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Clinical Assessment of Efficacy and Safety of Addyzoa Tablet in Male Infertile Patients with Oligospermia and Asthenospermia

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ABSTRACT

Infertility is defined as inability of a sexually active couple to conceive after 1 year of regular intercourse without contraception. Male factors account for 20%-50% of cases of infertility. Male infertility is primarily caused by low sperm count (Oligospermia) and reduced sperm motility (asthenospermia), and is an issue of global dimensions. Oligospermia in a clinically healthy man is one of the commonest conditions encountered in an infertility clinic. Medical management of oligospermia lags far behind expectations, and is still in experimental stage. The global deterioration of male reproductive health is of a major concern. The modern therapeutic approaches to combat male infertility are expensive, less accessible, have long term treatment tenure and possess various side effects. Whereas, the herbal therapies, are better positioned to offer more holistic approaches to improve male reproductive health. The present study was carried out to evaluate the efficacy and safety of Addyzoa Tablet manufactured by Charak Pharma Pvt. Ltd., an herbal formula comprising of extracts of *Withania somnifera, Tribulus terrestris, Mucuna pruriens, Chlorophytum arundinaceum etc.* Aim was to determine whether treatment would improve sperm count and morphology of sperms. The mechanisms involved in the efficacy of these medicinal plants in sperm abnormalities are antioxidant, anti-inflammatory, anti-oedematous and venotonic activity as well as containing precursors for sperm production and increasing blood testosterone level. It was concluded that Addyzoa Tablet improves the density and motility of the sperms and thus is effective in the management of oligospermia and asthenospermia and no adverse effects were reported.

Key words: *Oligospermia, Asthenospermia, Density, Male infertility, M. pruriens, Motility, Oligospermia, W. sominifera.*

INTRODUCTION

Male infertility refers to a male's inability to result pregnancy in a fertile female. “Male factor” infertility is seen as an alteration in sperm concentration and/or motility and/or morphology in at least one sample of two sperm analyses, collected 1 and 4 weeks apart.[1] In humans, it accounts for 40-50% of infertility[2,3,4] and affects approximately 7% of all men.[5] Male infertility is commonly due to deficiencies in the semen, and semen quality is used as a surrogate measure of male fecundity.[6]

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Males with sperm parameters below the WHO normal values are considered to have male factor infertility.[7] The most significant of these are low sperm concentration (oligospermia), poor sperm motility (asthenospermia). As high as 90% of male infertility problems are related to count and there is a positive association between the abnormal semen parameters and sperm count.[8]

Critical factors in male infertility are the sperm abnormalities and they include:

1. Abnormalities related to sperm count:
   - Azoospermia: Absence of sperm in seminal plasma
   - Low sperm count (oligozoospermia: <15 million sperms/mL).[6]

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2. Abnormalities related to sperm motility:

   - A normal semen analysis must contain at least 50% grade A and B, progressively motile spermatozoa. Persistent poor motility is a predictor of failure in fertilization.[9]

The exact reason for the decline in semen quality is not clear, but it may be due to oxidative stress, environmental toxins, nutritional causes, socioeconomic or other unknown causes.[10]

Oxidative stress disrupts the delicate equilibrium between ROS production and antioxidant defence mechanisms. This disruption can lead to irreparable oxidative damage to sperm cells, impairing their viability and function. Ultimately, this can result in significant male reproductive health impairments. Supplementing with exogenous antioxidants is one method to mitigate these harmful effects. It allows for scavenging excess ROS, restoring equilibrium, and protecting sperm cells from further oxidative damage.

By attempting to balance ROS and antioxidants, this supplementation has potential benefits for male reproductive health. Antioxidants, by decreasing oxidative stress and improving sperm quality, may enhance the likelihood of successful conception for couples facing infertility.[11]

The present study was carried out to evaluate the efficacy and safety of Addyzoa Tablet an herbal formula comprising of extracts of *Withania somnifera, Tribulus terrestris, Mucuna pruriens, Chlorophytum arundinaceum, Asparagus racemosus, Sida cordifolia* in improving number and morphology of sperms.

Aim and Objectives

The study was carried out to assess the efficacy of Addyzoa Tablet (an herbal formula comprising of extracts of *Withania somnifera, Tribulus terrestris, Mucuna pruriens, Chlorophytum arundinaceum, Asparagus racemosus, Sida cordifolia as key ingredients)* in improving semen parameters (density, motility, and morphology) in male patients with idiopathic infertility.

Materials and Methods

30 male patients aged 22-45 with idiopathic infertility were selected from the outpatient department (OPD). Semen evaluation was performed on each participant to assess various parameters such as sperm count, motility, morphology, volume, pH, etc. This evaluation helps establish a baseline for comparison with post-treatment values.

Data on semen parameters for each participant were collected systematically to ensure accuracy and reliability.

Oligospermic patients were administered Addyzoa Tablet at a dose of 2 tablets thrice daily for a period of 3 months. Semen analysis was repeated at the end of the 3-month intervention period, focusing on sperm density, motility, and morphology.

The patients were considered oligospermic when the total sperm count was <40 million/ml

Oligospermia is classified into 3 categories depending upon the sperm density:

1. Mild oligospermia: Comprised of patients in whom the sperm count was more than 20 million/cc but less than 40 million/cc.
2. Moderate oligospermia: The patient was classified into this category when the sperm count was more than 5 million but less than 20 million/cc.
3. Extreme oligospermia: The patient was assigned to this category when sperm density was less than 5 million/cc.

Of the 30 selected patients, eight patients had mild oligospermia, seventeen had moderate oligospermia, and five had extreme oligospermia. Additionally, nine patients had mild sperm motility defects, sixteen had moderate sperm motility defects, and five had extreme sperm motility defects.

Exclusion Criteria

- Azoospermia: Patients diagnosed with azoospermia, a condition characterized by the absence of sperm in the ejaculate, were excluded from the study. Azoospermia typically indicates a

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severe impairment of sperm production or obstruction of the reproductive tract.

- Other Major Systemic Illness: Patients with other major systemic illnesses such as renal disease, cardiac disease, or any other significant medical conditions were also excluded from the study. These conditions could potentially affect fertility or complicate the interpretation of study results.

This helps ensure a more homogeneous study population and facilitates a clearer evaluation of the effects of Addyzoa Tablet on semen parameters in this specific patient group.

Evaluation Parameters

1. **Sperm Density:** Sperm density refers to the concentration of sperm in a given volume of semen, typically measured in millions of sperm per milliliter (million/ml). For this study, changes in sperm density will be measured before and after the administration of Addyzoa Tablet.
2. **Sperm Motility:** Sperm motility refers to the ability of sperm to move effectively through the female reproductive tract. It is usually categorized into progressive motility (sperm moving in a forward direction), non-progressive motility (sperm moving but not in a straight line), and immotility (no movement).

By evaluating both sperm density and motility individually as well as collectively, the study aims to comprehensively assess the efficacy of Addyzoa Tablet in improving male fertility potential. These parameters provide important insights into the treatment impact on sperm production and function, which are key determinants of male fertility.

Observations and Results

The treatment with Addyzoa Tablet resulted in significant improvements in both total sperm count and motility. These findings suggest a potential positive effect of Addyzoa Tablet on male fertility parameters.

Increase in Total Sperm Count:

- The increase in total sperm count indicates an improvement in sperm production, as higher sperm count increases the chances of successful fertilization.

Table 1: Effect of Addyzoa Tablet on sperm count.

Type of Oligospermia	No. of patients	Good increase	Moderate increase	No increase
Mild	8	4	2	2
Moderate	17	8	6	3
Extreme	5	Nil	1	4

Good increase – Sperm count/c.c. increased to 40 million or above

Moderate increase – Sperm count/c.c. more than 15 million and less than 40 million.

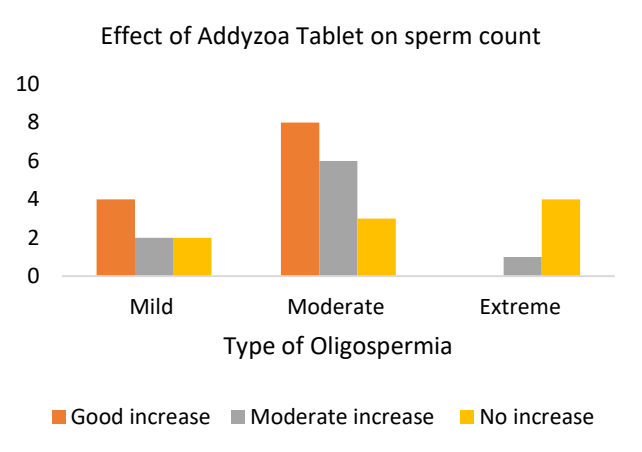

Table 2: Sperm count of the Addyzoa Tablet treated Oligospermic patients.

Sperm Conc. X 10^6/mL	Day Zero	Day 90	p-value
Mild (n=8)	28.43± 2.86	36.68 ± 7.81	0.004
Moderate (n=17)	15.44 ± 3.26	31.19± 11.79	0.00050
Extreme (n=5)	3.86± 0.71	5.92± 5.15	0.374

Values are expressed as Mean± SD

Treatment with the Addyzoa Tablet resulted in a highly significant increase in sperm concentration after 90 days of therapy, as compared to the baseline value on Day 0 of the study period (Table 2). The increase was

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from 28.43±2.86× 10/mL to 36.68±7.81× 10/mL, corresponding to a percentage increase of 29% in case of Mild Oligospermia. In Moderate Oligospermia the increase was 102.1% and in Extreme Oligospermia it was 53.6%.

Remarkable Improvement in Motility:

- Improved motility means that a higher proportion of sperm are capable of moving effectively, which is essential for sperm to reach and fertilize the egg, as sperm motility is a key determinant of fertility.

Table 3: Effect of Addyzoa Tablet on motility of sperms

Defect in Sperm motility	No. of patients	Good increase	Moderate increase	No increase
Mild	9	5	4	Nil
Moderate	16	10	2	4
Extreme	5	Nil	Nil	5

Good increase – Motile count increased more than 2 times.

Moderate increase – Motile count increased less than 2 times.

No increase – No change in motile count.

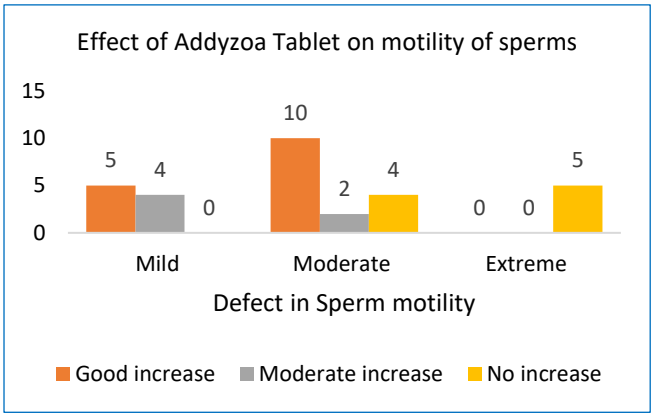

Table 4: Sperm motility of the Addyzoa Tablet treated Oligospermic patients

	Day Zero	Day 90	p-value
Mild (n=9)	17.75± 0.623	35.44 ± 2.96	0.005
Moderate (n=16)	17.51 ± 0.99	31.67± 8.24	0.005
Extreme (n=5)	16.4± 0.53	16.4± 0.53	-

Values are expressed as Mean± SD

The sperm motility in case of Mild Oligospermia increased from 17.75± 0.623 on day zero to 35.44 ± 2.96 on day 90 corresponding to a 99.66% increase. In case of Moderate Oligospermia cases, there was an 80.86% increase in the motility from a base value of 17.51 ± 0.99 on day zero to 31.67± 8.24 on day 90. (Table 4)

75% of the subjects with mild and moderate oligospermia showed a beneficial response to the treatment with Addyzoa Tablet, considering both sperm density and motility. This suggests that the majority of patients with mild and moderate oligospermia experienced improvements in both sperm density and motility after receiving Addyzoa Tablet.

DISCUSSION

Rationale for the combination

Non-Hormonal Herbal Composition:

Addyzoa Tablet is described as a non-hormonal herbal composition contains herbal ingredients that are believed to have therapeutic effects.

Addyzoa Tablets is a spermatogenic antioxidant which improve the functional competence of sperms. Addyzoa Tablets improves sperm count by restoring balance in Hypothalamus-Pituitary-Gonadal (HPG) axis and regulating the hormone levels of follicle-stimulating hormone (FSH), luteinizing hormone (LH) and the level of testosterone (T) to optimize the process of spermatogenesis. It ensures morphological sperm improvement by preventing the oxidative damage to sperm DNA. Addyzoa Tablets also increases linear progressive motility. *Withania somnifera,* is potent antioxidant in Addyzoa Tablets, which acts by reducing the excessive oxidative stress, which is responsible for sperm damage. *Mucuna pruriens* and *Withania somnifera* improves sperm count. *Mucuna pruriens* improves reproductive function and the quality of semen in infertile men. It helps to fight stress-mediated poor semen quality and acts as a

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restorative and invigorator aphrodisiac. *Withania somnifera* mitigates hormone imbalance, prevents stress-induced decrease in testosterone levels and helps to increase sperm count, semen volume, and sperm motility in infertile male. *Tribulus terrestris* exhibits androgen, testosterone, DHT and DHEA increasing properties and has stimulating effects on reproductive functions. With its high antioxidant content, it ensures healthy structural and functional aspects of reproductive tissues, qualitative and quantitative improvement in semen and also sperm morphology and motility. *Chlorophytum arundinaceum*, increases the sexual desire and helps to maintain the erection during intercourse. It also helps to increase the male potency as it has spermatogenic property. This helps to improve the sperm quality as well as the sperm count. Further it may also help in conditions like teratospermia and other spermatic deformities.

Withania somnifera

W. somnifera extract is one of the widely used herbal medicines for the treatment of infertility and sexual dysfunction. Its root is the most used part for certain purposes, as it has antioxidant, anti-apoptosis and anti-inflammatory properties and exerts positive effects on the male reproductive system, improving semen quality by regulating sex hormone levels and inhibiting lipid peroxidation.

Several studies have shown that its phytochemical components may exert major effects on the male reproductive system through antioxidant and detoxicant properties, regulation of sex hormones, GABA-mimetic action.[12]

W. somnifera root has also been shown to increase alanine concentration in semen. Alanine has a protective role against oxidative stress and can reduce LPO and thus increase sperm concentration and motility.[12,13]

Treatment with Ashwagandha root extract resulted in higher levels of testosterone and LH among infertile men, which had suboptimal values prior to therapy. Thus, they postulated that the probable reason for increased sperm concentration and motility was the higher testosterone levels provided by treatment with the extract.[14]

Withania somnifera therapy repairs the disturbed concentrations of lactate, alanine, citrate, GPC, histidine, and phenylalanine in seminal plasma and recovers the quality of semen of post-treated compared to pre-treated infertile men. Findings reveal that *Withania somnifera* not only reboots enzymatic activity of metabolic pathways and energy metabolism but also invigorates the harmonic balance of seminal plasma metabolites and reproductive hormones in infertile men.[13]

Treatment with *W. somnifera* significantly reduced apoptosis in normozoospermic and oligozoospermic men and ROS concentrations in oligozoospermic and asthenozoospermic men (all $P < 0.05$). Treatment also significantly improved metal ion concentrations in infertile men ($P < 0.01$). This concludes that *W. somnifera* improves semen quality by reducing oxidative stress and cell death, as well as improving essential metal ion concentrations.[15]

Tribulus terrestris

Tribulus terrestris, has been used for a long time in both the Indian and Chinese systems of medicine for treatment of various kinds of diseases. Its various parts contain a variety of chemical constituents which are medicinally important. It has diuretic, aphrodisiac, antiurolithic, immunomodulatory, antidiabetic, absorption enhancing, hypolipidemic, cardiotonic, central nervous system, hepatoprotective, anti-inflammatory, analgesic, antispasmodic, anticancer, antibacterial, anthelmintic, larvicidal, and anticariogenic activities.[16]

It was observed that *Tribulus* treatment increased the motility of slow and non-progressive spermatozoa, and decreased the proportion of immotile spermatozoa.[17]

Tribulus terrestris contains active phytochemicals. Protodioscin an active phytochemical is a potent natural precursor of the testosterone enhancer. *Tribulus* leads to the production of the luteinizing hormone (LH). When the LH levels are increased, the natural production of testosterone also increases. LH is

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a hormone that also deals with sex drive. LH has been used to increase fertility and helps to relieve impotence.[18]

Tribulus terrestris demonstrated a significant impact on sperm parameters (sperm concentration, sperm motility, and sperm viability) in humans and animal models. The profertility effect was seen not only in infertility but also in normal animals. Significant improvements in sperm parameters under stress and normal conditions suggests that *Tribulus terrestris* may be an excellent profertility medicine. Studies also support that *Tribulus terrestris* has significant aphrodisiac activity.[19]

Mucuna pruriens

Mucuna pruriens belongs to the Fabaceae family and is ordinarily known as velvet bean. The restorative quality of this bean makes it an excellent component in pharmaceutical and therapeutic applications. Apart from high protein and starch content, these beans contain (l-Dopa) 3, 4-dihydroxy-l-phenylalanine, which exhibits several medicinal properties which include anticholesterolemic, anti-Parkinson, antioxidant, antidiabetic, sexual enhancing, anti-inflammatory, antimicrobial, and antivenom activities.

Treatment of infertile subjects with *M. pruriens* for 3 months significantly improved sperm concentration and motility. It has been reported that *M. pruriens* helps in some central mechanism to increase secretion of semen, decrease spermatorrhea, and act as a restorative and invigorating tonic and aphrodisiac in diseases characterized by weakness or loss of sexual power.[20]

The beneficial effect of *M. pruriens* may be attributed to its antioxidant and neurostimulatory properties.[21]

Lipid peroxidation is involved in the pathophysiology of male infertility. Treatment with *M. pruriens* significantly decreased the lipid peroxide levels in infertile men. There have been reports that lipid peroxide levels are significantly elevated in the seminal plasma of infertile men.[22] It is known that lipid peroxidation is a free radical–mediated phenomenon and that the lipids in spermatozoa are susceptible to peroxidation.[23]

Seminal plasma levels of vitamins A, C, and E were significantly increased in infertile men after treatment with *M. pruriens*. This might have contributed to the improvement in sperm concentration and motility and the lowering of lipid peroxide levels in the seminal plasma of infertile men. Vitamins A, C, and E are biological antioxidants that function as detoxifying agents, immunopotentiators, and immunoactivators.[24]

Chlorophytum arundinaceum

Chlorophytum arundinaceum, is used in the Indian traditional system of medicine for improving the general state of health and for stress-related immune disorders. It is known to have aphrodisiac properties and is used in many preparations of vital tonics to cure general debility. The extracts were shown to exert an inhibitory effect on pro-inflammatory cytokines.

Tubers of *Chlorophytum arundinaceum* have medicinal value are used as general tonic and for its aphrodisiac property. [25]

A comparative study of two species of *Chlorophytum arundinaceum* and *Chlorophytum* borivilianum which is the only cultivated species was conducted. Meiotic study revealed the allopolyploid nature of both the species. Upper leaf surface of *C. borivilianum* was devoid of stomata which might be due to the distribution in arid climate. HPTLC analysis of fasciculated root extract of the two species showed similarity in majority of bands in both the species. Therefore, *C. arundinaceum* could be cultivated as a substitute of *C. borivilianum*, thereby decrease the collection pressure of *C. borivilianum* from wild habitats.[26]

Asparagus racemosus

1. The study was carried out to evaluate the effect of *Asparagus racemosus* (*Shatavari*) aqueous extract on buck semen quality during preservation. In the current study, 8 ejaculates from 8 Jakhrana bucks maintained at Jakhrana unit of ICAR-CIRG (semi-arid region) were collected (total 64 ejaculates) during the period from April to June, 2022. Good quality semen samples were pooled

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during each collection. Pooled semen samples were then divided into 4 equal parts, and diluted in TRIS buffer containing different concentration of Shatavari aqueous extract (Different groups, i.e. Gr1-5 mg, Gr2-2.5 mg, Gr3-1.25 mg, Gr4-0 mg of Shatavari aqueous extract/ml of semen diluent). All the diluted semen samples were kept at refrigerated temperature (5°C) for seven days, and on each day, diluted semen was evaluated for various sperm characteristics and antioxidant status. Gr3 showed significantly better results in terms of sperm viability, sperm motility, acrosomal integrity and plasma membrane integrity. Along with this, the longevity of sperm was also enhanced in Shatavari supplemented group.[27]

2. In this study, the hydro-alcoholic and aqueous extracts of the roots of *Asparagus racemosus* were subjected to preliminary phytochemical screening which showed the presence of saponins, carbohydrates, glycosides and mucilages. The total extracts were tested for their aphrodisiac activity in experimental rats. The hydro-alcoholic extract of *Asparagus racemosus* root at higher concentration (400 mg/kg body weight) showed significant aphrodisiac activity on male wistar albino rats as evidenced by an increase in number of mounts and mating performance. On the other hand, hydro-alcoholic extract at lower dose (200 mg/kg. body weight) and aqueous extract (400 mg/kg body weight) showed moderate aphrodisiac property. Thus, in experimental rats, the results of the present study suggest that the extracts of *Asparagus racemosus* exert significant aphrodisiac activity.[28]

Sida cordifolia

In vitro assessment of the sperm quality in terms of its motility, morphological abnormalities and viability due to treatment with aqueous extract of *Sida cordifolia* indicated no spermicidal or toxic effect. On the other hand, there was a small but significant enhancement in the sperm parameters, reduction in abnormalities and increase in viability of sperms which was found to be concentration-dependent.[29]

Promotion of Spermatogenesis and Motility:

As the Ingredients in Addyzoa Tablet are reported to be effective in promoting spermatogenesis (sperm production) and motility, particularly in patients with mild and moderate oligospermia. Accordingly, the observations we have in this study it was also noted that, Addyzoa Tablet exert its effects by enhancing the processes involved in sperm production and improving the sperm motility.

The observed improvements in spermatogenesis and motility indicates that Addyzoa Tablet has the ability to restore normal functioning of the germinal epithelium, the tissue in the testicles where sperm production occurs and addresses underlying factors contributing to oligospermia and improve overall testicular health.

In the present study Addyzoa Tablet – 2 tablets, thrice a daily for 3 months on 30 oligospermic patients showed 75 % improvement in mild to moderate case of oligospermia. Patients of extreme oligospermia showed insignificant response.

CONCLUSION

The study underscores the significance of Addyzoa Tablet as an effective treatment option for oligospermic patients. The documented improvements in sperm density and motility contribute to its clinical importance in managing oligospermia.

Addyzoa Tablet has been shown to improve both sperm density and motility in oligospermic patients. This improvement suggests that Addyzoa Tablet may address underlying factors contributing to oligospermia and enhance overall sperm health and function and also it may help in Teratospermia and other spermatic deformities. Importantly, no adverse effects were reported in the study, suggesting that Addyzoa Tablet is well-tolerated by patients.

Overall, the conclusion drawn from the study emphasizes the clinical importance, effectiveness and safety of Addyzoa Tablet in improving sperm parameters and managing oligospermia. This supports its use as a therapeutic option for patients seeking treatment for this condition.

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REFERENCES

1. 4th ed. Cambridge: Cambridge University Press; 1999. World Health Organization. *WHO Laboratory Manual for the Examination of Human Semen and Semen-Cervical Mucus Interaction;* pp. 1–86.
2. *Men's Health – Male Factor Infertility*. University of Utah Health Sciences Center. 04 January, 2003. Archived from the Original on 04 July 2007.
3. Brugh VM, 3rd, Lipshultz LI. *Male factor infertility: Evaluation and management*. Med Clin North Am. 2004;88:367–85.
4. Hirsh A. *Male subfertility*. BMJ. 2003;327:669–72.
5. Lotti F, Maggi M. *Ultrasound of the male genital tract in relation to male reproductive health*. Hum Reprod Update. 2015;21:56–83.
6. Cooper TG, Noonan E, von Eckardstein S, Auger J, Baker HW, Behre HM, et al. *World Health Organization reference values for human semen characteristics.* Hum Reprod Update. 2010;16:231–45.
7. Plachot M, Belaisch-Allart J, Mayenga JM, Chouraqui A, Tesquier L, Serkine AM. *Outcome of conventional IVF and ICSI on sibling oocytes in mild male factor infertility*. Hum Reprod. 2002;17:362–9.
8. Sabra SM, Al-Harbi MS. *An influential relationship of seminal fluid microbial infections and infertility,* Taif Region, KSA. World J Med Sci. 2014;10:32–7.
9. Aitken RJ, Sutton M, Warner P, Richardson DW. *Relationship between the movement characteristics of human spermatozoa and their ability to penetrate cervical mucus and zona-free hamster oocytes*. J Reprod Fertil. 1985;73:441–9.
10. Carlsen E, Giwercman A, Keiding N, Skakkebaek NE. *Evidence for decreasing quality of semen during past 50 years.* BMJ. 1992;305:609–13.
11. Kaltsas A. *Oxidative Stress and Male Infertility*: The Protective Role of Antioxidants. Medicina. 2023; 59(10):1769. https://doi.org/10.3390/medicina59101769
12. Tahvilzadeh M, Hajimahmoodi M, Toliyat T, Karimi M, Rahimi R (2016). *An evidence-based approach to medicinal plants for the treatment of sperm abnormalities in traditional Persian medicine.* Andrologia 48(8):860-879.
13. Gupta A, Mahdi AA, Shukla KK, Ahmad MK, Bansal N, Sankhwar P, Sankhwar SN (2013). *Efficacy of Withania somnifera on seminal plasma metabolites of infertile males: a proton NMR study at 800 MHz.* Journal of Ethnopharmacology 149(1):208-214.
14. Ambiye VR, Langade D, Dongre S, Aptikar P, Kulkarni M, Dongre A (2013). *Clinical evaluation of the spermatogenic activity of the root extract of Ashwagandha (Withania somnifera) in oligospermic males: a pilot study. Evidence-Based Complementary and Alternative Medicine.* Volume 2013, Article ID 571420, 6 pages.
15. Kamla Kant Shukla, Abbas Ali Mahdi, Vivek Mishra, Singh Rajender, Satya Narain Sankhwar, Devender Patel, Mukul Das. *Withania somnifera improves semen quality by combating oxidative stress and cell death and improving essential metal concentrations.,*Reproductive BioMedicine Online (2011) 22, 421– 427
16. Saurabh Chhatre, Tanuja Nesari, Gauresh Somani,1 Divya Kanchan, and Sadhana Sathaye *Phytopharmacological overview of* Tribulus terrestris Pharmacogn Rev. 2014 Jan-Jun; 8(15): 45–51.
17. *Tribulus terrestris L. extract improves spermatozoa motility and increases the efficiency of acrosome reaction in subjects diagnosed with oligoasthenoteratozoospermia* L. Setiawan Airlangga University, Surabaya, Indonesia (1996)
18. Gauthaman K, Adaikan PG, Prasad RN. *Aphrodisiac properties of Tribulus Terrestris extract (Protodioscin) in normal and castrated rats* Life Sci. 2002;71:1385–96
19. Anam Ara, Rahul Vishvkarma, Poonam Mehta, Singh Rajender, *"The Profertility and Aphrodisiac Activities of Tribulus terrestris L.: Evidence from Meta-Analyses*", Andrologia, vol. 2023, Article ID 7118431, 21 pages, 2023. https://doi.org/10.1155/2023/7118431
20. Nandkarni KM. Indian materia medica. Bombay: Popular Prakashan, 1986. 153–5.
21. Misra L, Wagner H. *Extraction of bioactive principle from Mucuna pruriens seeds*. Indian J Biochem Biophys 2007;44:56–60
22. Bano F, Singh RK, Singh R, Siddiqui MS, Mahdi AA. *Seminal plasma lipid profiles and lipid peroxide in infertile men.* J Endocrinol Reprod 1999;3:20–8.
23. Iwasaki A, Gagnon C. *Formation of reactive oxygen species in spermatozoa of infertile patients.* Fertil Steril 1992;57:409–16.

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24. Ames BN, Shigenaga MK, Hagen TM. *Oxidants, antioxidants and the degenerative diseases of aging.* Proc Natl Acad Sci U S A 1993;90:7915–22
25. https://echarak.in/echarak/templates/Chlorophytum%20arundinaceum%20Baker.pdf
26. Phurailatpam, & Geetha, K.A. & Gajbhiye, N. & Saravanan, Raju. (2009). *Comparative study of Chlorophytum borivilianum and C. arundinaceum – two safed musli species used as vital tonic in Indian Systems of Medicine*. Phytomorphology: An International Journal of Plant Morphology. 59. 77-81.
27. Chetna Gangwar, Ashok Kumar, Anil Kumar Mishra, S D Kharche, et al, *Asparagus racemosus improves seminal antioxidant status and sperm characteristics in buck semen at refrigeration temperature.,* Indian Journal of Animal Sciences 93(11): 1072–1076, November 2023.
28. Javeed Ahmed Wani, Rajeshwara N. Achur, R. K. Nema, *Phytochemical Screening and Aphrodisiac Activity of Asparagus racemosus.,* IJPSDR April-June, 2011, Vol 3, Issue 2 (112-115).
29. Mradu Gupta, Saikat Chowdhury and Sukumar Manna, *In vitro Impact Assessment of Aqueous Extract of Sida cordifolia Linn. Upon Rat Spermatozoa Parameters*., Asian Journal of Medicine and Health 1(2): 1-10, 2016.

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