

Evaluating the Efficacy of *Yashtimadhu Ghrita* Eye Drops versus *Chakshushya Basti* with *Panchatikta Ksheera Basti* in Dry Eye Associated Osteoarthritis: A Randomised Control Trial Research Protocol

ROSHNA SANJAY BHUTADA / RATHI¹, SHWETA PARWE², KOMAL KEDAR³, MITALI SANJAY RATHI⁴

ABSTRACT

Introduction: Dry eye is one of the most commonly observed conditions, with a prevalence of about 5-50% in all ocular conditions and higher variations in clinical practice. The prevalence of Osteoarthritis (OA) was revealed to be a significant risk factor for Dry Eye Syndrome (DES) in the twins UK cohort. According to research, DES is far more likely to occur in places with high levels of air pollution than in cities with cleaner air.

Need of the study: Conventional allopathic care is confined to symptomatic relief via lubricating eye drops and does not address the underlying tear-film instability or meibomian gland dysfunction. This gap in effective, mechanism-based therapy highlights the need for studies that explore alternative interventions capable of restoring tear-film homeostasis and improving long-term ocular surface health.

Aim: To study efficacy of *Yashtimadhu Ghrita* eye drops along with *Panchatikta ksheera basti* versus *Yashhtimadhu Ghrita* eye

drops and *Chakshushya basti* in the management of dry eye associated osteoarthritis disease-associated OA.

Materials and Methods: A randomised standard control, single-blinded trial will be conducted at Mahatma Gandhi Ayurved College, Hospital and Research Centre Salod, Maharashtra, India from May 2025 to December 2025, involving 25 subjects in each group. Parameters that will be evaluated are the Womac scale, Schirmer's test, and the Tear film break-up test. *Chakshushya* and *Yashtimadhu Ghrita* eye drops will be administered in Trial Group A. In control Group B, *Panchatikta ksheera basti* and *Yashhtimadhu Ghrita* eye will be given. The therapeutic enema, *Yog Basti*, will be provided for the first eight days, followed by a gap period (*Parihar ka*) of eight days. After this, *Aschyotan* (eye drops) will be administered for the next eight days, leading up to the last follow-up on the 48th day. The routes of administration will be anal and topical. Data analysis will be conducted using the paired t-test, Wilcoxon signed-rank test, and Mann-Whitney U test, with significance set at $p < 0.05$.

Keywords: *Aschyotan*, *Ayurveda*, *Basti*, *Pariharkal*, Schirmer's test, *Yogbasti*

INTRODUCTION

The prevalence of OA has been identified as a significant risk factor for developing DES within the TwinsUK cohort, which highlights the intricate relationship between systemic conditions and ocular health [1]. DES is defined as a multifactorial disease of the ocular surface, characterised by an array of aetiological factors that disrupt the delicate balance of the tear film. According to the TFOS DEWS II report published in 2017, these factors include loss of homeostasis of the tear film, instability, hyperosmolality, damage, and neurosensory inflammation [2]. Tears are essential for maintaining both moisture and lubrication for optimal vision, playing a vital role in overall eye health. The tear film comprises three primary layers: the lipid layer, which prevents evaporation and provides lubrication; the aqueous layer, which ensures a clean and moist environment on the ocular surface; and the mucus layer, which serves to bind the tear film to the eye. Moreover, tears contain lysozymes and other antimicrobial proteins that function as natural antibiotics, helping to fend off pathogens and maintain a healthy surface in the eye [3]. Any abnormalities-whether in the quantity or quality- of these components can lead to instability in the tear film, resulting in symptoms of ocular dryness and discomfort [4]. Research has consistently shown that eye-related symptoms rank among the most frequently reported health issues experienced by users of Video Display Terminals (VDTs), including computers and smartphones [5]. Various factors can contribute to

the development of dry eyes, including age-related hypofunction of the lacrimal glands, deficiencies in mucin production, conjunctival scarring, and prolonged exposure to screens in low-humidity environmental conditions that are particularly exacerbated among contact lens users. Increased screen time is now recognised as a significant risk factor in the emergence of dry eye symptoms, significantly influencing the prevalence of the condition in today's digital age [6]. Interestingly, DES is reported to be more common in densely populated metropolitan areas. Epidemiological studies indicate that the likelihood of developing dry eyes is substantially higher in locations with elevated levels of air pollution, as compared to regions with cleaner air [7]. According to recent data from the United States, over 3.2 million women and 1.6 million men aged 50 year and older suffer from moderate to severe dry eye symptoms. Notably, the prevalence of dry eye increases by 14.4% within the age range of 48 to 91 year, with the incidence of the disorder more than doubling after the age of 59 years [8]. Additionally, a significant correlation has been observed between OA and fibromyalgia, with studies indicating that approximately 50% of patients diagnosed with OA also report symptoms of fibromyalgia. This condition is characterised by chronic, widespread musculoskeletal pain and is often associated with fatigue, sleep disturbances, and cognitive difficulties. Previous evidence has established fibromyalgia as a notable co-morbidity linked to DES, further illustrating the multifaceted nature of these health issues and their interaction [9].

Through a better understanding of these relationships, healthcare providers can improve diagnostic accuracy and treatment strategies for patients presenting with these interconnected conditions.

REVIEW OF LITERATURE

Considering clinical features in dry eye diseases in *Ayurveda netra Chikista*, the disease closely resembles the condition *Shushkakshipaka*. *Shushkakshipaka* is a disease that *Acharya Sushruta* and *Vagbhata* describe as one among *sarvagata nethra rogas*. According to *Sushruta*, the predominant dosha is *vata* [10], while *Vagbhata* explains it as *vata pitta pradhana vyadhi*. Clinical features according to *Sushruta* include *Kunitam* (difficulty in eyelid movements), *darunavartma* (roughness), *rooksha* (dryness), *aviladarshana* (disturbance in vision), and *sudarunampratibhodane* (difficulty in opening eyes in the morning). *Acharya Vagbhata* mentions *gharsha* (grittiness), *toda* and *bheda* (foreign body sensation and pain), *upadeha* (sticky thick discharge), *rooksha darunavartmakshi* (dry eyes), *krichronmeelananimeelanam* (difficulty in eyelid movements), and *vishushkata* (dryness) [11]. From a modern perspective, the tear film provides nourishment to the ocular surface. Instability of the tear film causes burning sensation, foreign body sensation, watering, and mild inflammation, which can be analysed as subnormal functioning of *kapha*. The modern allopathic management of dry eyes, including tear substitutes, topical cyclosporine, and mucolytics, still does not offer a perfect medicine that can regulate dry eye and prevent complications without unwanted effects. Researchers find it challenging to discover an effective, non harmful therapy. It has become a significant challenge for *Ayurveda* practitioners to identify additional effective solutions for managing dry eyes associated with OA.

The trial medicine should have qualities antagonistic to *vata* and *pitta* and should help normalise the depleted *kapha*. *Yashtimadhu*, a *chakshushya dravya*, and *Ghrita*, which possesses *Snigdha Guna*, *Madhura Rasa*, and *Sheeta Veerya*, demonstrated superior outcomes in both *tarpana* and *aschyothna* treatments for DES [12]. DES is the most common eye condition among patients with OA [13]. Phapale PU et al., conducted a comparative clinical study evaluating *Yashtimadhu Ghrita Tarpan* versus 0.1% Sodium Hyaluronate eye drops in managing *Shushkakshipaka* (DES). Seventy patients aged 18-80 year were randomly selected from the *Shalakyatantra* OPD and divided equally into trial and control groups. The trial group received *Yashtimadhu Ghrita Tarpan*, while the control group was treated with Sodium Hyaluronate. Results showed that *Yashtimadhu Ghrita Tarpan* provided greater symptomatic relief and was more effective overall in treating *Shushkakshipaka* [14]. According to a literature review by author *Ayurveda* therapies like *Chakshushya Basti* are highly potent procedures that can help to reduce the oxidative stress and damage of thinned-out cornea and thus help to reduce the refractive error as well as check on the disease's further progression [15]. However, to our knowledge, limited research has been conducted on the comparative analysis of the drugs discussed above. Therefore, the present study aims to evaluate the efficacy of *Yashtimadhu Ghrita* eye drops combined with *Panchatikta Ksheera Basti*, compared to *Yashtimadhu Ghrita* eye drops used along side *Chakshushya Basti*, in the management of dry eye associated with OA.

Objectives:

1. To study the effect of *Chakshushya Basti* and *Yashtimadhu ghrita Aschyotan* in the management of dry eyes associated with OA;
2. To study the effect of *Panchatikta Ksheera Basti* and *Yashtimadhu Ghrita Aschyotan* in the treatment of dry eyes related OA;
3. To compare the efficacy of the two groups.

Null hypothesis: There is no significant difference between *Yashtimadhu Ghrita* eye drops combined with *Panchatikta Ksheera*

versus *Yashtimadhu Ghrita* eye drops and *Chakshushya basti* in the management of dry eye associated with OA.

Alternate hypothesis: There is a significant difference between *Yashtimadhu Ghrita* eye drops along with *Panchatikta ksheera basti* versus *Yashtimadhu Ghrita* eye drops and *Chakshushya basti* in the management of dry eye-associated OA before and after treatment.

MATERIALS AND METHODS

A randomised standard control single-blinded trial will be conducted at Mahatma Gandhi Ayurved College, Hospital and Research Centre Salod, Maharashtra, India from May 2025 to December 2025. IEC approval has been sought (Ref. IEC-MGACHRC/IEC/Oct-2024/885 dated 9.10.24), and the trial has been registered in Clinical Trials Registry India with reference no. CTRI/2024/12/078171.

Inclusion criteria:

1. Patient providing informed consent;
2. Age group between 45 to 70 years;
3. Patients with controlled hypertension up to normal to 140/90 mm of Hg.
4. Controlled diabetes mellitus patients range between 100 mg/dL and 160 mg/dL.
5. Patient with Body Mass Index (BMI) up to 30 kg/m².

Exclusion criteria:

1. Uncontrolled hypertension and diabetes mellitus;
2. Traumatic arthritis;
3. Postcataract surgery up to one year;
4. Knee joint replaced;
5. Contraindicated for *Basti* and *Aschyotan*;
6. Dry eyes not associated with OA, example: dry eye due to Graves' disease, Hashimoto's disease, primary and secondary Sjogren's syndrome

Withdrawal criteria: The participant can be withdrawn from the trial in case of.

1. Any drug adverse event;
2. Voluntary withdrawal by the participant;
3. Breach of inclusion and exclusion criteria;
4. There is non adherence to the treatment regimen (at least 80% adherence is necessary to continue with the study).

Discontinuation criteria from the trial- If the participant discontinues the course of *panchakarma* therapy and skips *Local Aschyotan* therapy for eight days, he/she will not be taken into account in the trial.

Sample size calculation: $n=2\sigma^2(Z_{1-\alpha/2}+Z_{1-\beta})^2/\delta^2$

Where:

$Z_{1-\alpha/2}$ at 1% level of significance=2.5758

Power (1- β)=99%

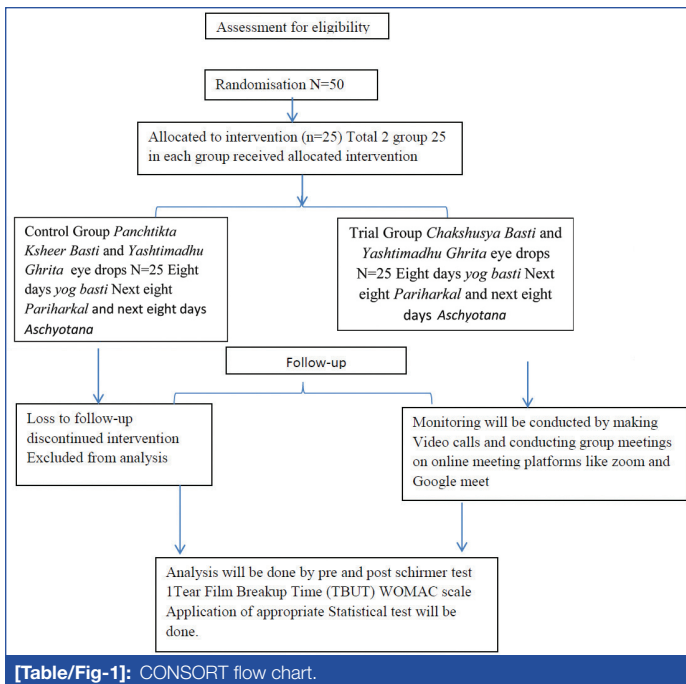
β (Type II error)=0.01

Mean difference (δ)=4.171

Standard deviation (σ)=2.56 [14]

Sample size $n=48.0627 / 2.6546+3.3174=22$ per group (Considering 12.5 per cent drop out, total of three patient dropouts per group. Total sample patient 50 participants: 25 samples in each group will be studied.

Computer-generated random numbers shall be utilised for the allocation to recruit the study participants. As this research is researcher-blind, the fellowship guide will assign and allocate the participants to a *Panchakarma* therapist for procedures of *basti* and *aschyotan*. We will administer the therapeutic enema for the first eight days, *Yog Basti*, then *Paihar kal* eight days, *Aschyotan* for the next eight days and the last follow-up will be taken at the 48th day. Group B: *Panchatikta Ksheera basti* and *Yashtimadhu Ghrita* eye drops [Table/Fig-1].



All the drugs will be procured from the Rasashala of MGACH and RC, Salod, Maharashtra, India.

Deepan-pachan: *Aampachak vati* is an Ayurvedic medication that will be administered orally, with a dosage of 500 mg BD, for three days. Before commencing *Basti* therapy, it will enhance a crucial factor, the appetite. The preparation will be conducted in the pharmacy of MGACH and RC, Salod, Maharashtra, India.

Ingredients

1. *Kwatha of Patola, Nimba, Bhunimba, Rasna, Saptaparna - 4 prasrta.*
2. *Kalka - Sarshapa.*
3. *Ghritha - 1 prasrta.*
4. *Madhu - 80mL.*
5. *Saindhava - 5g.*

Preparation: Combine four *prasrita* of the decoction made from *Patola, Bhunimba, Nimba Saptachada, and Rasna* with one *prasrita* of *ghrita*. The exact quantity of *Sarshapa* is not specified in this recipe. Therefore, it should be determined that for 12 *prasta*s of liquid used in the *niruha*, two *palas* of the *Sarshapa* paste are to be added [16].

Ingredients

- 1) *Erandamoola Kwatha: 4 prasrita (380mL);*
- 2) *Madhu: 2 prasrita;*
- 3) *Taila: 2 prasrita;*
- 4) *Kalka (Shatapushpa+Yashtimadhu: 1 prasrita;*
- 5) *Saindhava: 1 karsha Dose - 9 prasrita*

Preparation: Standard method of preparation of *Niruha Basti*.

Ingredient of *Yashtimadhu Ghrita -Yashtimadhu Kwath and ghrita* [Table/Fig-2-4].

The prepared drug will be standardised from a recognised GMP certified company. Drug analysis also carried out for all basic parameters for each formulation as per API guidelines. The raw medicines will be gathered, made ready, and made lukewarm by indirect heating. Materials will be inserted into an enema can. The participant will be requested to lie over the table in the left lateral position. The nozzle of the enema can be gradually inserted into the anal canal after rubbing oil on it. It will be inserted slowly until it reaches the rectum, and now the decoctions will enter the rectum. Soon after the administration of *Panchatikta Ksheera basti, Chakshushya basti* and Sesame oil, the participant will be permitted to defecate. The subject will be instructed to adhere



to a diet plan consisting of *Yusha* (vegetable soup or pulses) and rice, and to consume hot water during the course of *Panchatikta Ksheera Basti* and *Chakshushya Basti* (sesame oil enema therapy).

OUTCOMES

Clinical examination: Visual acuity of both eyes will be assessed with the Snellen chart. Dryness of the eye will be measured by Schirmer's test and Tear Film Break-up Time (TBUT) at baseline, 24th day and 48th day.

Schirmer's test 1: Wash hands before and after the procedure. Position the patient comfortably with head supported. Do not instil anaesthetic drops. Remove two strips from the sterile packet and label them 'R' for right and 'L' for left. Bend each strip at the notch to a 90° angle. Ask the patient to look up and, with an index finger, gently pull down the lower eyelid. Hook the bent end of the strip over the centre of the lower eyelid and allow it to sit inside. Repeat the procedure in the other eye and note the time. Ask the patient to keep their eyes gently closed. After five minutes, ask the patient to open both eyes and look up. Carefully remove both strips. Using the package scale, measure the length of the moistened area on the strip, from the notch, and indicate this with a pen mark. Stick the strips into the patient's documentation and record the measurements below each strip, e.g., "10 mm in five minutes". If the strips are completely moistened before five minutes, record appropriately, e.g., "30 mm in three minutes". Above 15 is normal. A 15 to 10 mm is mild dryness, 5-10 mm indicates moderate dryness, while 0-5 mm indicates severe dryness [17].

Tear film Break-Up Test (TBUT): Patient will be made to sit comfortably and asked to look downwards. The upper lid of the right eye slightly lifted, and the fluorescein strip moistened with saline. The excess fluid shaken off the strip, and it then used to stain the ocular surface. The subject was asked to keep their eyes open while looking straight ahead. The stopwatch will be started after the last blink and the appearance of dry spots on the cornea, and the stopwatch will be stopped. The time between the last blink and the first appearance of dry spots will be recorded in seconds as TBUT. The procedure will be repeated three times on both eyes, first right, then left. A single examiner will collect the data. Above 15 seconds is normal. 15 to 10 seconds is mild dryness, 10 to 5 seconds is moderate dryness, and 0 to 5 seconds is severe dryness [18].

The OA study will be done by Womac scale-pain, walking/ physical function and stiffness of joint - analogue- range of motion will be studied [19]. A difference of more than 20% from the baseline values of Schirmer's test, TBUT, will be considered superiority.

Values in the normal range will be used to establish the effect of the intervention. The study followed SPIRIT guidelines [Table/Fig-5].

STATISTICAL ANALYSIS

Data analysis will be using Statistical Package for the Social Sciences (SPSS) version 27.0. Initially, normality of the data will be assessed using the Shapiro-Wilk test. For within-group comparisons (i.e., pretreatment vs post-treatment in each group), the paired t-test will be used if the data are normally distributed; otherwise, the Wilcoxon signed-rank test will be applied. To compare post-treatment outcomes and change scores between the two groups (*Yashtimadhu Ghrita* eye drops with *Panchatikta Ksheera Basti* vs *Yashtimadhu Ghrita* with *Chakshushya Basti*), the independent samples t-test will be employed for normally distributed data, or the Mann-Whitney U test for non parametric data. A significance level of p-value <0.05 will be considered statistically significant for all comparisons.

Acknowledgements

The authors express gratitude to Dr. Bharat Rathi Dean of Mahatma Gandhi Ayurved College, Hospital and Research Centre; Datta Meghe Institute of Higher Education and Research (DMIHER).

	Enrollment	Allocation	Post-allocation				Follow-up
			0 th day	8 th day	16 th day	24 th day	
Time point							
enrollment							
eligibility							
screen							
informed							
consent	X						
allocation	X						
		X					
Intervention							
<i>Yog Basti</i> 8							
days							
<i>Parihar</i>							
<i>kal</i> 8 days							
<i>Aschyotan</i> 8							
days							
Assessment			↔				
Baseline				↔			
Post					↔		
intervention						X	
			↔				

[Table/Fig-5]: Show SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials).

Authors' contribution: RSB, SP (Guide), KK, MSR: reviewed literature, conceptualized study presented to the Institutional Ethical Committee (IEC), IEC approval received, CTRI registry, India CTRI/2024/12/078171.

REFERENCES

- Vehof J, Kozareva D, Hysi PG, Hammond CJ. Prevalence and risk factors of dry eye disease in a British female cohort. *Br J Ophthalmol*. 2014;98(12):1712-17.
- Craig JP, Nichols KK, Akpek EK, Caffery B, Dua HS, Joo CK, et al. TFOS DEWS II Definition and Classification Report. *Ocul Surf*. 2017;15(3):276-83. Doi: 10.1016/j.jtos.2017.05.008. Epub 2017 Jul 20. PMID: 28736335.
- Dhotre D, Mamatha KV, Sujathamma K. A single arm open label clinical study on daruharidradi seka in the management of shushkakshipak W.S.R. to dry eye. *Int Ayur Med J*. [online]. 2017;(V):1916-28.
- Mizoguchi S, Iwanishi H, Arita R, Shirai K, Sumioka T, Kokado M, et al. Ocular surface inflammation impairs structure and function of meibomian gland. *Exp Eye Res*. 2017;163:78-84.
- Bhutada RS. The effect of eye exercise, Triphala Kwath Eyewash, and instillation of distilled water on computer vision syndrome. *J Datta Meghe Inst Med Sci Univ*. 2019;14:S78-82.
- Hyon JY, Han SB. Dry eye disease and vitamins: A narrative literature review. *Applied Sciences* [Internet]. 2022 Apr 30 [cited 2022 Sep 13];12(9):4567. Available from: https://mdpi-res.com/d_attachment/applsci/applsci-12-04567/article_deploy/applsci-12-04567.pdf?version=1651315914.
- Dakhore J, Bhutada R, Kher P. Protocol of evaluation of the efficacy of Mudgaparni Ghrit Aaschyotana in the management of Shushkakshipaka (dry eye syndrome). *World Journal of Pharmaceutical Science and Research*. 2024;3(6):270-79. <https://doi.org/10.5281/zenodo.14576501>.
- Javadi MA, Feizi S. Dry eye syndrome. *J Ophthalmic Vis Res*. 2011;6(3):192-98. PMID: 22454735; PMCID: PMC3306104.
- Yoo TK, Oh E. Association between dry eye syndrome and osteoarthritis severity: A nationwide cross-sectional study (KNHANES V). *Pain Med*. 2021;22(11):2525-32. Doi: 10.1093/pm/pnab085. PMID: 33690820.
- Dhiman KS. Shushkakshipaka (dry eye syndrome): A case study. *Int J Ayurveda Res*. 2011;2(1):53-55.
- Pandit Harishastri Paradkar., editor. Varanasi: Chaukhamba Krishnadas Academy; 2006. Vagbhata, Ashtanga Hridaya, Uttar Sthanam, Sarvaakshiroga Vijnaniya Adhyaya, 15/16-17. reprint ed. 829.
- Chaitra TM, Varun TV, Akshitha P. Efficacy of Yashtimadhu Ghrita Tarpana in computer vision syndrome. *J Ayurveda Integr Med Sci*. 2024;3:6-13. <http://dx.doi.org/10.21760/jaims.9.3.2>.
- Moss SE, Klein R, Klein BE. Prevalence of and risk factors for dry eye syndrome. *Arch Ophthalmol*. 2000;118(9):1264-68.
- Phapale PU, Deshmukh A, Bargal R, Jori R. Comparative clinical study of Yashtimadhu ghrita tarpana and Sodium hyaluronate (0.1%) eye drop in the management of Shushkaakshipaka w.s.r to dry eyes. *International Int J Ayur Med*. 2023;14:90-98. Doi: 10.47552/ijam.v14i1.3027.
- Sudeshna SR, Patel K. Role of Chakshushya Basti in the management of keratoconus. *World Journal of Pharmaceutical and Medical Research; WJPMR*. 2022;8(4):59-61.
- Babu A, Hamsaveni V. Role of Chakshushya Basti in the management of diabetic retinopathy. *WJPLS*. 2024;10(3):109-12.

- [17] Bowling B. Kanski's Clinical Ophthalmology: A Systematic Approach. 8th ed. Elsevier; 2016. p. 110-12.
- [18] Khurana AK. Parson's Diseases of the Eye. 23rd ed. Elsevier; 2019. Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II Definition and Classification Report. Ocul Surf. 2017;15(3):276-83.
- [19] McConnell S, Kolopack P, Davis AM. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A review of its utility and measurement properties. Arthritis Rheum. 2001;45(5):453-61

PARTICULARS OF CONTRIBUTORS:

1. Professor, Department of Shalakyantra, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
2. Professor, Department of Panchkarma, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
3. Associate Professor, Department of Shalakyantra, Datta Meghe Medical College, Wanadongari, Nagpur, Maharashtra, India.
4. Undergraduate Student, Malla Reddy Institute of Medical Sciences, Hyderabad, Telangana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Roshna Sanjay Bhutada / Rathi,
Professor, Department of Shalakyantra, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
E-mail: drroshnarathi@gmail.com

PLAGIARISM CHECKING METHODS: [\[Jan H et al.\]](#)

- Plagiarism X-checker: Apr 13, 2025
- Manual Googling: Jan 11, 2026
- iThenticate Software: Jan 13, 2026 (1%)

ETYMOLOGY: Author Origin**EMENDATIONS:** 9**AUTHOR DECLARATION:**

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Apr 12, 2025**Date of Peer Review: **Jun 10, 2025**Date of Acceptance: **Jan 15, 2026**Date of Publishing: **Jul 01, 2026**