International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Kannan R et al. Int J Reprod Contracept Obstet Gynecol. 2026 Apr;15(4):1259-1264
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20260883

Original Research Article

Efficacy and safety of Y-spur in the treatment of male infertility disorders: an open-label clinical endpoint study

Ramesh Kannan[1], Sakthibalan Murugesan[2], Bijoy Deb[3], Gayathri Sivakumar[3]*

[1]Department of Pharmacology, PM Medical Centre, Walajapet, Tamil Nadu, India
[2]Department of Pharmacology, DK Elite Health Care, Puducherry, India
[3]Ki3 Private Limited, Chennai, Tamil Nadu, India

Received: 29 January 2026
Revised: 03 March 2026
Accepted: 05 March 2026

***Correspondence:**
Dr. Gayathri Sivakumar,
E-mail: kai3.mrg@gmail.com

ABSTRACT

Background: Idiopathic male infertility has a complex etiology that includes oxidative stress, hormonal dysregulation, genetics, lifestyle choices, and environmental pollutants that can affect spermatogenesis and lower the quality of sperm. A polyherbal formulation, Y-Spur Capsule contains various herbs that support reproductive health through different methods, improve semen quality, lowers oxidative stress, and increase sperm count, motility, morphology, and testosterone levels.
Methods: 30 males aged 18-45 years, diagnosed with idiopathic male infertility were enrolled in the study and followed for 9 months.
Results: Statistically significant and sustained improvements were observed over a period of 9 months compared to their baseline values in a. semen volume (1.85±0.48 to 2.11±0.51), b. sperm concentration (11.6±1.96 to 17.7±2.37), c. total sperm count (14.4±3.06 to 22.93±2.32), d. total motile sperm (14.1±2.92 to 50.13±6.27), e. normal sperm morphology (2.67±0.48 to 11.47±1.87) (p=0.0001).
Conclusions: The progressive improvement in sperm morphology and motility further supported the overall enhancement of sperm quality and reproductive potential and the safety evaluations confirmed that Y-Spur was well tolerated. In addition, Y-spur was well tolerated among the subjects and was considered safe when consumed over a period of 9 months.

Keywords: Idiopathic male infertility, Infertility disorders, Oligospermia, Sperm morphology, Y-Spur

INTRODUCTION

A major public health concern, infertility affects between 10-15% of couples globally, with male factors accounting for almost 50% of cases.[1,2] Despite normal hormonal and anatomical examinations, a significant percentage of men exhibit idiopathic infertility, which is defined by aberrant semen parameters such as decreased sperm count, motility, and morphology without any discernible underlying reason.[3,4] Idiopathic male infertility has a complex etiology that includes oxidative stress, hormonal dysregulation, genetics, lifestyle choices, and environmental pollutants that can affect spermatogenesis and lower the quality of sperm.[5,6] One of the main causes of sperm DNA damage, reduced motility, and low fertilization potential has been identified as oxidative stress in specific.[7]

Although ART is still the mainstay of treatment, interest in herbal and nutraceutical therapies is growing as they may have anti-inflammatory, anti-oxidant, and endocrine-modulating effects that enhance semen quality and reproductive outcomes.[8,9]

A polyherbal formulation, 'Y-Spur' Capsule was formulated to address several pathways linked to male infertility. It contains various herbs that support reproductive health through different methods, which includes Putranjeevak, Shatavari, Ashwagandha, Bael Phal, Palas Beej, Jatamanshi, Babool, Kanda, Jeevanti, Bhumi Amalki, and Pippali. In idiopathic infertile men, ashwagandha has been thoroughly researched for its potential to improve semen quality, lower oxidative stress, and increase sperm count, motility, morphology, and testosterone levels.[10,11]

Antioxidants and adaptogens, like shatavari and putranjeevak promote spermatogenesis and hormonal homeostasis.[12] While babool, bhumi amalki, and bael phal offers Strong antioxidant protection, which shield sperm cells from DNA damage and lipid peroxidation.[13,14] By regulating cortisol levels and improving reproductive function, Jatamanshi and Jeevanti assist in reducing stress-induced infertility.[12,14] Pippali maximizes the systemic and reproductive effects by increasing the absorption of active phytoconstituents.[15] The study objectives were to evaluate the efficacy and safety of Y-Spur in the treatment of male infertility disorders and improve spontaneous pregnancy rate. Also, to evaluate the efficacy of Y-Spur in the treatment of oligospermia and in improving the sperm morphology.

METHODS

Study design and centers

This open label clinical endpoint study included participants diagnosed with idiopathic male infertility. The study was conducted at a site in Walajapet, Tamilnadu, India (PM Medical Centre) between January 1, 2025, and October 11, 2025.

Ethical approval and trial registration

The study protocol was approved by the Ethics Committee, PM Ethics Committee (registration no: ECR/332/Indt/TN/2020). The trial was registered prospectively in the Clinical Trials Registry of India (CTRI) on December 17, 2024 (registration no: CTRI/2024/12/078251).

This study was conducted in compliance with the International Council for Harmonization-Good Clinical Practice (ICH-GCP) guidelines E6 (R2), 2016; the Declaration of Helsinki, 2013; and all applicable local regulatory requirements and institutional policies. Written informed consent was obtained from each participant prior to study initiation.

Study population

Male participants between the ages of 18 and 45 years, diagnosed with idiopathic male infertility, had a total sperm count of 1-39 million confirmed by two consecutive samples taken ≥2 weeks apart, semen volume ≥1.4 mL and total sperm motility ≥10% at screening (each confirmed by two samples ≥2 weeks apart), agreed to have regular intercourse with intent to achieve spontaneous conception within 9 months of randomization, and agreed to provide details of their partner's pregnancy test results, ultrasound findings, delivery, and neonatal/infant health.

Participants were excluded if they had any history of anatomical disorders of the pituitary gland or testes; structural abnormalities of the vas deferens; cryptorchidism, testicular torsion, or orchitis; abnormal karyotype including Y-chromosome microdeletion; current or past urogenital cancer or prior chemotherapy/radiotherapy affecting testicular function; uncontrolled non-gonadal endocrinopathies; prior use of hormonal preparations, agents impairing testicular function, sex-hormone affecting drugs, teratogens within 3 months, or anabolic steroids within 12 months before screening; hypersensitivity to the investigational product; drug or alcohol abuse within the past 6 months; or any clinically significant systemic disease that could adversely affect fertility.

Study procedure

After obtaining written informed consent, participants underwent a detailed screening procedure. Screening included medical and treatment history, physical examination, assessment of vital signs, total sperm count, semen volume and total sperm motility. Laboratory investigations included haematology, liver function, renal function, random blood glucose. Urine pregnancy test was conducted for the participant's female partner of childbearing potential.

Study endpoints

The primary efficacy endpoints included the semen volume, sperm concentration, total sperm count, total motile sperm count, and morphology evaluated from pre-randomization to 3, 6, and 9 months post-randomization. Spontaneous pregnancies and positive β-hCG results in female partners were assessed up to 9 months after randomization.

Clinical safety assessments, including weight, blood pressure, pulse, and adverse events, were conducted at 1, 3, 6, and 9 months, while laboratory evaluations (hematology, biochemistry, and urinalysis) were performed at baseline and at 9 months. Adverse events were continuously monitored and recorded at each visit throughout the 9-month study period.

Statistics

The baseline characteristics, including age and BMI, were summarised using descriptive statistics (numbers and percentages). Continuous variables from the study including semen volume, sperm concentration, total sperm

count, total motile sperm count, sperm morphology, weight, BP, pulse and lab parameters were assessed for normality and homogeneity of variance. For parameters that satisfied these assumptions, paired *t*-test was performed to compare follow-up values with baseline. For data that did not meet normality or homogeneity criteria, the Wilcoxon matched-pairs signed-rank test was applied to evaluate pre- and post-treatment differences. All statistical analyses were conducted using GraphPad Prism software, version 10.6.0.

RESULTS

Demographic details

A total of 30 participants were screened and successfully enrolled into the study, with all participants completing the 9 months duration without any dropouts (Figure 1). 18 participants (60%) were between 24 -30 years of age, 12 participants (40%) were between 31-35 years of age. 27 participants (90%) were healthy according to their body weight; 3 participants (10%) were in the overweight category at the baseline (Table 1).

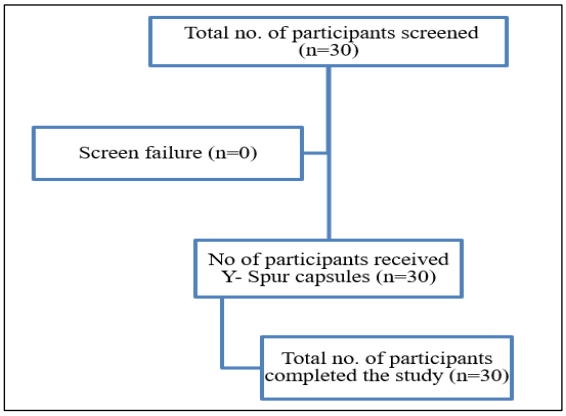

Figure 1: Participant flowchart.

Table 1: Age and BMI distribution in percentage.

Age in years	24-30	31-35	30
	18 (60%)	**12 (40%)**	**(100%)**
BMI (kg/m²)	18.5 to 24.9 (Healthy weight)	25 to 29.9 (Overweight)	30 (100%)
	27 (90%)	3 (10%)	

Clinical endpoints

Semen volume increased gradually from the third month onward, and the improvement was sustained through the 9th month. This improvement was statistically significant at all timepoint of visits. The mean percentage improvement relative to baseline also increased progressively over time, with 3.78% at 3 months, 8.10% at 6 months, and 14.05% at 9 month (Table 2). Sperm concentration showed a statistically significant improvement from month 3 onward, and this improvement was sustained throughout the study. The percentage improvement was 18.1% at month three, 33.01% at 6 months, and 52.59% at 9 months.

The consistent upward trend demonstrated that the Y-spur led to a significant reversal of oligospermia in the study population, improving the sperm concentration from subfertile levels at baseline to within the normal physiological range by 6 months and maintaining this improvement up to 9 months (Figure 2).

Total sperm count demonstrated a statistically significant improvement from month 3 onward compared to baseline, and this positive trend was sustained throughout the study period. The percentage improvement increased progressively over time, with percentage gains of 5.56% at 3 months, 12.71% at 6 months, and a substantial 59.23% at 9 months e (Figure 3).

Table 2: Mean change in semen volume.

Statistics	Baseline (n=30)	Month 3 (n=30)	Month 6 (n=30)	Month 9 (n=30)
Mean±SD	1.85±0.48	1.92±0.49	2±0.52	2.11±0.51
Median (Min-Max)	1.5 (1-2.8)	2 (1-2.9)	1.5 (1-3)	2 (1-3)
P value (compared to baseline)	-	0.0001	0.0001	0.0001
Mean % improvement compared to baseline	0	3.78	8.1	14.05

Total motile sperm count showed a statistically significant improvement from month 3 onward compared to baseline values, and this upward trend was sustained throughout the study period. The percentage improvement increased markedly over time, with a 1.3 fold increase at 3 months, 2.11 fold at 6 months, and 3.56 fold improvement by 9 months (Figure 4).

Normal sperm morphology showed a statistically significant improvement from month 3 onward. The percentage improvement continued to rise throughout the study, with increases of 1.71 fold at 3 months, 2.76 fold at 6 months, and a 4.3 fold by 9 months (Figure 5).

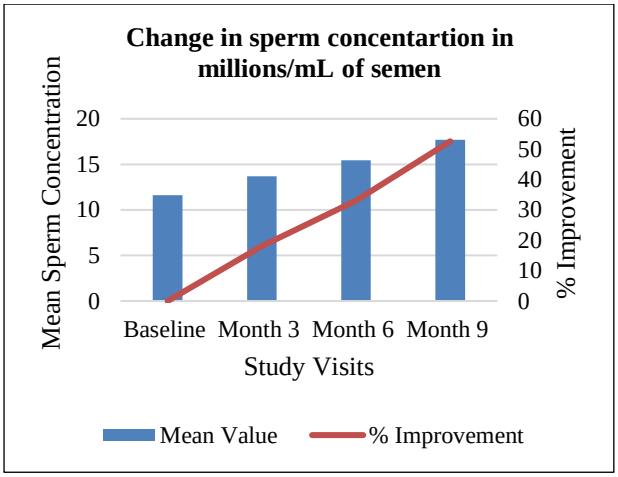

Figure 2: Mean change in sperm concentration.

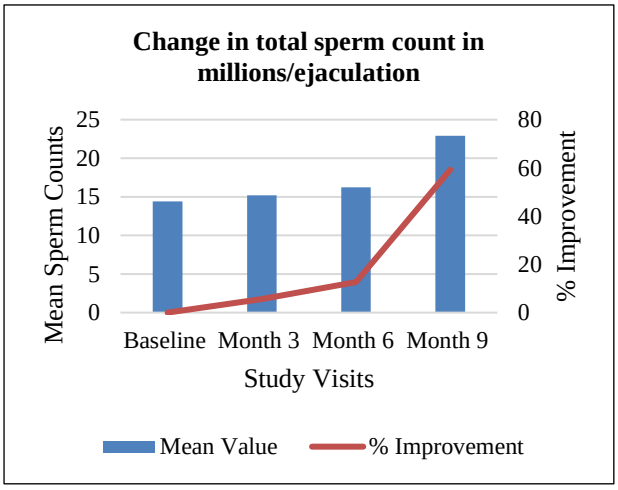

Figure 3: Mean change in total sperm count.

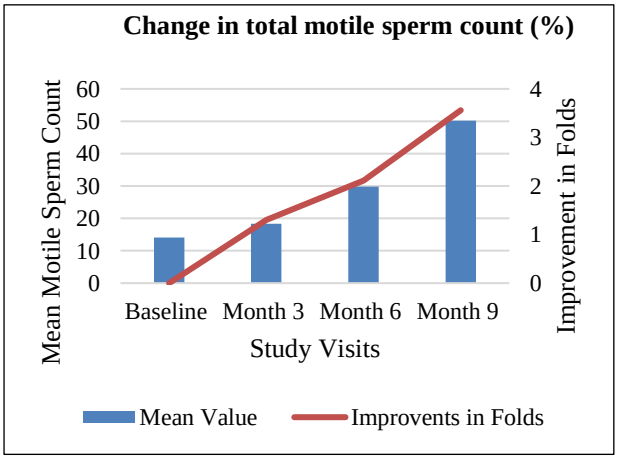

Figure 4: Mean change in total motile sperm count.

None of the participant's spouse reported positive pregnancy during the study period. Positive Beta-Human Chorionic Gonadotropin (β-hCG) was not observed in the spouse of any participant during the study period.

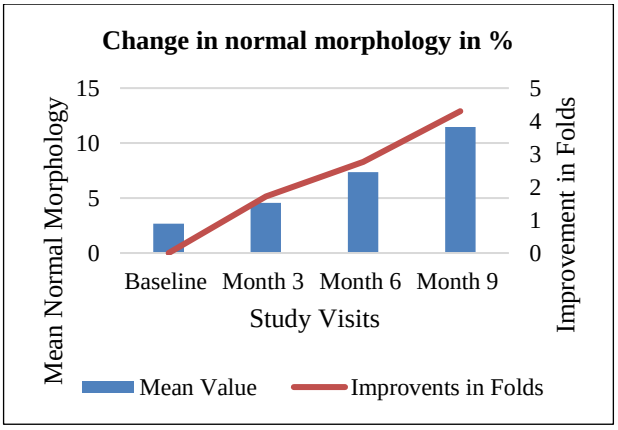

Figure 5: Mean improvement in normal morphology.

DISCUSSION

This study evaluated the efficacy and safety of Y-Spur in males with infertility disorders, particularly oligospermia and abnormal sperm morphology. The findings demonstrated significant and progressive improvements across all major semen parameters, including semen volume, sperm concentration, total sperm count, total motile sperm count, and normal sperm morphology. These outcomes collectively suggested that Y-Spur may play a beneficial role in enhancing male reproduction.

Semen volume increased steadily from the third month onward, with statistically significant improvements sustained through month 9. Adequate semen volume is essential for optimal sperm transport and has been shown to correlate with improved fertility outcomes.[16]

Sperm concentration and total sperm count also demonstrated statistically significant improvements beginning at month 3 and continued through month 9. Enhancements in these parameters are particularly important, as sperm density and total count are strong predictors of natural conception rates.[17,18] The percentage improvement observed particularly the 52.59% increase in sperm concentration and the 59.23% increase in total sperm count by month 9 suggested that Y-Spur may positively influence spermatogenesis. Similar improvements have been documented with antioxidant-rich or nutraceutical interventions in previous studies, supporting a possible mechanism involving reduced oxidative stress and improved testicular function.[19,20]

Total motile sperm count showed progressive improvements of 1.30 fold at month 3, 2.11 fold at month 6, and 3.56 fold by month 9. Motile sperm are essential for successful fertilization, and previous study has shown that interventions enhancing motility significantly increase the likelihood of spontaneous conception.[21] The substantial increase in motile sperm count observed in this study suggested that Y-Spur may enhance mitochondrial function and sperm motility pathways, consistent with findings from other fertility-enhancing formulations.

Normal sperm morphology also improved significantly, with a notable 4.3 fold increase by month 9. Morphology is widely recognized as a critical predictor of fertilization potential, and improvements in this parameter have been associated with increased pregnancy rates.[22,23] These results suggested that Y-Spur may help reduce teratozoospermia and improve the proportion of structurally competent spermatozoa capable of successful oocyte penetration.

In addition to improvements in semen parameters, abnormal sperm morphology showed a consistent decline throughout the study, further supporting the positive impact of the intervention on sperm quality. The downward trend in abnormal forms aligned with previous research indicating that nutritional or herbal interventions may help reduce sperm deformities by modulating oxidative stress and enhancing testicular microenvironment stability.[24]

Safety assessments showed that Y-Spur was well tolerated. Body weight, blood pressure, and pulse rate remained stable throughout the study. Laboratory investigations, including hematology, biochemistry, and urinalysis, revealed only minor, clinically insignificant variations, with all values remaining within normal ranges. These findings indicated a favorable safety profile, consistent with previous studies reporting the safety of nutraceutical formulations aimed at improving male fertility.[25,26]

Overall, the study findings suggested that Y-Spur significantly improved key semen parameters associated with male fertility, with a favorable safety profile. These results aligned with existing evidence on the beneficial effects of micronutrients, antioxidants, and herbal extracts on spermatogenesis and sperm function. In the present study, a significant improvement in sperm motility was observed following Y-Spur administration. The enhanced motility may indicate a higher proportion of functionally active spermatozoa, possibly because of increased activity of Y-bearing sperm, which has better motility. Previous studies have also demonstrated that human Y-chromosome-bearing sperm exhibit higher motility than X-bearing spermatozoa, suggesting the need for further confirmatory evaluations such as chromosomal or fluorescence-based sperm sorting in future studies.[27]

The study was conducted as an open-label clinical endpoint study without a placebo or control group, which was also a pilot study where the oligospermia and abnormal sperm morphology was considered and based on this the improvement in semen parameters have been evaluated and we need further large-scale, randomized, double-blind, placebo-controlled studies with longer follow-up to confirm pregnancy outcome.

CONCLUSION

The findings of this study demonstrated that Y-Spur was effective in improving multiple semen quality parameters in males with infertility disorders, particularly those presenting with oligospermia and abnormal sperm morphology. Statistically significant and sustained improvements were observed in semen volume, sperm concentration, total sperm count, total motile sperm count, and normal sperm morphology over the 9-month treatment period. Notably, sperm concentration increased from subfertile levels at baseline to within the normal physiological range by Month 6, indicating a meaningful reversal of oligospermia. The progressive improvement in sperm morphology and motility further supported the overall enhancement of sperm quality and reproductive potential.

Safety evaluations confirmed that Y-Spur was well tolerated, with no clinically significant changes in vital signs or laboratory parameters, and no safety concerns attributable to the intervention.

ACKNOWLEDGEMENTS

Authors would like to thank Vilco Laboratories Private Limited, India for funding the study and clinical supplies. We also thank Ki3 Private Limited, Chennai for the study conduct.

Funding: This study funded by Vilco Laboratories Private Limited
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of PM Medical Center (registration no: ECR/332/Indt/TN/2020)

REFERENCES

1. Agarwal A, Mulgund A, Hamada A, Chyatte MR. A unique view on male infertility around the globe. Reproduct Biol Endocrinol. 2015;13(1):37.
2. Vander Borght M, Wyns C. Fertility and infertility: Definition and epidemiology. Clin Biochem. 2018;62:2-10.
3. World Health Organization. WHO manual for the examination and processing of human semen, 6th edition. 2021. Available at: https://www.who.int/publications/i/item/9789240030787. Accessed 01 January 2026.
4. Krausz C. Male infertility: Pathogenesis and clinical diagnosis. Best Pract Res Clin Endocrinol Metabol. 2011;25(2):271-85.
5. Aitken RJ, Baker MA. Oxidative stress and male reproductive biology. Reproduct Fertil Development. 2004;16(5):581-8.
6. Tremellen K. Oxidative stress and male infertility-A clinical perspective. Human Reproduct Update. 2008;14(3):243-58.
7. Shukla KK, Mahdi AA, Rajender S. Oxidative stress and male infertility. Ind J Experimen Biol. 2009;47:963-8.
8. Ahmad MK, Mahdi AA, Shukla KK, Islam N, Rajender S, Madhukar D, et al. Withania somnifera

improves semen quality by regulating reproductive hormone levels and oxidative stress in seminal plasma of infertile males. Fertil Steril. 2010;94(3):989-96.
9. Agarwal A, Nallella KP, Allamaneni SS, Said TM. Role of antioxidants in treatment of male infertility: an overview of the literature. Reproduct Biomedi Online. 2004;8(6):616-27.
10. Ahmad MK, Mahdi AA, Shukla KK, Islam N, Rajender S, Madhukar D, et al. Withania somnifera improves semen quality by regulating reproductive hormone levels and oxidative stress in seminal plasma of infertile males. Fertil Steril. 2010;94(3):989-96.
11. Ambiye VR, Langade D, Dongre S, Aptikar P, Kulkarni M, Dongre A. Clinical evaluation of the spermatogenic activity of the root extract of Ashwagandha (Withania somnifera) in oligospermic males: a pilot study. Evidence-Based Complem Alternat Medi. 2013;2013(1):571420.
12. Kumar S, Gupta RS. Effect of Leptadenia reticulata on male reproductive system of rats. Andrologia. 2006;38(5):183-7.
13. Saini M, Sharma S. Role of antioxidants in male fertility. J Human Reproduct Sci. 2015;8(1):19-23.
14. Singh N, Nath R. Herbal interventions in male infertility. As Pac J Reprod. 2014;3(1):12-8.
15. Pandey MP, Mahdi AA. Pippali (Piper longum) as a bioavailability enhancer: Implications for reproductive health. Phytother Res. 2014;28:1436-42.
16. Cooper TG, Noonan E, Von Eckardstein S, Auger J, Baker HG, Behre HM, et al. World Health Organization reference values for human semen characteristics. Human Reproduct Update. 2010;16(3):231-45.
17. Irvine DS. Epidemiology and aetiology of male infertility. Hum Reprod. 1998;13(Suppl 1):33-44.
18. Jungwirth A, Diemer T, Dohle G, Giwercman A, Kopa Z, Krausz C, et al. EAU Guidelines on Male Infertility. Eur Urol. 2004;466162(512):555-8159.
19. Showell MG, Mackenzie-Proctor R, Brown J, Yazdani A, Stankiewicz MT, Hart RJ. Antioxidants for male subfertility. Cochrane Database Syst Rev. 2014;(12):CD007411.
20. Majzoub A, Agarwal A. Antioxidant therapy in idiopathic oligoasthenoteratozoospermia. World J Mens Health. 2018;36(2):77-85.
21. Guzick DS, Overstreet JW, Factor-Litvak P, Brazil CK, Nakajima ST, Coutifaris C, et al. Sperm morphology, motility, and concentration in fertile and infertile men. N Engl J Med. 2001;345(19):1388-93.
22. Kruger TF, Acosta AA, Simmons KF, Swanson RJ, Matta JF, Oehninger S. Predictive value of abnormal sperm morphology in in vitro fertilization. Fertil Steril. 1988;49(1):112-7.
23. Menkveld R, Wong WY, Lombard CJ, van der Hoven L, Franken DR, Kruger TF, et al. Semen parameters, including WHO and strict criteria morphology, in a fertile and subfertile population: an attempt to identify cut-off values. Hum Reprod. 2001;16(6):1165-71.
24. Agarwal A, Virk G, Ong C, du Plessis SS. Effect of oxidative stress on male reproduction. Reprod Biol Endocrinol. 2014;32(1):1.
25. Sharma R, Harlev A, Agarwal A, Esteves SC. Cigarette smoking and semen quality: a new meta-analysis examining the effect of the 2010 WHO laboratory methods for the examination of human semen. Reprod Biol Endocrinol. 2016;70(4):635-45.
26. Agarwal A, Baskaran S, Parekh N, Cho CL, Henkel R, Vij S, et al. Male infertility. Andrologia. 2021;53(1):e13676.
27. Goodall H, Roberts AM. Differences in motility of human X- and Y-bearing spermatozoa. J Reproduct Fertil. 1976;48(2):433-6.

Cite this article as: Kannan R, Murugesan S, Deb B, Sivakumar G. Efficacy and safety of Y-spur in the treatment of male infertility disorders: an open-label clinical endpoint study. Int J Reprod Contracept Obstet Gynecol 2026;15:1259-64.