms or allergies0 not present1 nasal stuffiness or unusually moist eyes2 nose running or tearing			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort	Runny nose or tearing Not accountedfor by coldsymptoms or allergies0 not present1 nasal stuffiness or unusually moist eyes2 nose running or tearing4 nose constantly running or tears			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of	Runny nose or tearing Not accountedfor by coldsymptoms or allergies0 not present1 nasal stuffiness or unusually moist eyes2 nose running or tearing4 nose constantly running or tearsstreaming down cheeks			
seconds <b>Bone or Joint aches</b> If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles	Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and	Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of	Runny nose or tearing Not accounted         for by cold         symptoms or allergies         0 not present         1 nasal stuffiness or unusually moist eyes         2 nose running or tearing         4 nose constantly running or tears         streaming down cheeks			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort GI Upset: over last ½ hour	Runny nose or tearing Not accounted         for by cold         symptoms or allergies         0 not present         1 nasal stuffiness or unusually moist eyes         2 nose running or tearing         4 nose constantly running or tears         streaming down cheeks			
seconds Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort GI Upset: over last ½ hour 0 no GI symptoms	Runny nose or tearing Not accounted         for by cold         symptoms or allergies         0 not present         1 nasal stuffiness or unusually moist eyes         2 nose running or tearing         4 nose constantly running or tears         streaming down cheeks         Tremor observation of outstretched         hands			

2 nausea or loose stool	1 tremor can be felt, but not observed
3 vomiting or diarrhea	2 slight tremor observable
5 Multiple episodes of diarrhea or	4 gross tremor or muscle twitching
vomiting	
Yawning Observation during assessment	Anxiety or Irritability
0 no yawning	0 none
1 yawning once or twice during	1 patient reports increasing irritability or
assessment	anxiousness
2 yawning three or more times during	2 patient obviously irritable anxious
assessment	4 patient so irritable or anxious that
4 yawning several times/minute	participation in the assessment is difficult
Gooseflesh skin	Total scores:
0 skin is smooth	
3 piloerrection of skin can be felt or hairs	
standing up on	
arms	
5 prominent piloerrection	

# ANNEXURE-11 ARIZONA SEXUAL EXPERIENCE SCALE (ASEX) QUESTIONNAIRE

#### ARIZONA SEXUAL EXPERIENCES SCALE (ASEX)-MALE

For each item, please indicate your **OVERALL** level during the **PAST WEEK**, including **TODAY**.

1. How strong is your sex drive?

1 extremely strong	2 very strong	3 somewhat strong	4 somewhat weak	5 very weak	6 no sex drive	
2. How easil	2. How easily are you sexually aroused (turned on)?					
1 extremely easily	2 very easily	3 somewhat easily	4 somewhat difficult	5 very difficult	6 never aroused	
3. Can you easily get and keep an erection?						
1 extremely easily	2 very easily	3 somewhat easily	4 somewhat difficult	5 very difficult	6 never	
4. How easily can you reach an orgasm?						
1 extremely easily	2 very easily	3 somewhat easily	4 somewhat difficult	5 very difficult	6 never reach orgasm	
5. Are your orgasms satisfying?						
1 extremely satisfying	2 very satisfying	3 somewhat satisfying	4 somewhat unsatisfying	5 very unsatisfying	6 can't reach orgasm	
COMMENTS:						
#### अरिजोना लैंगिक अनुभव स्केल (ASEX)

आज सहित, पिछले सप्ताह के दौरान कुल मिलाकर आपकी स्थिति को सुचित करने वाले जवाब पर निशान लगाएं

- आपकी काम इच्छा कितनी तेज़ (ज़्यादा) है ? 1
  - 1। अत्यधिक तेज़
    - 2। बहुत तेज़
    - 8। कुछ कुछ तेज़
    - 4 | कुछ कुछ कमज़ोर
    - 5। बहुत कमज़ोर
    - 6 | कोई काम इच्छा नहीं

आपकी काम इच्छा कितनी आसानी से जाग गई ? 2

- 1। अत्यधिक आसानी से
- 2। बहुत आसानी से
- 8। कुछ कुछ आसानी से
- 4 | कुछ कुछ मुश्किल से
- 5। बहुत मुश्किल से
- 6। कभी उत्तेजित नहीं होते
- क्या आपका लिंग आसानी से खड़ा हो जाता है और तना रहता है? 3
  - 1। अत्यधिक आसानी से
  - 2 | बहत आसानी से
  - 8 | कुछ कुछ आसानी से
  - 4 | कुछ कुछ मुश्किल से
  - 5। बहुत मुश्किल से
  - 6 | कभी नहीं
  - आप काम आनंद की चरम सीमा तक कितनी आसानी आसानी से पहुंच सकते हैं ? 4
    - 1। अत्यधिक आसानी से
    - 2। बहत आसानी से
    - 8। कुछ कुछ आसानी से
    - 4। कुछ कुछ मुश्किल से
    - 5। बहुत मुश्किल से
    - 6 | यौन आनंद की चरम सीमा तक कभी नहीं पहुंचता
  - क्या आप अपने काम आनंद की चरम सीमा से संतुष्ट है ? 5
    - 1। अत्यधिक संतुष्ट
    - 2। बहुत संतुष्ट
    - 3। कुछ कुछ संतुष्ट
    - 4। कुछ कुछ असंतुष्ट
    - 5। बहुत असंतुष्ट
    - 6 | यौन आनंद की चरम सीमा तक कभी नहीं पहुंचता

## **ANNEXURE-12 INTERNATIONAL INDEX OF ERECTILE FUNCTION** (IIEF) QUESTIONNAIRE

इंटरनेशनल इंडेक्स ऑफ़ इरेक्टाइल फ़ंक्शन (आई. आई. ई. एफ़.) (उद्धर्षन क्रिया का अंतर्राष्ट्रीय निर्देशांक) 🗍 (1) किया नहीं

6								
1.	पिछले चार सप्ताहों के दौरान यौन क्रिया** के समय आप अपने लिंग (इन्द्रि) में कितनी बार तनाव ला पाये?							
	कृपया एक खाने में ही (X) का चिन्ह लगाइए							
	🛄 (1) थौन क्रिया नहीं की							
	(2) हमेशा या लगभग हमेशा							
	(3) अधिकांश बार (आधे से काफी अधिक बार)							
	[] (4)) कभी-कभी (लगभग आधी बार)							
	[] (5) कुछ ही बार (आधे से बहुत कम बार)							
	(6) कभी नहीं या लगभग कभी नहीं							
L								
2.	पेछले चार सम्ताहों के दौरान काम उत्तेजक**** स्थितियों में जब जब आपके लिंग में तनाव आया, उसमें से कितनी बार यह तनाव इतना कड़ा							
	आ कि प्रवेश कर सकें?							
	ृष्पया एक खाने में ही (X) का चिन्ह लगाइए							
	🛄 (1) काम उत्तेजना नहीं हुई							
	(2) हमेशा था लगभग हमेशा							
	🗌 (3) अधिकांश बार (आधे से काफी अधिक बार)							
	[_] (4) कथी-कभी (लगभग आधी बार)							
	(5) कुछ ही बार (आधे से बहुत कम बार)							
	ि(G) कभी नहीं या लगभग कभी नहीं							

### अगले तीन प्रश्न यौन सम्भोग\* के समय आपके लिंग के तनाव के बारे में हैं.

3.	पिछले चार सप्ताहों के दौरान जब जब आपने यौन सम्भोग* का प्रयत्न किया, उनमें से कितनी बार आप संगिनी (पार्टनर) में लिंग प्रवेश कर गण-2
	कृषया एक खाने में ही (X) का चिन्हें लगाइए
	(1) यौन सम्भोग का प्रयत्न नहीं किया
	[]] (2) हमेशा या लगभग हमेशा
	[]]](3) अधिकांश बार (आधे से काफी अधिक बार)
	(4) कभी-कभी (लगभग आधी धार)
	(5) कुछ ही बार (आधे से बहुत कम बार)
	🖂 (6)) कभी नहीं या लगभग कभी नहीं
4.	<u>धिछले चार सप्ताहों</u> के दौरान यौन सम्भोग <sup>*</sup> के समय संगिनी (पार्टनर) में लिंग प्रवेश के बाद, <u>कितनी बार</u> आप अपने लिंग का तनाव बनाए रख सके?
	कृषया एक खाने में ही (X) का चिन्ह लगाइए
	(1) यौन सम्भोग का प्रयत्न नहीं किया
	[]] (2)   हमेशा या लगभग हमेशा
	(3) अधिकांश बार (आधे से काफी अधिक बार)

(1)	यान सम्भाग का प्रयत्न
(2)	हमेशा या लगभग हमेश
(3)	अधिकांश बार (आधे र
(d)	कभी-कभी (लगभग अ

- आधी बार) [ (5) कुछ ही बार (आधे से बहुत कम बार)
- (6) कभी नहीं या लगभग कभी नहीं

5. पिछले चार सप्ताहों के दौरान बौन सम्भोग\* के समय, सम्भोग पूरा होने तक लिंग का तनाब बनाए रखना आपके लिए कितना कठिन था?

State (as one is the factor of the state of
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

- [ (1) यौन सम्भोग का प्रयत्न नहीं किया
  - 🔄 (2) अत्याधिक कठिन
  - 🗌 (3) बहुत कठिन
  - [ (4) कठिन
  - 📋 (5) कुछ कठिन
  - 🗌 (6) कठिन नहीं

पिछले चार सप्ताहों के दौरान कितनी बार आपने यौन सम्पोग<sup>\*</sup> का प्रयत्न किया?

कृपया एक खाने में ही (X) का चिन्ह लगाइए

- [ (1) एक बार भी नहीं
- [](2) १-२ बार [ (3) ३-४ बार
- 🗋 (4) ५-६ वार
- [](5) ७-१० बार
- [] (6) ११ बार या अधिक

पिछले चार सप्ताहों के दौरान जब-जब आपने यौन सम्भोग\* का प्रयत्न किया, उनमें से कितनी बार यह आपके लिए संतोषजनक रहा?

कृपया एक खाने में ही (X) का चिन्ह लगाइए

- 🛄 (1) थौन सम्भोग का प्रयत्न नहीं किया
  - 📋 (2) हमेशा या लगभग हमेशा
  - (3) अधिकांश बार (आधे से काफी अधिक बार)
  - (4) कभी-कभी (लगभग आधी बार)
  - [ (5) कुछ ही बार (आधे से बहुत कम बार)
  - 🛄 (6) कभी नहीं या लगभग कभी नहीं

पिछले चार सप्ताहों के दौरान यौन सम्भोग\* में आपको कितना आनन्द मिला है?

कृपया एक खाने में ही (X) का चिन्ह लगाइए

- 🛄 (1) यौन सम्भोग नहीं किया
- (2) बहुत अधिक आनन्द
- [ (3) बहुत आनन्द
- 📋 (4) ठीक सा आनन्द
- 🔄 (5)) बहुत आनन्द नहीं
- 🗌 (6) आनन्द नहीं

पिछले चार सप्ताहों के दौरान जब-जब आप काम उत्तेजक स्थितियों\*\*\*\* में थे, या आपने यौन संबंध\* किया, उनमें से कितनी बार आपका स्थलन\*\*\* (बीर्य निकलना, इंजेक्युलेशन) हुआ?

- कृपया एक खाने में ही (X) का चिन्ह लगाइए
  - 🗔 (1) काम उत्तेजन या यौन संबंध नहीं किया
    - (2) हमेशा या लगभग हमेशा
    - (3) अधिकांश बार (आधे से काफी अधिक बार)
    - [ (4) कभी-कभी (लगभग आधी बार)
    - 🗌 (5) कुछ ही बार (आधे से बहुत कम बार)
    - 🗌 (6)) कभी नहीं या लगभग कभी नहीं

				_
10.	पिछले चार सप्ताहों	के दौरान जब जब आप काम उत्तेजक स्थितियों**** में थे, या आपने यौन संबंध* किया,	उनमें से कितनी बार आप	को
	सम्भोग चरम तृष्ति (	औगजिम) का अनुभव हुआ, वीर्य*** चाहे निकला हो या नहीं?		

कृपया एक खाने में ही (X) का चिन्ह लगाइए

- 🛄 (1) काम उत्तेजन या यौन संबंध नहीं किया
- 🗌 (2) हमेशा या लगभग हमेशा
- []](3) अधिकांश धार (आधे से काफी अधिक बार)
- 🔄 (4) कभी-कभी (लगभग आधी बार)
- 🛄 (5) कुछ ही बार (आधे से बहुत कम बार)
- (6) कभी नहीं या लगभग कभी नहीं

अगले दो प्रश्नों में काम इच्छा के बारे में पूछा गया है. परिभाषा के लिए मान सकते हैं कि काम इच्छा एक ऐसी भावना है, जिसमें काम अनुभव (जैसे हस्तमैथुन या यौन सम्भोग\*) की चाह, काम (सेक्स) के बारे में सोचना या काम क्रिया के अभाव में निराशा होना इत्यादि शामिल हैं.

1	11. पिछले चार सप्ताहों वे	5 दौरान आपने कितनी बार <b>काम इच्छा</b> का अनुभव किया है?
	कृपया एक खाने में	ही (X) का धिन्ह लगाइए
	[]](1)	हमेशा या लगभग हमेशा
	(2)	अधिकतर समय
	(3)	कभी-कभी
	(4)	कुछ ही बार
	(5)	कभी नहीं या लगभग कभी नहीं
1		
	12. पिछले चार सप्ताहों,	के दौरान आ <b>पकी काम इच्छा</b> का स्तर कितना रहा है?
	कप्रधा एक खाने में	ही (X) का चिन्ह लगाइए

कृपया एक खान म	हा (X) का जिन्ह लगाइए
[](1)	बहुत ऊँचा
(2)	ऊँचा
(3)	मध्यम
(4)	नीचा
(5)	बहुत भीचा या बिल्कुल नहीं

<b>र स</b> प्ताहों वे	त दौरान अपने सगरत काम जीवन (सेक्स लाइफ़) से आप कितने संतुष्ट रहे हैं?	
ज्खाने में ही <b>(</b>	X) का चिन्ह लगाइए	
(1)	बहुत संतुष्ट	
(2)	सामान्यतः संतुष्ट	
(3)	लगभग बराबर संतुष्ट और असंतुष्ट	
[](4)	सामान्यतः असंतुष्ट	
[](5)	बहुत असंतुष्ट	
ार सप्ताहों वे	रू दौरान अपनी संगिनी के साथ यौन संबंधो से आप कितने संतुष्ट रहे हैं?	
ठ खाने में ही (	(X) का चिन्ह लगाइए	
[](1)	बहुत संतुष्ट	
(2)	सामान्यतः संतुष्ट	
(3)	लगभग बराबर संतुष्ट और असंतुष्ट	
(4)	सामान्यतः असंतुष्ट	
(5)	बहुत असंतुष्ट	
	र सप्ताहों वे ज्ञाने में ही ( (1) (2) (3) (4) (5) ह खाने में ही (1) (2) (2) (3) (4) (2) (3) (4) (5)	र सम्ताहों के दौरान अपने सनरत काम जीवन (सेक्स लाइफ) से आप कितने संतुष्ट रहे हैं? 5 खाने में ही (X) का चिन्ह लगाइए (1) बहुत संतुष्ट (2) सामान्यत: संतुष्ट (3) लगभग बराबर संतुष्ट और अर्सतुष्ट (4) सामान्यत: असंतुष्ट (5) बहुत असंतुष्ट (5) बहुत असंतुष्ट (1) बहुत संतुष्ट (1) बहुत संतुष्ट (2) सामान्यत: संतुष्ट (3) लगभग बराबर संतुष्ट (3) लगभग बराबर संतुष्ट (4) सामान्यत: असंतुष्ट (5) बहुत असंतुष्ट (5) बहुत असंतुष्ट

15. पिछले चार सप्ताहों वे	5 दौरान अपने लिंग में तनाव लाने और उसको बनाए रखने की शक्ति में आपका <b>विश्वास</b> कितना रहा है?
कृपया एक खाने में ही (	X) का चिन्ह लगाइए
(5)	बहुत अधिक
(4)	अधिक
(3)	मध्यम
[](2)	कम
(1)	बहुत कम

# ANNEXURE-13 SEXUAL QUALITY OF LIFE QUESTIONNAIRE- MALE (SQoL-M)

1. When I think about my sexual life, I feel	completely	moderatelv	slightly	slightly	moderately	completelv
frustrated	agree	agree	agree	disagree	disagree	disagree
2. When I think about my sexual life, I feel	completelv	moderately	slightly	slightly	moderately	completelv
depressed	agree	agree	agree	disagree	disagree	disagree
urpressed.	-0					
3. When I think about my sexual life, I feel	completelv	moderately	slightly	slightly	moderately	completelv
less of a man	agree	agree	agree	disagree	disagree	disagree
			U U	U U	Ŭ	
4. I have lost confidence in myself as a	completely	moderately	slightly	slightly	moderately	completely
sexual partner	agree	agree	agree	disagree	disagree	disagree
-	_	_		_		_
5. When I think about my sexual life, I feel	completely	moderately	slightly	slightly	moderately	completely
anxious	agree	agree	agree	disagree	disagree	disagree
6. When I think about my sexual life, I feel	completely	moderately	slightly	slightly	moderately	completely
angry	agree	agree	agree	disagree	disagree	disagree
7. I worry about the future of my sexual	completely	moderately	slightly	slightly	moderately	completely
life	agree	agree	agree	disagree	disagree	disagree
8. When I think about my sexual life, I am	completely	moderately	slightly	slightly	moderately	completely
embarrassed	agree	agree	agree	disagree	disagree	disagree
9. When I think about my sexual life, I feel	completely	moderately	slightly	slightly	moderately	completely
guilty	agree	agree	agree	disagree	disagree	disagree
10. When I think about my sexual life, I	completely	moderately	slightly	slightly	moderately	completely
worry that my partner feels hurt or	agree	agree	agree	disagree	disagree	disagree
rejected						
-						
11. When I think about my sexual life, I	completely	moderately	slightly	slightly	moderately	completely
feel as if I have lost something	agree	agree	agree	disagree	disagree	disagree

		पूर्ण रूप से	कुछ हद	थोड़ा	थोड़ा	कुछ हद	पूर्ण रूप से
		सहमत	तक	सहमत	असहमत	तक	असहमत
			सहमत			असहमत	
1.	जब मैं अपने यौन जीवन के बारे में सोचता हूं	1	2	3	4	5	6
	तो मुझे निराशा होती है						
2.	जब मैं अपने यौन जीवन के बारे में सोचता हूं	1	2	3	4	5	6
	तो मैं उदास हो जाता हूं						
3.	जब मैं अपने यौन जीवन के बारे में सोचता हूं	1	2	3	4	5	6
	तो मुझे कम मर्द महसूस होता है						

4.	मैंने एक यौन माथी के रूप में खट पर विश्वास खो	1	2	3	4	5	6
	34						
	दिया है						
5.	जब मैं अपने यौन जीवन के बारे में सोचता हं, तो	1	2	3	4	5	6
	*						
	मुझे चिंता होती है						
6.	जब मैं अपने यौन जीवन के बारे में सोचता हूं, तो	1	2	3	4	5	6
	मुझे चिंता होती है						
7.	मुझे अपने यौन जीवन के भविष्य की चिंता है	1	2	3	4	5	6
8.	जब मैं अपने यौन जीवन के बारे में सोचता हूं तो	1	2	3	4	5	6
	मुझे शर्मिंदगी महसूस होती है						
•		1	2	2	4	-	6
9.	जब मैं अपने यौन जीवन के बारे में सोचता हूं, तो	1	2	3	4	5	6
	* > >						
	म दाषा महस्रस करता हू						
10		1	2	3	4	5	6
10	• जब में अपने यान जावन के बार में साचता हू, तो	-	-	5	1	5	0
	गरो चिंचा रोची है कि मेम माशी भारन मा						
	नुज विता हाता है कि नरा साथा आहत था						
	भम्वीकार महसम करता है।						
11	• जब मैं अपने यौन जीवन के बारे में सोचता हूं. तो	1	2	3	4	5	6
	मुझे ऐसा लगता है जैसे मैंने कुछ खो दिया है						

## ANNEXURE-14 SEX KNOWLEDGE AND ATTITUDE QUESTIONNAIRE

#### (SKAQ)-II

## SEX KNOWLEDGE AND ATTITUDE QUESTIONNAIRE-II AJIT K. AVASTHI, VIJOY K. VARMA, RITU NEHRA, KAROBI DAS भाग – 'क'

नीचे कुछ वाक्य लिखें गये है प्रत्येक वाक्य को पढ़के उसके आगे दिये गये विकल्पों में से जो भी विकल्प आपको लगता है कि आप पर लागू होता है उसे गोल दायरा लागें।

1.	कामुक किताबों को पढ़ने से बच्चों के सैक्स सम्बन्धी रवैये पर असर पड़ता है।	<b>.</b>	हाँ	नहीं
2.	पुरूष – पुरूष या स्त्री–स्त्री सम्भोग करने की आदत सीखने या देखने से बढ़ती है।	-	នាំ	नहीं
3.	अंडकोष निकाल देने पर नामर्दगी हो जाती है।		हाँ	नहीं
4.	विवाहित व्यक्ति का हस्तमैथुन (डेंजनतइंजपवद) करना बिगडे हुए सैक्स सम्बन्धों की निशानी है।		តាំ	नहीं
5.	यदि स्त्री सम्भोग के चरम आनन्द का अनुभव करे तो गर्भ ठहरने की सम्भावना बढ़ जाती है।	-	តាំ	नहीं
6.	बच्चा न होने का आम कारण नामर्दगी है।	_	हाँ	नहीं
7.	खाने-की कुछ चीजें काम वासना को तेज करती हैं।		हाँ	नहीं
8.	जब तक मां बच्चें को अपना दूध पिलाती रहे उसे गर्भ नहीं ठहराता।		हाँ	नहीं
9.	ज्यादा काम वासना होने से गलत काम क्रिया की आदत पड़ती है।		हाँ	न्हीं
10.	हस्तमैथुन के कारण कई तरह के दिमागी असंतुलन पैदा होते है।		हाँ	नहीं
11.	विवाह से पहले कई पुरूषों के साथ सैक्स सम्बन्ध रखने वाली औरतों, विवाह के बाद दूसरों के मुकाबले कम वफादार होती है।	_	हाँ	नहीं

12. स्त्रियों के मुकाबले पुरूषों की काम क्रिया पर उम्र का असर अधिक पढ़ता है।		តាំ	नहीं
13. ज्यादातर निचले वर्ग के लोग संभोग के कई तरीकों का इस्तेमाल करते हैं।		เรื	नहीं
14. बलात्कार करने वालों में काम वासना ज्यादा होती है।		हाँ	नहीं
15. उंचे वर्ग के लोगो के मुकाबले निचले वर्ग के लोग ज्यादा सम्भोग करते हैं।		ខា	नहीं
16. निचले वर्ग के लोग परिवार नियोजन पर ज्यादा ध्यान नहीं देते।		<b>ត</b> ាំ	नहीं
17. बचपन और युवावस्था में बहुत ज्यादा काम क्रिया से विवाहित सम्बन्धों पर बुरा असर पड़ता है।		ាំ	नहीं
18. नशीली दवाईयां काम वासना को तेज करती है।		हाँ	नहीं
19. ज्यादा काम क्रिया से वीर्य कमजोर हो जाता है।		हाँ	नहीं
20. लिंग जितना बड़ा हो, मर्दानगी भी उतनी ही ज्यादा होती है।		हाँ	नहीं
21. यौनीद्धार के पर्दे (हाईमन) का फटा हुआ न होना कुवारेपन का पक्का सबूत नहीं है।	_	हाँ	नहीं
22. स्त्रिया भी हस्तमैथुन करती है।		<u> </u>	नहीं
23. हस्तमैथुन से नामर्दगी हो जाती है		हाँ	नहीं
24. हस्तमैथुन से कोई शारीरिक कमजोरी नहीं होती		हाँ	नहीं
25. वीर्य खून का निचोड़ होता है।		៩ា័	नहीं
26. माहावारी के सूखने के बाद भी गर्भ ठहर सकता है।		हाँ	नहीं
27. माहवारी शुरू होने से पहले भी गर्भ ठहर सकता है।		हाँ	नहीं
28. ज्यादा हस्तमैथुन करने से दिमागी रोग पैदा होते है।		हाँ	नहीं
29. युवावस्था में ज्यादा हस्तमैथुन करने से वीर्य जल्दी खलास होने लगता है	n	हाँ	नहीं
30. निरोध के प्रयोग से सैक्स सम्बन्धी बिमारियों की रोकथाम हो सकती है।		हाँ	नहीं
31. माहवारी के दौरान स्त्रियां जल्दी गर्भवती हो सकती हैं।		हाँ	नहीं

<ol> <li>माहवारी के समय स्त्रियों को रसोई में नहीं जाना चाहिये क्योंकि इससे खाना दूषित हो सकता है।</li> </ol>	 हाँ	नहीं
33. स्त्रिया दूसरी स्त्रियों के साथ सम्भोग नहीं करती हैं।	 हाँ	नहीं
34. बच्चा पैदा करने से संभोग के आनन्द में कमी आ जाती है।	 តាំ	नहीं
35 कुंवारी लड़की के साथ संभोग करने से सैक्स सम्बन्धी रोग (सुजाक सिफलिस) ठीक हो सकते हैं।	 តាំ	नहीं

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		सहमत	अनिश्चित	असहमत
1.	सैक्स सम्बन्धी शिक्षा का प्रचार समाज में विवाह से पहले ही सैक्स सम्बन्धों को बढ़ा रहा है।	1	2	3
2.	लड़कों में पुरूष-पुरूष सम्भोग अक्सर उनके आपसी हस्तमैथुन से ही शुरू होता है।	1	2	3
3.	विवाह के बाद पति या पत्नी के इलावा किसी के साथ संभोग करना हमेशा नुक्सानदेह है।	1	2	3
4.	गर्भ रोकने के तरीकों की जानकारी अक्सर गलत तरह से संभोग करने की क्रियाओं को बढ़ावा देती है।			
5.	मां–बाप को चाहिए कि वह अपने बच्चों को हस्त–मैथुन करने से रोकें।	1	2	3
6.	औरतों को शादी से पहले संभोग का अनुभव होना चाहिए।	1	2	3
7.	गर्भपात हत्या नहीं है।	1	2	3
8.	लड़कियों को हस्तमैथुन करने की मनाही होनी चाहिए।	1	2	3
9.	गर्भपात की इजाजत देने वाले सभी कानूनों को समाप्त कर देना चाहिए।	1	2	3
10.	संभोग केवल पति-पत्नी के बीच ही होना चाहिए।			
11.	हस्तमैथुन आम तौर पर सेहत के लिए नुक्सानदेह है।	1	2	3

		सहमत	अनिश्चित	असहमत
12.	यह डाक्टर की कोई जिम्मेदारी नहीं कि वह जिस स्त्री का गर्भ गिराए उसके पति, या मां-बाप को			
	इसके बारे में खबर करें।	1	2	3
13.	गर्भपात की हर हालत में मंजूरी होनी चाहिए।	1	2	3
14.	पुरूषों को शादी से पहले संभोग का अनुभव होना चाहिए।	1	2	3
15.	परिवार के लोगों को नंगा देखने से बच्चों में सैक्स को जानने की इच्छा पैछा होती है।	1	2	3
16.	हस्त-मैथुन लड़कियों की काम वासना को अक्सर ठंडा कर देती है।	1	2	3
17.	छोटे वर्ग की औरतों खास तौर पर काम–क्रिया के दौरान ज्यादा भाग लेती हैं।	1	2	3
18.	अनचाहे बच्चें के जन्म की तुलना में गर्भपात ज्यादा बड़ी बुराई है।			14 6 1100 14 120
19.	बचपन में आपसी हस्थ-मैथुन पर रोक नहीं होनी चाहिए।	1	2	3
20.	हमारे समाज में बिन-ब्याही लड़कियों में कुवारेपन (virginity) को बढ़ावा मिलना चाहिए	1	2	3

## ANNEXURE-15 RELATIONSHIP ASSESSMENT SCALE

## Scale:

	Low				High
1. How well does your partner meet your needs?	1	2	3	4	5
2. In general, how satisfied are you with your relationship?	1	2	3	4	5
3. How good is your relationship compared to most?	1	2	3	4	5
4. How often do you wish you hadn't gotten into this relationship?	1	2	3	4	5
5. To what extent has your relationship met your original expectations?	1	2	3	4	5
6. How much do you love your partner?	1	2	3	4	5
7. How many problems are there in your relationship?	1	2	3	4	5

#### Scoring:

Items 4 and 7 are reverse-scored.

Scoring is kept continuous. The higher the score, the more satisfied the respondent is with his/her relationship.

## संबंध मूल्यांकन स्केल

1. आपका साथी आपकी ज़रूरतों को कितनी अच्छी तरह	1	2	3	4	5
पूरा करता है					
2. सामान्य तौर पर, आप अपने रिश्ते से कितने संतुष्ट हैं	1	2	3	4	5
<ol> <li>सामान्य तौर पर, आप अपने रिश्ते से कितने संतुष्ट हैं</li> </ol>	1	2	3	4	5
<ol> <li>आप कितनी बार ऐसा सोचते हैं कि आप इस रिश्ते में न</li> </ol>	1	2	3	4	5
आए होते					
<ol> <li>आपका रिश्ता आपकी मूल अपेक्षाओं पर कितना खरा</li> </ol>	1	2	3	4	5
उतरा है					
<ol> <li>आप अपने पार्टनर से कितना प्यार करते हैं</li> </ol>	1	2	3	4	5
7. आपके रिश्ते में कितनी समस्याएं हैं	1	2	3	4	5
कुल स्कोर					