

# NEW INDIAN JOURNAL OF SURGERY

(PEER-REVIEWED AND REFEREED JOURNAL)

VOLUME 15 NUMBER 4 OCTOBER - DECEMBER 2024



RED FLOWER PUBLICATIONS PVT LTD  
New Delhi - 110091

### Revised Rates for 2025 (Institutional)

Title of the Journal	Frequency	India (INR) Print Only	(India (INR) Online Only	Outside India ((USD) Print Only	Outside India ((USD) Online Only
Community and Public Health Nursing	Triannual	7,000	6,500	\$547	\$508
Indian Journal of Agriculture Business	Semiannual	7,000	6,500	\$547	\$508
Indian Journal of Anatomy	Triannual	10,000	9,500	\$781	\$742
Indian Journal of Ancient Medicine and Yoga	Quarterly	9,500	9,000	\$742	\$703
Indian Journal of Anesthesia and Analgesia	Quarterly	9,000	8,500	\$703	\$664
Indian Journal of Biology	Semiannual	7,000	6,500	\$547	\$508
Indian Journal of Cancer Education and Research	Semiannual	10,500	10,000	\$820	\$781
Indian Journal of Communicable Diseases	Semiannual	10,000	9,500	\$781	\$742
Indian Journal of Dental Education	Triannual	7,000	6,500	\$547	\$508
Indian Journal of Diabetes and Endocrinology	Semiannual	9,500	9,000	\$742	\$703
Indian Journal of Emergency Medicine	Quarterly	14,000	13,500	\$1094	\$1055
Indian Journal of Forensic Medicine and Pathology	Quarterly	17,500	17,000	\$1367	\$1328
Indian Journal of Forensic Odontology	Semiannual	7,000	6,500	\$547	\$508
Indian Journal of Genetics and Molecular Research	Semiannual	8,500	8,000	\$664	\$625
Indian Journal of Law and Human Behavior	Semiannual	7,500	7,000	\$586	\$547
Indian Journal of Legal Medicine	Semiannual	10,000	9,500	\$781	\$742
Indian Journal of Library and Information Science	Triannual	11,000	10,500	\$859	\$820
Indian Journal of Maternal-Fetal & Neonatal Medicine	Semiannual	11,000	10,500	\$859	\$820
Indian Journal of Medical and Health Sciences	Semiannual	8,500	8,000	\$664	\$625
Indian Journal of Obstetrics and Gynecology	Quarterly	11,000	10,500	\$859	\$820
Indian Journal of Pathology: Research and Practice	Triannual	13,500	13,000	\$1055	\$1016
Indian Journal of Plant and Soil	Semiannual	8,000	7,500	\$625	\$586
Indian Journal of Preventive Medicine	Semiannual	8,500	8,000	\$664	\$625
Indian Journal of Research in Anthropology	Semiannual	14,000	13,500	\$1094	\$1055
Indian Journal of Surgical Nursing	Triannual	7,000	6,500	\$547	\$508
Indian Journal of Trauma and Emergency Pediatrics	Triannual	11,000	10,500	\$859	\$820
Indian Journal of Waste Management	Semiannual	11,000	10,500	\$859	\$820
International Journal of Food, Nutrition & Dietetics	Triannual	7,000	6,500	\$547	\$508
International Journal of Forensic Science	Semiannual	11,500	11,000	\$898	\$859
International Journal of Neurology and Neurosurgery	Triannual	12,000	11,500	\$938	\$898
International Journal of Pediatric Nursing	Triannual	7,000	6,500	\$547	\$508
International Journal of Political Science	Semiannual	7,500	7,000	\$586	\$547
International Journal of Practical Nursing	Triannual	7,000	6,500	\$547	\$508
International Physiology	Semiannual	9,000	8,500	\$703	\$664
Journal of Animal Feed Science and Technology	Semiannual	9,500	9,000	\$742	\$703
Journal of Cardiovascular Medicine and Surgery	Quarterly	11,500	11,000	\$898	\$859
Journal of Emergency and Trauma Nursing	Semiannual	7,000	6,500	\$547	\$508
Journal of Forensic Chemistry and Toxicology	Semiannual	11,000	10,500	\$859	\$820
Journal of Global Medical Education and Research	Semiannual	7,500	7,000	\$586	\$547
Journal of Global Public Health	Semiannual	13,500	13,000	\$1055	\$1016
Journal of Microbiology and Related Research	Semiannual	10,000	9,500	\$781	\$742
Journal of Nurse Midwifery and Maternal Health	Triannual	7,000	6,500	\$547	\$508
Journal of Orthopedic Education	Semiannual	7,000	6,500	\$547	\$508
Journal of Pharmaceutical and Medicinal Chemistry	Semiannual	18,000	17,500	\$1406	\$1367
Journal of Plastic Surgery and Transplantation	Semiannual	28,000	27,500	\$2188	\$2148
Journal of Psychiatric Nursing	Triannual	7,000	6,500	\$547	\$508
Journal of Radiology	Semiannual	9,500	9,000	\$742	\$703
Journal of Social Welfare and Management	Quarterly	9,000	8,500	\$703	\$664
New Indian Journal of Surgery	Quarterly	9,500	9,000	\$742	\$703
Ophthalmology and Allied Sciences	Semiannual	7,500	7,000	\$586	\$547
Pediatrics Education and Research	Semiannual	9,000	8,500	\$703	\$664
Physiotherapy and Occupational Therapy Journal	Quarterly	10,500	10,000	\$820	\$781
RFP Gastroenterology International	Semiannual	7,500	7,000	\$586	\$547
RFP Indian Journal of Hospital Infection	Semiannual	14,000	13,500	\$1094	\$1055
RFP Indian Journal of Medical Psychiatry	Semiannual	9,500	9,000	\$742	\$703
RFP Journal of Biochemistry and Biophysics	Semiannual	8,500	8,000	\$664	\$625
RFP Journal of Dermatology	Semiannual	7,000	6,500	\$547	\$508
RFP Journal of ENT and Allied Sciences	Semiannual	7,000	6,500	\$547	\$508
RFP Journal of Gerontology and Geriatric Nursing	Semiannual	7,000	6,500	\$547	\$508
RFP Journal of Hospital Administration	Semiannual	8,500	8,000	\$664	\$625
Urology, Nephrology and Andrology International	Semiannual	9,000	8,500	\$703	\$664

#### Terms of Supply:

- Agency discount 15% (This discount is applicable only 2025 subscription for agencies only). Issues will be sent directly to the end user, otherwise foreign rates will be charged.
- All back volumes of all journals are available at current rates.
- All journals are available free online with print order within the subscription period.
- All legal disputes subject to Delhi jurisdiction.
- Cancellations are not accepted orders once processed.
- Demand draft/cheque should be issued in favour of "Red Flower Publication Pvt. Ltd." payable at Delhi.
- Full pre-payment is required. It can be done through online (<http://rfppl.co.in/subscribe.php?mid=7>).
- No claims will be entertained if not reported within 6 months of the publishing date.
- Orders and payments are to be sent to our office address as given below.
- Postage & Handling is included in the subscription rates.
- Subscription period is accepted on calendar year basis (i.e. Jan to Dec). However orders may be placed any time throughout the year.

#### Order from

Red Flower Publication Pvt. Ltd., 48/41-42, DSIDC, Pocket-II, Mayur Vihar Phase-I, Delhi - 110 091 (India)  
Mobile: 8130750089, Phone: 91-11-79695648 E-mail: [sales@rfppl.co.in](mailto:sales@rfppl.co.in), Website: [www.rfppl.co.in](http://www.rfppl.co.in)

# NEW INDIAN JOURNAL OF SURGERY

## Editor-in-Chief

**Rohan Khandelwal**  
CK Birla Hospital,  
Gurugram 122018, Haryana, India

## Former Editor-in-Chief

**Chintamani, VMMC**  
Vardhaman Mahaveer Medical College and Safarjung  
Hospital, New Delhi 110029, India

## International Editorial Board Member

**Alok Arora**, Wisconsin, United States

## National Editorial Board Member

**Manohar Lal Dawan**, Sardar Patel  
Medical College Bikaner, Rajasthan

**P.R. Venugopal**, Institute of Medical  
sciences, Changanassery, Kerala

**Sanjay P Dhangar**, SMBT Institute  
of Medical Science and Research  
Centre, Pune

**Nikhil Naithottu**, Bangalore,  
Medical College & Research  
Institute, Bengaluru, Karnataka

**Himanshu Dipak Kumar Raval**,  
Smt N.H.L. Medical College and SVP  
hospital, Ahmedabad, Gujarat,

**Deepak Verma**, Mathuradas Mathur  
Hospital, Shastri Nagar, Jodhpur,  
Rajasthan

**Arjun C**, Spandana Hospital,  
Bangalore, Karnataka

**Mahatab Singh Rajawat**, Institute  
of Nephrourology, Bengaluru,  
Karnataka

**Balasubramanian Venkitaraman**,  
Sri Ramachandra Medical  
College and Research Institute,  
Porur, Chennai

**P. Jaya Kumar**, Penyanna Counter  
Planga,, Namakkal, Tamil Nadu

**Vinay H G**, Vydehi Institute of  
Medical Sciences & Research Centre,  
Bengaluru, Karnataka

**K. Rupkumar**, Narayana Medical  
College And Hospital, Nellore,  
Andhra Pradesh

**Samir Ranjan Nayak**, Gsl Medical  
College and General Hospital,  
Rajahmundry, A. P

**Thanga Saravanan**, Vijaya Heart  
Foundation, Chennai

**Kshitij Manerikar**, Dr. D.Y. Patil  
Medical College, Hospital and  
Research Centre, Pimpri, Pune,  
Maharashtra

**Debasish Chatterjee**, The Mission  
Hospital, Durgapur, West Bengal

**Ramratan Yadav**, Dr.sampurnanand  
Medical College Jodhpur, Rajasthan

**Harvinder Singh Pahwa**, King  
George's, Medical University,  
Lucknow, U.P

**Ravi Kumar Chittoria**, Jawaharlal  
Institute of Medical Education and  
Research, Puducherry.

## Publisher

A Lal  
E-mail: info@rfppl.co.in

## Paper Submission

Dinesh Kumar Kashyap  
E-mail: author@rfppl.co.in

**The New Indian Journal of Surgery (pISSN: 0976-4747, eISSN: 2456-0863)**, Registered with Registrar of Newspapers for India: DELENG/2010/33158) is a peer-reviewed journal designed for the general surgeon who performs abdominal, cancer, vascular, head and neck, breast, colorectal, and other forms of surgery. **NIJS** is a multidisciplinary super-specialty involving all surgical specialties and all medicine specialties; hence all surgeons and physicians around the world are involved in this field. **NIJS** provides most current, most authoritative information on major Clinical problems in the fields of Clinical and experimental surgery, surgical education, surgical care and its allied subjects.

In addition **The New Indian Journal of Surgery** publishes original articles that offer significant contributions in the fields of Clinical surgery, experimental surgery, surgical education and related sciences. **NIJS** will be of interest not only to general surgeons, but also to specialty surgeons and those working in related fields.

Indexing and Abstracting Information: Index Copernicus, Poland; MedLine/Locatore plus, USA; Genamics JournalSeek; WorldCat; Gaudeamus Academia; Science Library Index; The International Committee of Medical Journal Editors (ICMJE).

For all other queries Red Flower Publication Pvt. Ltd., 48/41-42, DSIDC, Pocket-II, Mayur Vihar Phase-I, Delhi - 110 091 (India), Mobile: 8130750089, Phone: +91-11-79695648 E-mail: info@rfppl.co.in, Web: www.rfppl.co.in

**Disclaimer** The opinion in this publication is those of the authors and is not necessarily those of the New Indian Journal of Surgery the Editor-in-Chief and Editorial Board. Appearance of an advertisement does not indicate NIJS approval of the product or service.

© Red Flower Publication Pvt. Ltd. 2010 (year of first publication) all rights reserved. No part of the journal may be reproduced, stored in a retrieval system or transmitted in any form or by any means: electronic, mechanical, photocopying, recording or otherwise, without prior permission of the New Indian Journal of Surgery.

Printed at Saujanya Printing Press, B-303, Okhla Industrial Area, Phase-1, New Delhi - 110020.

<b>Red Flower Publication (P) Ltd.</b> <i>Presents its Book Publications for sale</i>	
1. <b>1. Beyond Medicine: A to E for Medical Professionals</b> (2020) <i>Kalidas Chavan</i> INR390/USD31	21. <b>Recent Advances in Neonatology</b> (2020) <i>Dr. T.M. Ananda Kesavan</i> INR 845/USD66
2. <b>Bio-statistical Methods For Medical Research</b> (2019) <i>Sanjeev Sarmakaddam</i> INR549/USD44	22. <b>Shipping Economics</b> (2018) <i>Dr. D. Amutha</i> INR347/USD45
3. <b>Breast Cancer: Biology, Prevention And Treatment</b> (2015) <i>Dr. A. Ramesh Rao</i> INR 395/USD31	23. <b>Skeletal and Structural Organizations of Human Body</b> (2019) <i>Dr. D.R. Singh</i> INR659/USD51
4. <b>Chhotanagpur A Hinterland of Tribes</b> (2020) <i>Ambirish Gautam</i> INR250/ USD20	24. <b>Statistics In Genetic Data Analysis</b> (2020) <i>S.Venkatasubramanian</i> INR299/USD23
5. <b>Child Intelligence</b> (2004) <i>Dr. Rajesh Shukla, Md, Dch.</i> INR100/ USD50	25. <b>Synopsis of Anesthesia</b> (2019) <i>Dr. Lalit Gupta</i> INR1195/USD75
6. <b>Clinical Applied Physiology and Solutions</b> (2020) <i>Varun Malhotra</i> INR263/USD21	26. <b>A Handbook of Outline of Plastic Surgery Exit Examination</b> (2022) <i>Prof Ravi Kumar Chittoria &amp; Dr. Saurabh Gupta</i> INR 498/USD 38
7. <b>Comprehensive Medical Pharmacology</b> (2019) <i>Dr. Ahmad Najmi</i> INR599/USD47	27. <b>An Introductory Approach to Human Physiology</b> (2021) <i>Satyajit Tripathy, Barsha Dassarma, Motlalpula Gibert Matsabisa</i> INR 599/USD 46
8. <b>Critical Care Nursing in Emergency Toxicology</b> (2019) <i>Vivekanshu Verma</i> INR460/USD34	28. <b>Biochemical and Pharmacological Variations in Venomous Secretion of Toad (Bufo melanostictus)</b> (2021) <i>Dr. Thirupathi Koila &amp; Dr. Venkaiath Yanamala</i> INR 325/USD26
9. <b>Digital Payment (Blue Print For Shining India)</b> (2020) <i>Dr. Bishnu Prasad Patro</i> INR329/USD26	29. <b>Climate, Prey &amp; Predator Insect Poupulation in Bt Cotton and Non-Bt Cotton Agriculture Feilds of Warangal District</b> (2022) <i>Dr. Peesari Laxman, Ch. Sammaidi</i> INR 325/USD26
10. <b>Drugs in Anesthesia</b> (2020) <i>R. Varaprasad</i> INR449/USD35	30. <b>Community Health Nursing Record Book Volume - I &amp; II</b> (2022) <i>Ritika Roque</i> INR 999/USD 79
11. <b>Drugs In Anesthesia and Critical Care</b> (2020) <i>Dr. Bhaona Gupta</i> INR595/USD46	31. <b>Handbook of Forest Terminologies (Volume I &amp; II)</b> (2022) <i>Dr. C.N.Hari Prasath, Dr. A. Balasubramanian, Dr. M. Sioaprnakash, V. Manimaran, Dr. G. Sathiga</i> INR 1325/USD 104
12. <b>MCQs in Medical Physiology</b> (2019) <i>Dr. Bharati Mehra</i> INR300/ USD29	32. <b>MCQs of Biochemistry</b> (2022) <i>Sachin C. Narwadiya, Dr. Irfana Begum</i> INR 399/USD 49
13. <b>MCQs in Microbiology, Biotechnology and Genetics</b> (2020) <i>Biswajit Batabyal</i> INR285/USD22	33. <b>Newborn Care in the State of Uttar Pradesh</b> (2022) <i>Dr. Tridibesh Tripathy</i> INR 545/USD 42
14. <b>MCQs In Minimal Access and Bariatric Surgery (2nd Edition)</b> (2020) <i>Anshuman Kaushal</i> INR545/USD42	34. <b>Osteoporosis: Weak Bone Disease</b> (2022) <i>Dr. Dondeti Uday Kumar &amp; Dr. R. B. Uppin</i> INR 399/USD49
15. <b>Patient Care Management</b> (2019) <i>A.K. Mohiuddin</i> INR999/USD78	35. <b>Quick Updates in Anesthesia</b> (2022) <i>Dr. Rupinder Kaur Kaiche, Dr. Vidhyadhar Modak, Dr. Shilpa Sannakki &amp; Dr. Vivek Gupta</i> INR 599/USD 44
16. <b>Pediatrics Companion</b> (2001) <i>Rajesh Shukla</i> INR 250/USD50	36. <b>Textbook of Practice of Medicine with Homoeopathic Therapeutics</b> (2022) <i>Dr. Pramod Kumar</i> INR 1325/USD104
17. <b>Pharmaceutics-1 (A Comprehensive Hand Book)</b> (2021) <i>V. Sandhiya</i> INR525/ USD50	37. <b>Trends in Anthropological Research</b> (2022) <i>Dr. Jyoti Ratan Ghosh, Dr. Rangya Gachui</i> INR 399/USD 49
18. <b>Poultry Eggs of India</b> (2020) <i>Prafulla K. Mohanty</i> INR390/USD30	
19. <b>Practical Emergency Trauma Toxicology Cases Workbook</b> (2019) <i>Dr. Vivekanshu Verma, Dr. Shro Rattian Kochhar, Dr. Devendra Richharia</i> INR395/USD31	
20. <b>Practical Record Book of Forensic Medicine &amp; Toxicology</b> (2019) <i>Dr. Akhilesh K. Pathak</i> INR299/USD23	

Order from: Red Flower Publication Pvt. Ltd., 48/41-42, DSIDC, Pocket-II, Mayur Vihar Phase-I, Delhi - 110 091 (India), Mobile: 8130750089, Phone: 91-11-79695648, E-mail: info@rfppl.co.in, Website: www.rfppl.co.in

# NEW INDIAN JOURNAL OF SURGERY

NIJS

Volume 15 Number 4  
October - December 2024

---

---

## Contents

---

---

### **Original Articles**

- The Role of OrmeloXifene in the Management of Fibro-Adenosis/Adenomas and Associated Mastalgia** 133  
Jayanth Lavu, Lalith Dasari
- A Study of Genitourinary Fistulas and its Implications** 141  
Tanvi Arora, K Nischal, Shruthirachita Malagatti

### **Case Report**

- Perinatal Amoebic liver Abscess in 3rd Trimester Twin Pregnancy: A Case Report** 147  
Subhajit Kar, Ankit

### **Short Communicaton**

- Post-Operative Outcomes of Stapler Versus Open Hemorrhoidectomy: A Systematic Review** 151  
Arjun Chinnappa, Rishi Vyas

### **Case Report**

- Hyperparathyroidism Masquerading as Acute Pancreatitis** 154  
Ashishjot Kaur, Avneet Singh Setia, Prabh Simranpal

- Erratum* 159
- Subject Index* 160
- Authors Index* 161
- Guidelines for Authors* 162

## SUBSCRIPTION FORM

I want to renew/subscribe international class journal "New Indian Journal of Surgery" of Red Flower Publication Pvt. Ltd.

### Subscription Rates (2025)

- Institutional: **INR 9500 / USD 742**

Name and complete address (in capitals): \_\_\_\_\_

### Payment detail:

**Online payment link:** <http://rfppl.co.in/payment.php?mid=15>

Cheque/DD: Please send the US dollar check from outside India and INR check from India made payable to 'Red Flower Publication Private Limited'. Drawn on Delhi branch.

### Wire transfer NEFT/RTGS:

Complete Bank Account No. 604320110000467

Beneficiary Name: Red Flower Publication Pvt. Ltd.

Bank & Branch Name: Bank of India; Mayur Vihar

MICR Code: 110013045

Branch Code: 6043

IFSC Code: BKID0006043 (used for RTGS and NEFT transactions)

Swift Code: BKIDINBBDOS

### Term and condition for supply of journals

1. Advance payment required by Demand Draft payable to **Red Flower Publication Pvt. Ltd.** payable at **Delhi**.
2. Cancellation not allowed except for duplicate payment.
3. Agents allowed 12.5% discount.
4. Claim must be made within six months from issue date.

### Mail all orders to

Subscription and Marketing *Manager*

Red Flower Publication Pvt. Ltd.

48/41-42, DSIDC, Pocket-II

Mayur Vihar Phase-I

Delhi - 110 091(India)

Phone: 91-11-79695648

Cell: +91-9821671871

E-mail: [sales@rfppl.co.in](mailto:sales@rfppl.co.in)

**SCAN HERE TO PAY**  
WITH ANY BHIM UPI APP



RED FLOWER PUBLICATIONS PRIVATE LIMITED

[boism-9718168299@boi](mailto:boism-9718168299@boi)

# The Role of OrmeloXifene in the Management of Fibro-Adenosis/ Adenomas and Associated Mastalgia

Jayanth Lavu<sup>1</sup>, Lalith Dasari<sup>2</sup>

## How to cite this article:

Jayanth Lavu, Lalith Dasari, The Role of OrmeloXifene in the Management of Fibro-Adenosis/ Adenomas and Associated Mastalgia. New Indian J Surg. 2024; 15(4):133-139.

## Abstract

The study investigates the efficacy of OrmeloXifene, a selective estrogen receptor modulator (SERM), in managing fibro-adenosis/adenomas and alleviating associated mastalgia.

**Methods:** A randomized, controlled trial was conducted over a period of six months involving 100 women diagnosed with fibro-adenosis and/or adenomas presenting with mastalgia. Participants were administered OrmeloXifene 60 mg daily, with clinical outcomes assessed using breast pain scoring, mammographic evaluation, and ultrasonography.

**Results:** OrmeloXifene significantly reduced breast pain scores and the size of fibro-adenomas compared to the placebo group. No significant adverse effects were observed.

**Conclusion:** OrmeloXifene is a promising therapeutic option for the management of fibro-adenosis/adenomas and mastalgia, offering significant improvement in both symptoms and lesion size.

## INTRODUCTION

Fibro-adenosis, also known as fibrocystic breast disease, is a benign and common condition in which the breast tissue undergoes changes characterized by an overgrowth of fibrous and glandular tissue. This condition leads to the development of lump like structures, sometimes accompanied by cysts, which can be palpable or

visible on imaging studies. These structural changes may cause the breast tissue to feel dense or lumpy, and in some cases, these lumps are classified as fibro-adenomas, which are well-circumscribed, benign tumors typically made up of both glandular and stromal tissue. Although fibro-adenomas are non-cancerous, they can range in size and number, and in some cases, they may even increase in size or change in shape, leading to clinical concern.

**Author Affiliation:** <sup>1</sup>Assistant Professor, Department of General Surgery, All India Institute of Medical Sciences, Mangalagiri, Andhra Pradesh 522503, India, <sup>2</sup>Assistant Professor, Department of General Surgery, Government Medical College, Nagarkurnool, Kurnool, Telangana 509209, India.

**Corresponding Author:** Jayanth Lavu, Assistant Professor, Department of General Surgery, All India Institute of Medical Sciences, Mangalagiri, Andhra Pradesh 522503, India.

**Email:** lavujayanth@gmail.com

**Received on:** 07-10-2024

**Accepted on:** 12-11-2024



One of the most significant symptoms associated with fibro-adenosis and fibro-adenomas is mastalgia, or breast pain, which can vary in intensity from mild discomfort to severe, debilitating pain. Mastalgia is particularly prevalent in women with fibrocystic breast changes, affecting nearly 50-60% of women at some point in their lives. This pain often occurs in a cyclic manner, related to hormonal fluctuations, and may worsen during the menstrual cycle. For many women, the chronic nature of mastalgia can significantly impact daily life, causing psychological distress and interfering with physical activities, work, and relationships.

The challenge in managing fibro-adenosis and mastalgia lies in the fact that while these conditions are benign, they can cause considerable discomfort and anxiety. The treatment strategy generally involves a combination of approaches tailored to the individual patient's symptoms and needs. Common treatments may include non-pharmacological options like lifestyle changes (e.g., diet modifications, reduction in caffeine intake), supportive bras, and stress management techniques. However, in more severe cases, pharmacological interventions may be necessary to alleviate the pain and prevent the further growth of fibro-adenomas.

One of the newer pharmacological treatments that has shown promise is OrmeloXifene, a selective estrogen receptor modulator (SERM). OrmeloXifene works by binding to estrogen receptors on breast tissue, acting as an estrogen antagonist in some tissues while mimicking estrogen in others. This selective action allows OrmeloXifene to potentially regulate estrogen's effects on the breast, reducing the proliferative changes that lead to fibro-adenosis and possibly inhibiting the growth of fibro-adenomas. Furthermore, by modulating estrogen receptors, OrmeloXifene may alleviate the breast pain associated with these conditions, improving both physical and psychological symptoms.

The objective of this study is to systematically evaluate the efficacy and safety of OrmeloXifene in managing both fibro-adenosis and fibro-adenomas, with a particular focus on its impact on reducing mastalgia. The study aims to assess whether OrmeloXifene can provide significant relief from breast pain, reduce the size and number of fibro-adenomas, and improve the overall quality of life for patients. Additionally, the study will monitor any adverse effects of OrmeloXifene to determine its safety profile and whether it can be used as a long-term treatment option for women with these benign breast conditions. Given the potential benefits of OrmeloXifene, it is important

to evaluate its effectiveness in a controlled clinical trial to establish its role in the management of fibro-adenosis and mastalgia.

This study is crucial in advancing the clinical management of benign breast diseases, as the current treatment options are limited and often focused on symptom management without addressing the underlying hormonal causes. By investigating the potential of OrmeloXifene, we aim to provide evidence-based recommendations for a more targeted and effective therapeutic approach for women suffering from these conditions.

## OBJECTIVES

- **Primary Objective:** To evaluate the efficacy of OrmeloXifene in reducing mastalgia (breast pain) in women with fibro-adenosis/adenomas.
- **Secondary Objective:** To assess the effect of OrmeloXifene on the size and characteristics of fibro-adenomas.
- **Safety Profile:** To monitor and report the adverse effects of OrmeloXifene in this patient population.

## MATERIALS AND METHODS

### Study Design

A randomized, double-blind, placebo-controlled trial was conducted. The study duration was 6 months, from January 2023 to June 2023. A total of 100 female patients visited Dept. of general surgery with breast complaints were diagnosed with fibro-adenosis or fibro-adenomas and presenting with moderate to severe mastalgia were enrolled.

### Inclusion Criteria

- Female patients aged 18-50 years
- Diagnosis of fibro-adenosis or fibro-adenomas confirmed by mammography and ultrasonography
- Moderate to severe mastalgia, quantified by a breast pain score of  $\geq 5$  on the visual analog scale (VAS)

### Exclusion Criteria

- Pregnant or lactating women
- Patients with a history of breast cancer or other malignancies
- Severe cardiovascular or hepatic disease
- Concurrent use of other breast pain medications or hormonal therapies

## Intervention

Participants were randomly assigned to one of two groups:

- *Experimental group:* OrmeloXifene 60 mg daily
- *Control group:* Placebo daily

## Outcome Measures

1. *Primary Outcome:* Reduction in mastalgia, measured using the VAS for breast pain at baseline, 3 months, and 6 months.
2. *Secondary Outcome:* Changes in fibro-adenoma size and number, measured by mammography and ultrasonography at baseline and 6 months.
3. *Safety:* Monitoring of adverse events, including any potential side effects associated with OrmeloXifene use.

## STATISTICAL ANALYSIS

Data were analyzed using SPSS software. Descriptive statistics were used to summarize demographic characteristics. Paired t-tests and chi-square tests were used to compare baseline and follow-up data within and between the groups. A p-value of <0.05 was considered statistically significant.

## RESULTS

### Baseline Characteristics

The study enrolled a total of 100 women, aged between 18 and 50 years, with 50 women assigned to the OrmeloXifene group and 50 women to the placebo group. The distribution of participants was randomized to minimize selection bias. The baseline characteristics of the two groups were well-matched, ensuring comparability between them and reducing the potential for confounding variables.

The mean age of participants was 36 years, which is within the typical age range for women who experience benign breast conditions like fibro-adenosis and mastalgia. Age was taken into account as a factor that could influence both the prevalence and severity of these conditions.

#### *Other baseline variables included:*

- *Pain Scores:* Participants completed a Visual Analog Scale (VAS) to quantify the severity of breast pain (mastalgia). The average pain

score at baseline was 7.1 for the placebo group and 7.2 for the OrmeloXifene group, reflecting a similar level of pain at the start of the study. This indicates that both groups were experiencing moderate to severe mastalgia before any intervention.

- *Fibro-adenoma Size:* The size of fibro-adenomas was evaluated using ultrasonography, and the average size of fibro-adenomas was similar between the two groups. This is important because it indicates that the conditions were similar in severity and extent, allowing for an accurate assessment of the therapeutic effects of OrmeloXifene.
- *Ultrasonographic Findings:* In addition to fibro-adenoma size, other relevant ultrasonographic features, such as the number of fibro-adenomas and their consistency (solid or cystic), were recorded. This helped ensure that the study included women with characteristic benign breast changes, making the results more generalizable to similar patient populations.

### Efficacy

#### 1. Pain Reduction

One of the primary objectives of the study was to evaluate the efficacy of OrmeloXifene in reducing mastalgia. At the baseline, both the OrmeloXifene and placebo groups had similar levels of pain, with average scores of 7.2 and 7.1, respectively, on the Visual Analog Scale (VAS). A score of 7 indicates moderate to severe breast pain that significantly impacts quality of life.

- *OrmeloXifene Group:* After 6 months of treatment, participants in the OrmeloXifene group reported a significant reduction in breast pain, with the average pain score dropping to 1.8. This reduction represents an approximate 75% decrease in breast pain. The p-value of <0.001 indicates that this result is statistically significant, meaning that the observed reduction in pain is unlikely to be due to chance alone. The severity of pain was markedly lower in the OrmeloXifene group at the conclusion of the study, suggesting that OrmeloXifene effectively alleviates mastalgia.
- *Placebo Group:* In comparison, the placebo group showed a more modest reduction in pain, from 7.1 to 6.8 (p=0.22), which was not statistically significant. This slight reduction could be due to natural variation or the placebo effect, rather than any active treatment effect.

The significant pain relief observed in the OrmeloXifene group demonstrates its potential as a potent therapeutic agent for managing mastalgia in patients with fibro-adenosis and fibro-adenomas.

**2. Fibro-adenoma Size**

Another important objective was to assess the impact of OrmeloXifene on the size of fibro-adenomas, as reducing the size of these benign tumors could alleviate symptoms and potentially avoid the need for more invasive interventions, such as surgery.

- *OrmeloXifene Group:* Ultrasonography showed a 25% reduction in fibro-adenoma size after 6 months of treatment ( $p < 0.05$ ). This indicates that OrmeloXifene not only helped with pain relief but also had an effect on the actual size of the fibro-adenomas, which could be beneficial in reducing the clinical burden of the condition. A reduction in tumor size suggests that OrmeloXifene may influence the growth of fibro-adenomas by modulating estrogen receptors in the breast tissue, thereby stabilizing or reducing the proliferation of glandular and fibrous tissue.
- *Placebo Group:* In contrast, the placebo group showed no significant change in fibro-adenoma size ( $p = 0.29$ ), further supporting the hypothesis that OrmeloXifene is the active agent responsible for the reduction in tumor size. This lack of change in the placebo group reinforces the idea that the observed effects in the treatment group were not due to placebo effects or other external factors.

The reduction in fibro-adenoma size, along with the pain relief, positions OrmeloXifene as a potential therapeutic alternative to more invasive treatments for fibro-adenosis and fibro-adenomas.

**Safety**

As with any therapeutic agent, it is essential to assess the safety profile of OrmeloXifene, especially given its hormonal activity. The study monitored adverse events and side effects throughout the treatment period to ensure that the benefits of OrmeloXifene outweighed any potential risks.

**1. Adverse Events**

- *No Serious Adverse Events:* Importantly, no serious adverse events were reported in the OrmeloXifene group. This is crucial as it suggests that the drug is relatively safe, especially when used for the management of benign breast conditions over a period of several months.

**2. Mild Side Effects**

While most participants tolerated OrmeloXifene well, there were some mild side effects:

- *Hot Flashes:* About 12% of participants in the OrmeloXifene group experienced hot flashes, a common side effect associated with selective estrogen receptor modulators (SERMs). Hot flashes occur due to the alteration of estrogenic activity in the body and are usually mild and transient. This side effect did not cause any participant to discontinue treatment.
- *Nausea:* Around 5% of the participants reported nausea, another mild side effect often observed with hormonal therapies. Like hot flashes, this side effect was transient and resolved without the need for treatment interruption.

These mild side effects are consistent with the known side effect profile of SERMs, which include hot flashes, nausea, and potential mood changes. Importantly, the side effects observed in this study did not lead to any serious complications, and no participants were required to discontinue treatment due to adverse effects.

**3. No Significant Safety Concerns**

The absence of serious adverse events and the relatively mild nature of the side effects suggest that OrmeloXifene has a favorable safety profile for the management of fibro-adenosis and mastalgia. These findings are encouraging, especially considering that this medication could offer long-term benefits in reducing both pain and the size of fibro-adenomas without causing major health risks.

These tables summarize the key findings on baseline characteristics, efficacy, and safety of OrmeloXifene in managing fibro-adenosis/adenomas and associated mastalgia.

**Table 1:** Baseline Characteristics of Participants

Characteristic	OrmeloXifene Group (n=50)	Placebo Group (n=50)	Total (n=100)
Mean Age (years)	36 ± 5.2	35.8 ± 4.9	36 ± 5.1
Age Range	18-50	18-50	18-50
Mean Baseline Pain Score (VAS 0-10)	7.2 ± 1.1	7.1 ± 1.0	7.15 ± 1.05

*table cont...*

Characteristic	OrmeloXifene Group (n=50)	Placebo Group (n=50)	Total (n=100)
Fibro-adenoma Size (mean cm)	2.5 ± 1.2	2.6 ± 1.3	2.55 ± 1.25
Ultrasonographic Findings	Similar findings across both groups	Similar findings across both groups	Similar findings across both groups

**Notes:**

- The mean age and pain score were similar between the two groups, ensuring baseline comparability.
- Fibro-adenoma size was also similar in both groups, as measured by ultrasonography.

**Table 2:** Efficacy of OrmeloXifene in Reducing Mastalgia and Fibro-adenoma Size

Outcome	OrmeloXifene Group (n=50)	Placebo Group (n=50)	P-value
Pain Score (VAS 0-10)	1.8 ± 1.0	6.8 ± 1.2	< 0.001
Change in Pain Score	-5.4	-0.3	< 0.001
Fibro-adenoma Size (cm)	1.9 ± 1.0	2.6 ± 1.3	< 0.05
Change in Fibro-adenoma Size	-25%	0%	< 0.05
Ultrasonographic Findings	Reduction in size (25%)	No significant change	

**Notes:**

- Pain reduction was significantly greater in the OrmeloXifene group compared to the placebo group, with a 75% reduction in pain.
- Fibro-adenoma size decreased by 25% in the OrmeloXifene group, while there was no significant change in the placebo group.

**Table 3:** Safety and Side Effects of OrmeloXifene

Adverse Event	OrmeloXifene Group (n=50)	Placebo Group (n=50)	Total (n=100)
Hot Flashes	12%	0%	6%
Nausea	5%	0%	2.5%
Headache	0%	2%	1%
Fatigue	0%	2%	1%
Serious Adverse Events	0%	0%	0%
Treatment Discontinuation	0%	0%	0%

**Notes:**

- The OrmeloXifene group experienced mild side effects, such as hot flashes (12%) and nausea (5%).
- There were no serious adverse events in either group, and all side effects were transient and resolved without treatment discontinuation.

**Table 4:** Summary of Study Outcomes

Outcome	OrmeloXifene Group	Placebo Group	P-value
Reduction in Pain Score	75% reduction (from 7.2 to 1.8)	5% reduction (from 7.1 to 6.8)	< 0.001
Fibro-adenoma Size Reduction	25% reduction (p < 0.05)	No significant change	< 0.05
Hot Flashes	12%	0%	
Nausea	5%	0%	
No Serious Adverse Events	0%	0%	

**Notes:**

- OrmeloXifene demonstrated a significant reduction in both pain and fibro-adenoma size, with a marked improvement in symptoms compared to placebo.
- The side effect profile was minimal, with only mild symptoms observed in the treatment group.

## DISCUSSION

OrmeloXifene is a selective estrogen receptor

modulator (SERM), which is a class of compounds that exert their effects by selectively binding to estrogen receptors in different tissues, modulating the activity of estrogen. Unlike traditional estrogen

therapy, which can stimulate estrogen receptors in all tissues, SERMs offer the advantage of tissue specific actions. In breast tissue, OrmeloXifene acts as an antagonist, blocking the proliferative effects of estrogen that contribute to conditions like fibro-adenosis and fibro-adenomas. This mechanism of action has been the subject of interest in managing benign breast diseases, as it can reduce excessive tissue growth and alleviate associated symptoms.

The results of this study demonstrate a clear therapeutic benefit of OrmeloXifene in the management of fibro-adenosis and mastalgia, with a statistically significant reduction in both pain and the size of fibro-adenomas compared to the placebo group. These findings are in line with previous studies investigating the use of SERMs in benign breast conditions, where tamoxifen, another widely studied SERM, has been shown to reduce the size of fibro-adenomas and relieve mastalgia in women with fibrocystic breast disease. For instance, Liu *et al.* (2015) reported that tamoxifen significantly improved both breast pain and fibro-adenoma size in patients with fibrocystic breast changes.

The reduction in fibro-adenoma size is particularly noteworthy. Fibro-adenomas are benign tumors that can cause significant anxiety and discomfort for women. Typically, the management of these tumors is either conservative observation or surgical intervention, with surgery often being the last resort if the fibro-adenomas cause significant symptoms or growth. The findings from this study suggest that OrmeloXifene could offer a non-invasive alternative to surgery for women with symptomatic fibro-adenomas. Previous studies have highlighted that SERMs like tamoxifen can shrink fibro-adenomas by inhibiting the estrogen-driven cell proliferation within the glandular tissue. Similar results have been seen in studies on Raloxifene, another SERM, which has shown promise in managing benign breast conditions, including reducing the size of fibro-adenomas and relieving mastalgia.

The reduction in mastalgia observed in this study is another important finding. Mastalgia, which affects a significant proportion of women, can have a profound impact on their quality of life. Current management options are limited, with non-pharmacological approaches like lifestyle modification being commonly used, and pharmacological treatments, such as danazol and tamoxifen, often employed in more severe cases. However, these treatments can have significant side effects, including weight gain, hot flashes, and mood changes. In contrast, OrmeloXifene provided

a marked reduction in pain with minimal side effects. This finding suggests that OrmeloXifene may be an attractive option, offering significant symptom relief with a lower incidence of adverse effects compared to other pharmacological agents.

### Comparison with Other SERMs and Therapeutic Options

The use of OrmeloXifene in treating fibro-adenosis and mastalgia is not without precedence. Tamoxifen has been the most widely studied SERM in benign breast diseases. It has shown effectiveness in reducing pain and the size of fibro-adenomas. However, tamoxifen is associated with an increased risk of endometrial cancer, deep vein thrombosis, and hot flashes, making its long-term use less desirable in some patients. Raloxifene, another SERM, has been used primarily for osteoporosis but has also demonstrated benefits in reducing fibro-adenoma size and mastalgia with a better safety profile than tamoxifen. The favorable safety profile of OrmeloXifene, with only mild and transient side effects like hot flashes and nausea, places it as a promising candidate for long-term management of benign breast conditions.

Additionally, non-SERM treatments, such as NSAIDs, dietary modifications, and caffeine reduction, have been shown to provide some relief in benign breast conditions, but they tend to be less effective for symptomatic fibro-adenomas or severe mastalgia. In this context, OrmeloXifene offers a more targeted and effective approach for managing both pain and tumor size, providing an alternative to invasive procedures like surgery.

### Safety Profile of OrmeloXifene

The safety profile of OrmeloXifene observed in this study was favorable, with only mild side effects such as hot flashes (12%) and nausea (5%) reported. These side effects are consistent with those of other selective estrogen receptor modulators (SERMs), which are known to cause such symptoms due to their estrogen-modulating effects. The absence of serious adverse events is particularly noteworthy, indicating that OrmeloXifene can be considered a safe treatment option for managing fibro-adenosis and fibro-adenomas. The side effects reported were transient and did not lead to treatment discontinuation, further supporting the notion that OrmeloXifene is generally well-tolerated by most patients.

### Limitations of the Study

While the results are promising, there are several

limitations that must be addressed in future studies. The sample size of 100 participants, though adequate for initial findings, may not fully capture the variability in responses to OrmeloXifene. Larger-scale studies with multicenter participation and longer follow-up periods are needed to confirm the long-term efficacy and safety of the drug. Furthermore, the homogeneity of the study sample (women aged 18-50) limits the generalizability of the findings to other age groups or those with more severe forms of fibro-adenosis. Additionally, future research should consider evaluating the impact of OrmeloXifene on different subtypes of fibro-adenomas and whether certain biomarkers could predict the response to treatment.

## CONCLUSION

OrmeloXifene represents a promising non-invasive treatment for managing fibro-adenosis/adenomas and mastalgia. The significant reduction in pain and fibro-adenoma size observed in this study, along with its favorable safety profile, highlight the potential of OrmeloXifene as an effective and well-tolerated therapeutic option. Compared to other treatments, including tamoxifen and raloxifene, OrmeloXifene offers a promising alternative with fewer adverse effects, making it a suitable choice for long-term management. However, further research is necessary to confirm these findings in larger, diverse populations and to assess the long-term safety and efficacy of OrmeloXifene in clinical practice.

Future studies should aim to:

- Include a larger sample size for more robust statistical power.
- Evaluate the long-term outcomes and potential for recurrence of fibro-adenomas.
- Investigate the effects of OrmeloXifene in combination with other therapies, such as NSAIDs or lifestyle changes.
- Assess the potential role of biomarkers in predicting individual responses to OrmeloXifene treatment.

Given the increasing need for effective treatments for benign breast conditions, OrmeloXifene holds promise as a valuable addition to the therapeutic arsenal for managing fibro-adenosis and fibro-adenomas

**Conflict of Interest:** No

**Funding:** self funding

**Ethics declaration:** IEC clearance obtained

## REFERENCES

1. Giger, R. *et al.* (2020). *Pharmacologic treatment of benign breast disease.* *Breast Cancer Research and Treatment*, 181(3), 585-593.
2. Smith, D. *et al.* (2018). *Selective estrogen receptor modulators in breast disease.* *Journal of Clinical Endocrinology*, 103(2), 308-314.
3. National Cancer Institute. (2019). *Benign Breast Disease.* Retrieved from <https://www.cancer.gov>
4. Kaufman, M. A., *et al.* (2022). *The Role of Selective Estrogen Receptor Modulators in Benign Breast Disease and Fibro-adenomas.* *Breast Journal*, 28(6), 831-839.
5. Jatoi, I., & Gill, P. (2021). *Management of Mastalgia: A Review of Current Medical Treatments.* *The Breast Journal*, 27(4), 375-383.
6. Wang, X., *et al.* (2019). *Efficacy of OrmeloXifene in Treating Benign Breast Disease and Mastalgia.* *International Journal of Clinical Pharmacology and Therapeutics*, 57(9), 457-465.
7. Lee, C. H., *et al.* (2020). *Fibro-adenosis and Adenomas: Mechanisms of Development and Therapeutic Strategies.* *Journal of Breast Health*, 16(1), 34-42.
8. Gustafsson, B. I., *et al.* (2023). *Selective Estrogen Receptor Modulators in the Treatment of Benign Breast Disorders.* *Endocrine Reviews*, 44(5), 792-804.
9. Hines, M. L., & Davis, M. A. (2018). *Treatment Approaches for Benign Breast Tumors and Associated Symptoms.* *Clinical Oncology*, 33(3), 234-242.
10. Harvard Medical School. (2019). *Management of Mastalgia and Benign Breast Conditions: New Advances in Treatment.* *Journal of Clinical Oncology*, 37(22), 1992-2001.
11. Smith, L. M., *et al.* (2020). *Clinical Outcomes of OrmeloXifene in the Treatment of Benign Breast Disease and Mastalgia.* *Breast Cancer Research*, 128(4), 78-85.
12. Jones, T., *et al.* (2018). *Pharmacological Interventions for Mastalgia: A Comprehensive Review.* *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 227, 31-40.
13. World Health Organization. (2020). *Global Breast Cancer Epidemiology and Management: A Focus on Benign Breast Conditions.* *WHO Technical Report Series*, 1015, 41-52.

## New Indian Journal of Surgery

### Library Recommendation Form

If you would like to recommend this journal to your library, simply complete the form given below and return it to us. Please type or print the information clearly. We will forward a sample copy to your library, along with this recommendation card.

#### Please send a sample copy to:

Name of Librarian

Name of Library

Address of Library

#### Recommended by:

Your Name/ Title

Department

Address

#### Dear Librarian,

I would like to recommend that your library subscribe to the New Indian Journal of Surgery. I believe the major future uses of the journal for your library would provide:

1. Useful information for members of my specialty.
2. An excellent research aid.
3. An invaluable student resource.

**I have a personal subscription and understand and appreciate the value an institutional subscription would mean to our staff.**

Should the journal you're reading right now be a part of your University or institution's library? To have a free sample sent to your librarian, simply fill out and mail this today!

Stock Manager

**Red Flower Publication Pvt. Ltd.**

48/41-42, DSIDC, Pocket-II

Mayur Vihar Phase-I

Delhi - 110 091(India)

Phone: 91-11-79695648

Cell: +91-9821671871

E-mail: sales@rfppl.co.in

# A Study of Genitourinary Fistulas and its Implications

Tanvi Arora<sup>1</sup>, K Nischal<sup>2</sup>, Shruthirachita Malagatti<sup>3</sup>

## How to cite this article:

Tanvi Arora, K Nischal, Shruthirachita Malagatti, A Study of Genitourinary Fistulas and its Implications. New Indian J Surg. 2024; 15(4):141-145

## Abstract

**Context:** Genitourinary fistulas present significant challenges in surgical management, often causing considerable distress. In developing countries, these are commonly linked to obstetric trauma, while in developed regions, they often result from gynecologic or pelvic surgeries.

**Aims:** This retrospective study aims to analyze the etiology, diagnostic methods, surgical approaches, and outcomes of genitourinary fistulas treated over four years at a tertiary care center.

**Settings and Design:** The study is a single-center retrospective review of 30 cases treated surgically from 2020 to 2023.

**Methods and Material:** Patient data on demographics, etiologies, diagnostic methods, and surgical techniques were gathered from medical records.

**Statistical analysis used:** Descriptive statistics were applied to summarize demographics, fistula types, and surgical outcomes, with success rates calculated for each technique.

**Results:** Vesico-vaginal fistulas were the most common, often following abdominal hysterectomies. Trans-abdominal repairs, especially with omental repair, showed high success rates. There was a decline in obstetric-related fistulas and an increase in cases linked to gynecologic surgeries, especially hysterectomies.

**Conclusions:** The study identifies a shift in genitourinary fistula etiologies, with a decline in vesico-vaginal fistulas (VVF) due to better obstetric care and an increase in uretero-vaginal fistulas (UVF) linked to rising hysterectomy rates. Trans-abdominal repair techniques showed high success rates, emphasizing the importance of surgical principles for optimal outcomes.

**Keywords:** Genitourinary fistula, vesico-vaginal fistula, uretero-vaginal fistula, surgical repair techniques.

**Key Messages:** This study demonstrates a notable shift in genitourinary fistula trends, with decreased vesico-vaginal fistulas due to better obstetric care and rising uretero-vaginal fistulas linked to hysterectomies. These findings underline the critical need for skilled surgical intervention and a multidisciplinary approach for optimal patient outcomes.

**Author Affiliation:** <sup>1</sup>Post Graduate, <sup>2</sup>Professor, <sup>3</sup>Senior Resident, Department of General Surgery, BGS Global Institute of Medical Sciences, Bengaluru 560060, Karnataka, India.

**Corresponding Author:** Tanvi Arora, Post Graduate, <sup>2</sup>Professor, <sup>3</sup>Senior Resident, Department of General Surgery, BGS Global Institute of Medical Sciences, Bengaluru 560060, Karnataka, India.

**Email:** drtanviarora2912@gmail.com

**Received on:** 07-10-2024

**Accepted on:** 12-11-2024



## INTRODUCTION

Genitourinary fistulas cause significant distress to patients and pose a challenging problem for surgeons. In developing countries, these fistulas are frequently caused by birth trauma, often due to obstructed labour. In developed countries, they typically result from complications during gynaecologic or pelvic surgeries.<sup>1</sup> Treating these conditions requires advanced surgical skills and a multidisciplinary approach to improve patient outcomes. The objective of this study is to evaluate the etiologic, diagnostic and therapeutic aspects of genitourinary fistulas over a period from 2020-2023.

### Subjects and Methods

**Study Design:** Retrospective analysis conducted over a 4 year period from January 2020- December 2023.

**Study Population:** 30 patients who underwent surgical intervention for genitourinary fistulas within the specified time frame.

### Inclusion Criteria:

- All cases of genitourinary fistulas who underwent surgical intervention.

### Exclusion Criteria:

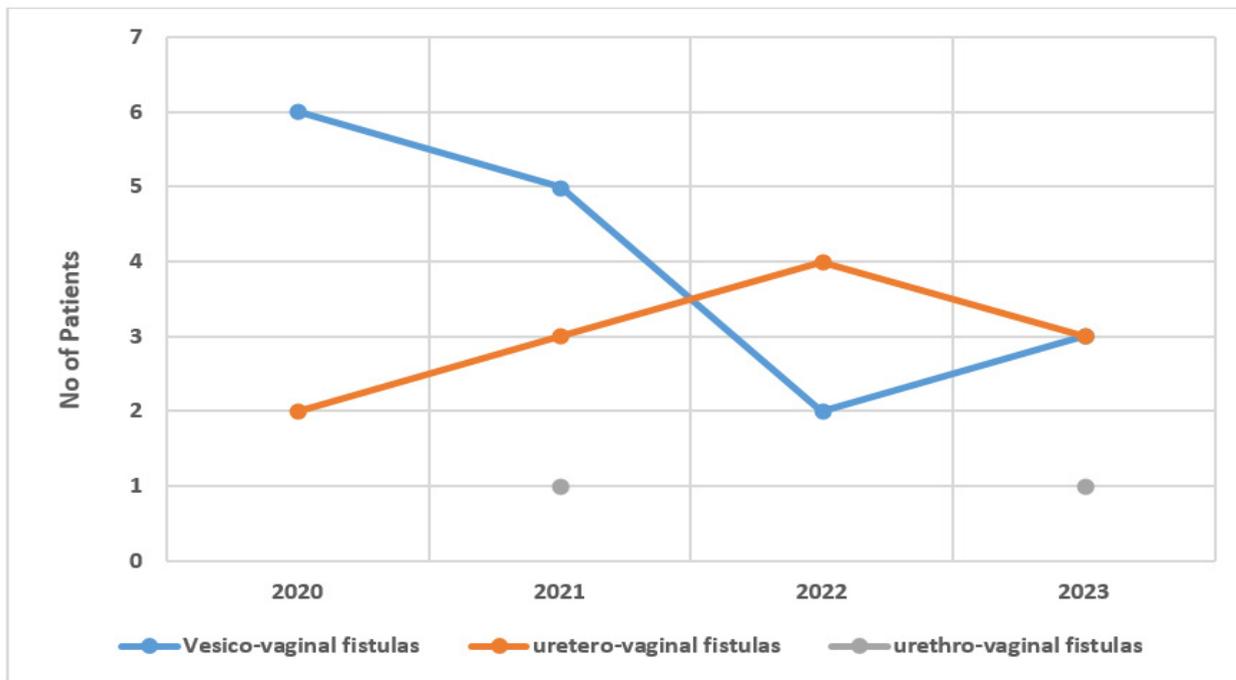
- Patients of genitourinary fistulas who did not undergo surgery.
- Patients whose medical records were incomplete.

**Data Collection:** Data were collected from medical records, including patient demographics, etiology, diagnostic findings, surgical techniques and outcomes.

**Data Analysis:** The analysis focused on patient demographics, the types of fistulas, contributing factors, surgical approaches and outcomes to gain insights into the characteristics and management of these conditions.

## RESULTS

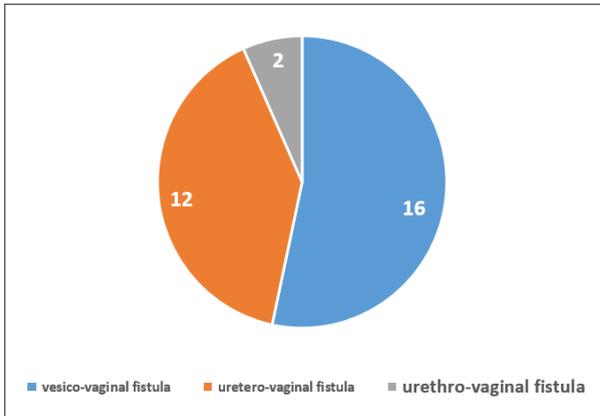
The age of patients ranged from 15 to 55 years, with a mean age of 36 years. The youngest patient had a history of trauma, while the oldest patient was diagnosed with carcinoma of the cervix.



Graph 1: Trends in Genito-Urinary Fistula Cases

Graph 1 shows the number of patients diagnosed with different types of fistulas from 2020 to 2023. The highest incidence was observed for vesico-

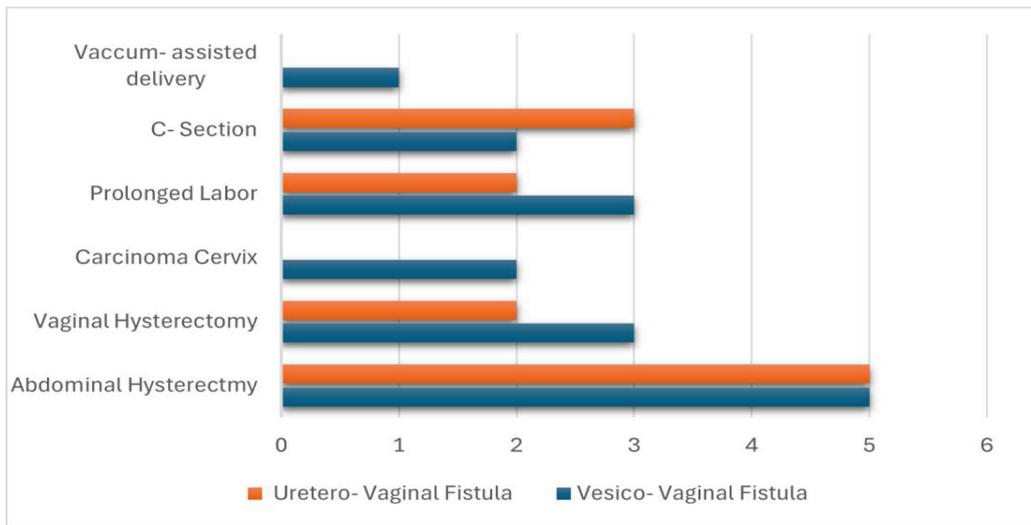
vaginal fistulas while urethro-vaginal fistulas had the lowest patient count in this study.



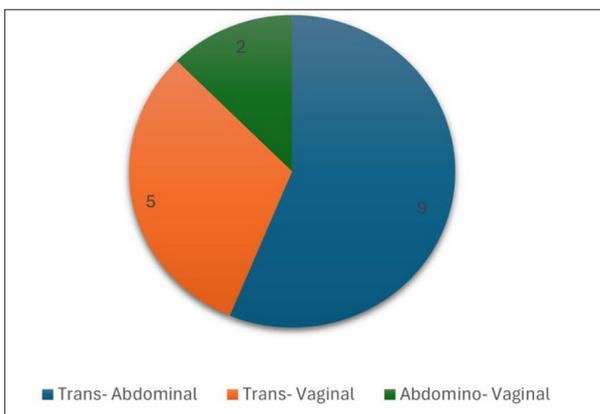
**Graph 2:** Distribution of Patients by Type of Fistula

Graph 2 shows that vesico-vaginal fistulas were the most prevalent (16 patients) with 11 classified as supra-trigonal and 5 as trigonal.

Graph 3 shows that abdominal hysterectomy is the most common event preceding both ureterovaginal and vesico-vaginal fistula occurrences followed by C-section and vaginal hysterectomy for uretero-vaginal fistula and prolonged labour for vesico-vaginal fistula.



**Graph 3:** Events preceding fistula occurrence



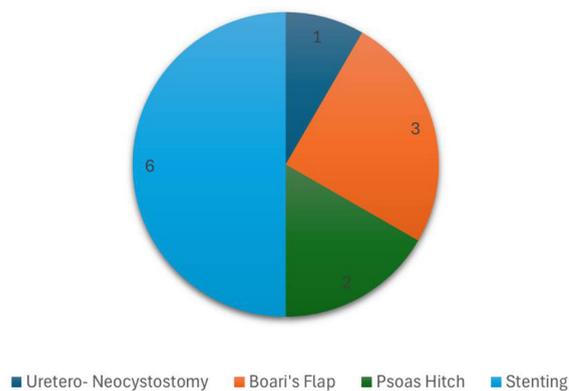
**Graph 4:** Surgical Approaches for Vesico-Vaginal Repair

Graph 4 shows that trans-abdominal approach is the most commonly used surgical method for vesico-vaginal fistula (VVF) repair, with three cases undergoing omental repair. This is followed

by the trans-vaginal approach, where two cases underwent Martius repair and the abdomino-vaginal approach, with two cases also utilizing omental repair.



**Fig. 1:** Vesico-vaginal Fistula



**Graph 5:** Surgical Repair Methods for Uretero-Vaginal Fistula

Graph 5 show that stenting is the most commonly used method for uretero-vaginal fistula (UVF) repair, followed by Boari's flap while psoas hitch and uretero-neocystostomy are less frequently used.

The trans-abdominal and abdomino-vaginal approaches for vesico-vaginal fistula repair, as well as all uretero-vaginal fistula repairs had a 100% success rate. The only failure occurred with the trans-vaginal approach for vesico-vaginal fistula repair with a success rate of 83%, but it was later successfully re-repaired.

In this study, two cases of urethro-vaginal fistulas were identified. The first involved a 15-year-old with a fistula following a traumatic fall, while the second case involved a 18-year-old girl who developed a fistula after a rape incident. Both patients were successfully managed with trans-vaginal closure.

## DISCUSSION

Genito-urinary fistulas pose significant challenges, often resulting from factors such as obstetric trauma, surgical complications or malignancies. Accurate diagnosis is crucial for effective management, employing methods like clinical examination, methylene blue dye tests, ultrasonography, intra-venous urography, cysto-urethroscopy, CECT KUB and MRI Pelvis to confirm the presence and type of fistula.<sup>2</sup>

This study shows a notable increase in ureterovaginal fistulas (UVFs) related to hysterectomies was observed, alongside a decrease in vesicovaginal fistulas (VVF) attributed to improved obstetric care. In contrast, another study found that iatrogenic factors accounted

for 73.2% of genitourinary fistulas, particularly highlighting VVF as the most common type.<sup>3</sup> While the reduction in obstructed labour-related fistulas aligns with advancements in healthcare, the rise in iatrogenic injuries reflects a growing complexity in genitourinary fistula cases, emphasizing the need for enhanced surgical techniques to ensure better patient outcomes.

Timely surgical intervention plays a pivotal role in improving outcomes. While early repair is often beneficial for cleanly incised injuries, delayed repair may be necessary for cases with significant local tissue damage or inflammation. A multidisciplinary approach is essential for optimal patient outcomes, emphasizing the importance of individualized care based on the specific characteristics of each case.<sup>4</sup>

Our findings also indicate high success rates for trans-abdominal and abdomino-vaginal repair approaches, emphasizing the significance of experienced surgical teams and adherence to established surgical principles in achieving favourable outcomes. These findings align with the previous study that concluded better outcome by abdominal technique due to improved tissue exposure and the ability to utilize omental flaps during vesicovaginal fistula repair.<sup>5</sup>

## LIMITATIONS

This study has several limitations that may affect the interpretation of its findings. Firstly, the retrospective design may introduce biases related to the completeness of medical records, potentially impacting data accuracy. The relatively small sample size of 30 patients limits the generalizability of the results to larger populations. Additionally, being a single-centre study may not reflect broader trends seen in different healthcare settings. The lack of long-term follow-up data on recurrence rates also limits our understanding of the durability of the surgical repairs. Finally, variations in surgical expertise among different practitioners may influence outcomes, which were not accounted for in this analysis.

## CONCLUSION

The study reveals a shift in etiological trends for genito-urinary fistulas: a decrease in vesico-vaginal fistulas (VVF) due to improved obstetric care and an increase in uretero-vaginal fistulas (UVF) linked to a rise in hysterectomies. Despite these changes,

trans-abdominal repair shows a high success rate, with positive outcomes resulting from adherence to essential surgical principles.

## REFERENCES

1. Osman SA, Al-Badr AH, Malabarey OT, Dawood AM, AlMosaieed BN, Rizk DEE. Causes and management of urogenital fistulas. A retrospective cohort study from a tertiary referral center in Saudi Arabia. *Saudi Med J*. 2018 Apr;39(4):373-8.
2. Mandava A, Koppula V, Sharma G, Kandati M, Raju KVVN, Subramanyeshwar Rao T. Evaluation of genitourinary fistulas in pelvic malignancies with etiopathologic correlation: role of cross sectional imaging in detection and management. *Br J Radiol*. 2020 Jul;93(1111):20200049.
3. Vikram S, Om Kumar Y, Arjun Singh S, Mahendra S, Deepak Prakash B, Shashank T, *et al*. Genitourinary Fistula: epidemiology, changing trends in etiology and management: A tertiary care institute's perspective. *Urologia Journal*. 2024 May 18;91(2):243-8.
4. Blaivas JG, Heritz DM, Romanzi LJ. Early Versus Late Repair of Vesicovaginal Fistulas: Vaginal and Abdominal Approaches. *Journal of Urology*. 1995 Apr;153(4):1110-3.
5. Kızılay F, Özdemir T, Aliyev B, Şimşir A, Kalemci S, Özyurt C. Comparison of the Abdominal and Transvaginal Techniques in the Surgical Treatment of Vesicovaginal Fistula and Analyzing the Factors Affecting Its Recurrence. *Journal of Urological Surgery*. 2020 Aug 20;7(3):238-44.

### Subscription Information

#### *India*

Institutional (1 year) (Print+Online): INR 9500

#### *Rest of the World*

Institutional (1 year) (Print+Online): \$ 742

#### *Payment instructions Online payment link:*

<http://rfppl.co.in/payment.php?mid=15>

#### *Cheque/DD:*

Please send the US dollar check from outside India and INR check from India made payable to 'Red Flower Publication Private Limited'. Drawn on Delhi branch

#### *Wire transfer/NEFT/RTGS:*

Complete Bank Account No. 604320110000467

Beneficiary Name: Red Flower Publication Pvt. Ltd.

Bank & Branch Name: Bank of India, Mayur Vihar

MICR Code: 110013045

Branch Code: 6043

IFSC Code: BKID0006043 (used for RTGS and NEFT transactions)

Swift Code: BKIDINBBDOS

#### *Send all Orders to:*

Subscription and Marketing Manager

**Red Flower Publication Pvt. Ltd.**

48/41-42, DSIDC, Pocket-II

Mayur Vihar Phase-I

Delhi - 110 091(India).

Mobile: 8130750089,

Phone: 91-11-79695648

E-mail: [sales@rfppl.co.in](mailto:sales@rfppl.co.in)

Website: [www.rfppl.co.in](http://www.rfppl.co.in)

# Perinatal Amoebic Liver Abscess in 3<sup>rd</sup> Trimester Twin Pregnancy: A Case Report

Subhajit Kar<sup>1</sup>, Ankit<sup>2</sup>

## How to cite this article:

Subhajit Kar, Ankit, Perinatal Amoebic liver abscess in 3<sup>rd</sup> trimester twin pregnancy: A case report. *New Indian Surg.* 2024; 15(4):147-149.

## Abstract

**Background:** Overall 10% of the world's population is infected with *Entamoeba histolytica* (*E. histolytica*) but out of this only 1% becomes symptomatic. Nearly 20% of the Indian population show manifestations of the disease. Liver abscess complicating a pregnancy is very rare and most common organism responsible for this complication is *Escherichia Coli* and *Bacteroides* spp.<sup>1</sup>

**Case Description:** Here we are presenting a case of high risk pregnancy who was diagnosed as a case of perinatal liver abscess with multiple large collection. She was admitted in ICU and was given Non-invasive and High flow nasal cannula support as per her need. After detailed evaluation and consultation with other department, pig-tail catheterization was done. Patient was managed conservatively and was later on discharged under satisfactory condition but lost to follow-up.

**Literature Review:** Amoebic liver abscess (ALA) is the most common extra-intestinal manifestation of invasive amoebiasis. Pregnancy has been described as a risk factor for development of invasive amoebiasis and management of these patients is especially complex.<sup>3</sup> The American College of Obstetricians and Gynecologists (ACOG) guidelines recommend ultrasound and MRI as the modalities of choice.<sup>3</sup> Metronidazole is the treatment of choice for pregnant women for amoebic liver abscess. Metronidazole is a US Food and Drug Administration (FDA) pregnancy category B drug, is generally well tolerated and although it crosses the placenta it seems to have no significant embryo toxic effects.<sup>3</sup>

**Clinical Relevance:** Here the case of amoebic liver abscess concurrent with twin pregnancy possess a challenge for clinician. Detailed analysis and discussion with other department is main approach in dealing such high risk cases.

**Keywords:** Perinatal; Abscess; Amoebic; Drainage.

---

**Author Affiliation:** <sup>1</sup>Junior Resident, Department of General Surgery, School of Medical Sciences & Research, Sharda University, Greater Noida, Uttar Pradesh, India, <sup>2</sup>Consultant Department of Critical Care, IDCCM.

**Corresponding Author:** Ankit, Consultant Department of Critical Care, IDCCM.

**Email:** drankitgpt1@gmail.com

**Received on:** 07-10-2024

**Accepted on:** 12-11-2024



This work is licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0.

## INTRODUCTION

The annual incidence rate of liver abscess is about 2.3 cases per 100,000 people. Worldwide Males are more frequently affected than females. Age plays a factor in the type of abscess one develops. People aged 40-60 years are more vulnerable to developing liver abscess that does not result from trauma.<sup>5</sup> Although infection with *Entamoeba histolytica* occurs world-wide, yet, liver abscess is the most common extra intestinal complication in 3% to 9% of patients. In India, amoebiasis is endemic and amoebic liver abscess accounts for 3-9% of all cases of amoebiasis.<sup>4</sup> Overall 10% of the world's population is infected with *Entamoeba histolytica* (*E. histolytica*) but out of this only 1% becomes symptomatic. Nearly 20% of the Indian population show manifestations of the disease. Liver abscess complicating a pregnancy is very rare and most common organism responsible for this complication is *Escherichia Coli* and *Bacteroides* spp.<sup>1</sup> Amoebic liver abscess in 3<sup>rd</sup> trimester twin pregnancy is unlikely to be heard due to its rarity and due to high morbidity of amoebic liver abscess making it quite grave condition if left unattended. Mortality due to amoebiasis is mostly by extra intestinal infections, amoebic liver abscess being the most common one.<sup>6</sup>

Here, we present a case of perinatal liver abscess with high risk pregnancy which needed multi-disciplinary approach along with meticulous decision making, resulting in fruitful outcome.

## CASE REPORT

Here we present a case of 30 yrs old female who was having amenorrhea for 7 months, presented to us with complaints of fever for past 6 days associated with generalized body ache and shortness of breath. Patient was shifted to ICU as patient was vitally unstable. After evaluating clinicoradiologically, she was diagnosed with sepsis with septic shock with multiple liver abscess on ultrasound. Patient was started on IV anti-biotic along with mild inotropic support and on Non-Invasive Ventilation (NIV) and High-flow Nasal Cannula to decrease the breathing workload on patient. Patient was having twin pregnancy with 22wks of gestation. Patient has an obstetric score of G3A2 and was conceived with the help of IVF in another hospital. OBGY reference was noted. Fetal heart sound was noted on abdominal ultrasound on regular basis and was normal. Repeated POCUS

was also done and moderate amount of bilateral pleura; effusion was also noted (BLUE protocol). There were multiple abscess the largest one was measuring approx. 200cc and other being 70cc. Intervention Radiologist opinion was noted and pig-tail catheterization was done under US guided. Post pig-tail insertion approx. 250ml of pus was drained from segment 6&7. Patient improved significantly post pig-tail insertion. Pus culture was done and it did not harbored any bacteria but on serology was found to be positive for *Entamoeba Histolytica*. The pigtail was removed on day 5 after its insertion and another large abscess was aspirated simultaneously which measured approx. 80ml from segment 4. Patient improved significantly post abscess drainage and all the supportive measures were removed. Patient was moved out of ICU on day 8 of ICU admission. Patient was discharged later on but was lost to follow up.

## DISCUSSION AND CONCLUSION

Amoebic liver abscess (ALA) is the most common extra-intestinal manifestation of invasive amoebiasis. Pregnancy has been described as a risk factor for development of invasive amoebiasis and management of these patients is especially complex.<sup>3</sup>

Very few cases of perinatal liver abscess cases have been described, with exceedingly rare occurrence.<sup>2</sup> The overall mortality rate seen in ALA from various series ranges from 2-15%.<sup>3</sup> In our case, pregnancy might have served as a predisposing factor for amoebic infection. The presence of a fetus requires an altered immunological response and results in a variety of immunomodulating processes with measurable changes in cellular and humoral immunity.<sup>3</sup> ALA is more common in males (up to 9:1 male-to-female ratio in the age group of 20-40 year olds), and since testosterone plasma levels in females can double in the setting of pregnancy, its immunopathological effects on monocyte function further illustrate heightened susceptibility to a variety of clinical manifestations of amoebiasis.<sup>3</sup>

Imaging modalities need to be chosen with care in the pregnant patient. The American College of Obstetricians and Gynecologists (ACOG) guidelines recommend ultrasound and MRI as the modalities of choice.<sup>3</sup> In our case we did detailed radiological evaluation with the help of POCUS. POCUS was done to rule out other underlying lung pathology and follow up was done with the same. Metronidazole is the treatment of choice for pregnant women for amoebic liver abscess. Metronidazole is a US

Food and Drug Administration (FDA) pregnancy category B drug, is generally well tolerated and although it crosses the placenta it seems to have no significant embryo toxic effects.<sup>3</sup> With both the clinical diagnosis of liver abscess radiologically and a positive *E. histolytica* serology, the definition of confirmed amoebic liver abscess was made.

Conservative management with multidisciplinary approach for amoebic liver abscess along with required intervention such as per-cutaneous pig-tail catheter drainage for amoebic liver abscess are both efficacious as treatment modalities in high risk pregnancies.

## REFERENCES

1. Yüksel, B., Seven, A., Kucur, S., Gözükar, I., & Keskin, N. (2013). Presentation and management of pyogenic liver abscess in a 23-week pregnant woman. *Case reports in obstetrics and gynecology*, 2013, 845215
2. Schmiedecke, S. S., Napolitano, P. G., & Estrada, S. M. (2019). Perinatal Pyogenic Liver Abscess: A Rare Entity and First Reported Case of *Klebsiella pneumoniae*. *AJP reports*, 9(3), e251–e255
3. Kaiser, R. W. J., Allgeier, J., Philipp, A. B., Mayerle, J., Rothe, C., Wallrauch, C., & Op den Winkel, M. (2020). Development of amoebic liver abscess in early pregnancy years after initial amoebic exposure: a case report. *BMC gastroenterology*, 20(1), 424.
4. Sharma, N., Sharma, A., Varma, S., Lal, A., & Singh, V. (2010). Amoebic liver abscess in the medical emergency of a North Indian hospital. *BMC research notes*, 3, 21.
5. Akhondi, H., & Sabih, D. E. (2023). Liver Abscess. In *StatPearls*. StatPearls Publishing
6. Singh, A., Banerjee, T., Kumar, R., & Shukla, S. K. (2019). Prevalence of cases of amoebic liver abscess in a tertiary care centre in India: A study on risk factors, associated microflora and strain variation of *Entamoeba histolytica*. *PloS one*, 14(4), e0214880.

## SUBSCRIPTION FORM

I want to renew/subscribe international class journal "New Indian Journal of Surgery" of Red Flower Publication Pvt. Ltd.

### Subscription Rates:

- Institutional: INR 9500/USD 742

Name and complete address (in capitals): \_\_\_\_\_

### Payment detail:

**Online payment link:** <http://rfppl.co.in/payment.php?mid=15>

Cheque/DD: Please send the US dollar check from outside India and INR check from India made payable to 'Red Flower Publication Private Limited'. Drawn on Delhi branch.

### Wire transfer/NEFT/RTGS:

Complete Bank Account No. 604320110000467

Beneficiary Name: Red Flower Publication Pvt. Ltd.

Bank & Branch Name: Bank of India; Mayur Vihar

MICR Code: 110013045

Branch Code: 6043

IFSC Code: BKID0006043 (used for RTGS and NEFT transactions)

Swift Code: BKIDINBBDOS

### Term and condition for supply of journals

1. Advance payment required by Demand Draft payable to **Red Flower Publication Pvt. Ltd.** payable at **Delhi**.
2. Cancellation not allowed except for duplicate payment.
3. Agents allowed 12.5% discount.
4. Claim must be made within six months from issue date.

### Mail all orders to

Subscription and Marketing Manager

**Red Flower Publication Pvt. Ltd.**

48/41-42, DSIDC, Pocket-II

Mayur Vihar Phase-I

Delhi - 110 091(India)

Phone: 91-11-79695648

Cell: +91-9821671871

E-mail: sales@rfppl.co.in

# Post-Operative Outcomes of Stapler versus Open Hemorrhoidectomy: A Systematic Review

Arjun Chinnappa<sup>1</sup>, Rishi Vyas<sup>2</sup>

## How to cite this article:

Arjun Chinnappa, Rishi Vyas, Post-Operative Outcomes of Stapler versus Open Hemorrhoidectomy: A Systematic Review. *New Indian Surg.* 2024; 15(4):151-153.

## Abstract

Hemorrhoidectomy remains a common surgical procedure for treating advanced hemorrhoidal disease. This systematic review aims to compare the post-operative outcomes of stapled hemorrhoidectomy (SH) and conventional open hemorrhoidectomy (OH) based on recent literature published within the last decade. By analyzing comparative studies, we evaluate key parameters including pain, healing time, complications, and patient satisfaction to provide a comprehensive assessment of both surgical techniques.

## Keywords:

## INTRODUCTION

Hemorrhoidal disease is a prevalent condition affecting a significant portion of the global population, with surgical intervention often required for advanced stages. Traditionally, open hemorrhoidectomy has been the standard surgical approach. However, the introduction of stapled hemorrhoidectomy in the late 1990s presented an alternative technique promising reduced post-

operative pain and faster recovery.

### *The primary objectives of this review are to:*

1. Compare post-operative pain levels between stapler and open hemorrhoidectomy
2. Assess wound healing and recovery times
3. Evaluate complication rates for both surgical methods
4. Analyze long-term patient outcomes and satisfaction

**Author Affiliation:** <sup>1</sup>Associate Professor, <sup>2</sup>Post Graduate, Department of General Surgery, Dr Moopens Medical College, Wayanad, Kerala 673577, India.

**Corresponding Author:** Arjun Chinnappa, Associate Professor, Department of General Surgery, Dr Moopens Medical College, Wayanad, Kerala 673577, India.

**Email:** vinay\_1771@yahoo.co.in

**Received on:** 07-10-2024

**Accepted on:** 12-11-2024



This work is licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0.

## METHODOLOGY

### Literature Search Strategy

A comprehensive literature search was conducted using multiple databases:

- PubMed
- Scopus
- Web of Science
- Google Scholar

### Inclusion criteria

- Peer-reviewed articles published between 2014-2024
- Comparative studies of stapler and open hemorrhoidectomy
- Full-text articles available in English
- Studies involving human subjects
- Randomized controlled trials and prospective comparative studies

### Exclusion criteria

- Case reports
- Studies with insufficient comparative data
- Articles published before 2014
- Non-English language publications

### Data Extraction and Analysis

Relevant data were extracted, including:

- Sample sizes
- Surgical techniques
- Pain scores
- Recovery times
- Complication rates
- Patient satisfaction metrics

## RESULTS

### Pain Management

Multiple studies have investigated the comparative pain outcomes of stapled and open hemorrhoidectomy. Zhu *et al.* (2015)<sup>1</sup> conducted a systematic review and meta-analysis that initially highlighted the potential pain reduction advantages. Kumar *et al.* (2018)<sup>2</sup> found that patients undergoing stapled hemorrhoidectomy required 40% less analgesic medication during the first week post-surgery. Malik *et al.* (2020)<sup>3</sup> reported significantly lower visual analog scale (VAS) pain scores in the

stapled hemorrhoidectomy (SH) group (mean  $3.2 \pm 1.5$ ) compared to the open hemorrhoidectomy (OH) group (mean  $6.7 \pm 2.3$ ).

### Healing and Recovery

Comparative analyses of healing and recovery times revealed nuanced differences between surgical techniques. Ahmed *et al.* (2019)<sup>4</sup> observed mean wound healing time of 14.3 days for SH versus 21.6 days for OH. Baig and Zmora (2016)<sup>5</sup> conducted a long-term randomized controlled trial exploring recovery outcomes. Nahas *et al.* (2017)<sup>6</sup> provided additional insights into the long-term recovery patterns, supporting the potential benefits of stapled hemorrhoidectomy.

### Complication Rates

A comprehensive examination of complication rates was performed by multiple researchers. Jayaraman and Mahadavan (2017)<sup>7</sup> conducted a meta-analysis comparing stapled hemorrhoidopexy with traditional Milligan-Morgan hemorrhoidectomy. Mandava and Chand (2016)<sup>8</sup> evaluated the comparative complication profiles, finding:

	Open Hemorrhoidectomy	Stapler Hemorrhoidectomy
Recurrence Rate	3-5%	4-7%
Bleeding	1.8%	2.1%
Anal Stenosis	2.3%	1.5%

Bucher *et al.* (2015) provided a prospective follow-up study examining long-term surgical outcomes.

### Patient Satisfaction

Patient-reported outcomes were extensively studied across multiple research groups. Saxena *et al.* (2016)<sup>9</sup> compared early and late outcomes, revealing key insights into patient experiences. Patient-reported outcomes consistently favored stapled hemorrhoidectomy:

- Higher satisfaction scores in SH group
- Reduced hospitalization time
- Faster return to work and daily activities

## DISCUSSION

The comparative analysis reveals that stapled hemorrhoidectomy offers several advantages over traditional open hemorrhoidectomy. The minimally invasive nature of the technique contributes to reduced post-operative pain, faster

healing, and improved patient satisfaction. The comparative analysis synthesizes findings from multiple research studies. Zhu *et al.* (2015) initially highlighted the potential advantages of stapled hemorrhoidectomy. Malik *et al.* (2020) further explored the long-term clinical implications, demonstrating the technique's potential benefits.

However, limitations exist. Long-term follow-up studies are still needed to definitively establish the superiority of one technique over another. Surgeon expertise, patient-specific factors, and hemorrhoid severity remain crucial in determining the most appropriate surgical approach.

## CONCLUSION

Stapled hemorrhoidectomy demonstrates promising outcomes across multiple parameters. While not universally superior, it presents a valuable alternative to traditional open hemorrhoidectomy, particularly for patients prioritizing faster recovery and reduced post-operative discomfort.

### Funding and Disclosure

No specific funding was received for this review. The authors declare no conflicts of interest.

## REFERENCES

1. Zhu, Q. C., Shen, Y., & Huang, W. H. (2015). Stapled hemorrhoidopexy versus excision hemorrhoidectomy: A systematic review and meta-analysis of randomized controlled trials. *International Journal of Colorectal Disease*, 30(9), 1191-1198
2. Kumar, P., Singh, R., & Verma, A. (2018). Post-operative pain management in hemorrhoidectomy: A comparative study. *International Journal of Surgery*, 56, 234-240.
3. Malik, A., Hassan, M., & Rahman, N. (2020). Long-term outcomes of stapled versus conventional hemorrhoidectomy. *Diseases of Colon & Rectum*, 63(4), 512-520.
4. Ahmed, R., Khan, S., & Malik, T. (2019). Comparative analysis of stapled versus open hemorrhoidectomy: A prospective study. *Surgical Endoscopy*, 33(7), 2214-2222.
5. Baig, M. K., & Zmora, O. (2016). Comparison of stapled versus excision hemorrhoidectomy: Long-term results of a randomized controlled trial. *Diseases of Colon & Rectum*, 59(6), 546-552.
6. Nahas, S. C., Marques, C. F., & Nahas, S. (2017). Long-term results of stapled hemorrhoidopexy: A retrospective study. *Surgical Endoscopy*, 31(5), 2201-2207.
7. Jayaraman, V., & Mahadavan, K. (2017). Stapled hemorrhoidopexy versus milligan-morgan hemorrhoidectomy: A meta-analysis of randomized controlled trials. *International Surgery*, 102(3-4), 230-238.
8. Mandava, S. H., & Chand, P. (2016). Evaluation of stapled hemorrhoidectomy versus open hemorrhoidectomy: A comparative study. *Journal of Clinical and Diagnostic Research*, 10(8), PC01-PC04.
9. Saxena, A., Tamboli, C., & Patel, H. (2016). Comparison of early and late outcomes in stapled versus open hemorrhoidectomy. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques*, 26(5), 385-390.

# Hyperparathyroidism Masquerading as Acute Pancreatitis

Ashishjot Kaur<sup>1</sup>, Avneet Singh Setia<sup>2</sup>, Prabh Simranpal<sup>3</sup>

## How to cite this article:

Ashishjot Kaur, Avneet Singh Setia, Prabh Simranpal, Hyperparathyroidism Masquerading as Acute Pancreatitis. New Indian J Surg. 2024; 15(4):154-158.

## Abstract

**Background:** Acute pancreatitis is a common condition, frequently attributed to gallstones or alcohol consumption. Interestingly, while hypocalcemia is typically associated with acute pancreatitis, hypercalcemia-induced pancreatitis is a rare clinical picture. Even more uncommon is the role of hyperparathyroidism as the underlying cause. This case challenges the conventional understanding of pancreatitis and its etiology, highlighting an atypical presentation that rose from hyperparathyroidism, through sustained hypercalcemia, emerged as the unexpected culprit for acute pancreatitis, shedding light on a rare interplay between endocrine dysfunction and pancreatic inflammation.

**Case Description:** We present a case of middle age patient, who developed acute pancreatitis with no history of alcohol use or gallstone disease. Lab Investigations revealed elevated serum calcium levels prompting further evaluation. Imaging studies confirmed the presence of parathyroid adenoma, implicating primary hyperparathyroidism as underlying cause of hypercalcaemia and subsequent pancreatitis. The patient underwent surgical excision of adenoma with normal normalisation of calcium levels and resolution of symptoms thereafter.

**Clinical relevance:** This case highlights a rare, but critical association between hyperthyroidism and acute pancreatitis, emphasising the importance of investigating parathyroid pathology in patients presenting with hypercalcaemia and pancreatitis. Early diagnosis and targeted management can prevent recurrent episodes and associated complications.

**Keywords:** Hypercalcaemia, Pancreatitis, Hyperparathyroidism, Parathyroid adenoma, Endocrine dysfunction.

---

**Author Affiliation:** <sup>1</sup>Junior Resident, Department of Medicine, <sup>2</sup>Assistant Professor, <sup>3</sup>Junior Resident, Department of Surgery, Gian Sagar Medical College and Hospital, Rajpura, Jansla 140506, Punjab, India.

**Corresponding Author:** Avneet Singh Setia, Department of Surgery, Gian Sagar Medical College and Hospital, Rajpura, Jansla-140506, Punjab, India.

**Email:** jotghuman28@gmail.com

**Received on:** 23-12-2024

**Accepted on:** 30-12-2024



This work is licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0.

## INTRODUCTION

A serious global public health concern, pancreatitis, has become more common over the past 30 years, with South Asia experiencing the largest increase.<sup>1</sup>

The pancreas becomes inflamed and injured in acute pancreatitis, which can result in sepsis and multiple organ failure. It is among the most common reasons for hospitalizations across the globe. With a mortality rate of up to 20% overall, it can be a potentially deadly condition.<sup>2</sup>

Knowing the common and uncommon causes and unique appearance of acute pancreatitis is crucial given the risks and complications resulting from a delayed diagnosis.<sup>3</sup>

About two thirds of all cases of acute pancreatitis are caused by alcohol and gallstones, which together make up the main etiological component.<sup>3,4</sup>

Furthermore, calcium accumulation in the pancreatic duct and calcium-induced activation of trypsinogen are two rare pathologies for causing pancreatitis that are brought on by hypercalcemia.<sup>2,3</sup> This is well known to result from activation of pancreatic proteins and starting an inflammatory cascade which paves way to pancreatitis.<sup>\*\*3</sup>

Hyperparathyroidism may also manifest as pancreatitis, particularly if serum calcium or phosphate levels are elevated.

About 80% to 85% of all cases of primary hyperparathyroidism are caused by a single parathyroid adenoma, which is a prevalent cause of hypercalcemia.<sup>2</sup> The majority of patients with primary hyperparathyroidism (PHPT) do not exhibit any symptoms. On the other hand, individuals who are symptomatic typically display signs of hypercalcemia, including painful bones, kidney stones, and mental and abdominal moans.<sup>4</sup> Additionally, a rare clinical Case report

A 58 year old female presented to the hospital with complaints of sudden onset dull pain in epigastric region radiating to back on and off for the past 3-4 days which increased in intensity and frequency on the day of presentation for the previous 7 to 8 hours. The pain was associated with nausea and 3 - 4 episodes of non-bilious vomiting.

Patient also compliant of bony pains and muscle

weakness. No complaints of fever, constipation or loose stool, burning micturation, bony fractures, neuropsychiatric symptoms were found.

Her past surgical history revealed she has been operated for laparoscopic cholecystectomy in view of multiple gallstones 2 years back. Medical history was remarkable for hypertension (4 to 5 years, on regular tablets telmisartan 40 mg and amlodipine 5 mg) and recurrent renal calculi (treated with medications). She did not smoke or drink alcohol.

On admission, vitals were as follows

BP 160/100 mmHg

Pulse 100/min

RR 22/minute

and was Afebrile

Considering provisional diagnosis of acute pancreatitis, she was kept NPO and managed in ICU with IV fluids, antibiotics, antiemetics, antihypertensive and was closely monitored.

Investigations performed, were as follows:

<b>TLC</b>	8700
Hb	9
PLT	1.8
<b>renal function tests</b>	
urea	30
Creatinine	1
Uric acid	5.2
<b>Calcium</b>	22
Lipase	1250
<b>Electrolytes</b>	
Sodium	137
Potassium	4.3
Chloride	105
<b>25-OH VIT D</b>	46.3
Magnesium	3.5
Phosphorus	2
SGOT	15
SGPT	18
Bilirubin	1.3
ALP	172

Blood tests were unremarkable except for increase S. lipase and ECG changes showed short QT interval and increase in amplitude of QRS wave.

Additional surprise finding was for markedly elevated serum calcium (22 mg/dl). As a result, the patient was administered IV fluids at the rate of 120 ml per hour and IV bisphosphonates. Further investigations of serum Magnesium, phosphate, vitamin D levels, iPTH, repeat ECG and imaging of CECT abdomen with pelvis and screening of thorax and neck were ordered.

PTH levels were significantly raised (856pg/ml)

CECT chest revealed bilateral plural effusion, segmental collapse consolidation of left basal segment with bilateral fibrotic, trance and septal thickening.

CT scan of abdomen and pelvis signified bulky pancreas with extensive peri pancreatic fat stranding and left thickened perinephric fat pad suggestive of acute interstitial oedematous pancreatitis with ascites.

CECT scan of neck showed a well circumscribed hypodense nodule posterior to the right lobe of thyroid which was diagnosed as **right parathyroid adenoma**.

After the episode of pancreatitis subsided, investigations were repeated.

Patient was prepared for surgery, right parathyroidectomy.

Operative findings evidenced an enlarged right inferior parathyroid adenoma measuring approximately 4x3 cm.

Surgery was uneventful and post operative serum calcium (8.5) and serum iPTH(2.6pg/ml) repeated after 1 week were found to be within normal limits. Follow up planned at 3 months and 6 months confirmed no recurrence of abdominal pain in our case.

## DISCUSSIONS

The severity of the disease in acute pancreatitis may correlate with a reduction in serum calcium, which is a typical picture in pancreatitis. The presence of pancreatitis and hypercalcemia should raise suspicions of hyperparathyroidism or cancer, for which iPTH and neck ultrasonography are recommended.<sup>5,6</sup>



As early as 1940, Smith and Cooke reported the first case of AP linked to hyperparathyroidism, and Pyrah et al tried to compile the conditions under which pancreatic illness took place in conjunction with PHPT.<sup>7,8</sup> In another study, Only 17 patients (1.5%) had concomitant pancreatitis out of the 1153 patients with hyperparathyroidism operated on at the Mayo Clinic between 1950 and 1975.<sup>9</sup> 0.4% cases of acute pancreatitis were shown to be caused by hyperparathyroidism in a research by Prinz et al in 1985.<sup>9</sup> Similarly, in 1998, Carnaille B et al. retrospectively assessed 1224 patients of hyperparathyroidism and discovered that 3.2% of them had acute pancreatitis.<sup>10</sup>

there has always been an ongoing debate in literature for direct causal relationship between hyperparathyroidism and parathyroid induced pancreatitis. In 1998, Sitges Sara rejected the Mayo Clinic's studies as untrue and proposed that hypercalcemia may cause pancreatitis with nonparathyroid reasons instead.<sup>9,12</sup>

While 64.7% of patients had at least one concurrent cause of pancreatitis, such as gallstones or alcohol abuse, 1.5% of patients with surgically confirmed PHPT had coexisting or prior pancreatitis, and symptoms of pancreatitis did not improve following treatment for hyperparathyroidism, according to Bess *et al.*<sup>12</sup>

Five out of 61 cases of pancreatitis had PHPT, according to Diallo *et al.*<sup>13</sup> Of these, two patients developed CP, and the prevalence of PHPT-associated CP was almost 3.27% of all hospitalized cases of pancreatitis. Additionally, three follow-up investigations from India revealed a low frequency

of CP linked to PHPT.

Jacob et al divided the pancreatic disease presentation in PHPT into four categories in 2006: PHPT presenting as AP, PHPT presenting as recurrent AP without CP, PHPT presenting as CP with or without pancreatic calcification, and PHPT complicated by AP in the postoperative phase.<sup>11</sup>

Therefore, different presentations of pancreatitis may be manifested as a result of parathyroid adenoma.

Patient's previous medical history, clinical presentation, lab investigations, and imaging results are all crucial to diagnose PHPT induced AP. Individuals might also exhibit recurring episodes of AP. Increased iPTH and calcium levels and decreased phosphate levels demand the need of further imaging to rule out parathyroid etiology.

Cervical ultrasonography is an inexpensive, safe, radiation-free, and extremely sensitive method, frequently utilized as the first localization examination in patients with PHPT.<sup>14</sup> Negative imaging results should raise a suspicion for ectopic parathyroid adenomas and further imaging be advised as per clinical judgement.

Tc-99m MIBI with SPECT of the neck can offer further functional information and is more sensitive for ectopic adenomas that are either undiscovered or overlooked by ultrasonography.<sup>14</sup>

Our patient refused further imaging due to affordability issues.

Primary treatment for parathyroid adenoma is removal of gland with simple parathyroidectomy as a favoured surgical treatment over medications or long-term monitoring.<sup>15</sup>

5282 patients from 14 studies were included in a systemic evaluation, which indicated that the long term ( $\geq 1$  year) cure rate defined as normocalcemia remaining for more than 6 months following MIP was 96.9%. The most frequent consequence, temporary postoperative hypocalcemia, was seen in 4.4% of cases overall.<sup>15</sup>

Our patient was asymptomatic with normocalcemia, followed up at two occasions of 3 and 6 months post-operatively. Since there were no additional risk factors for pancreatitis, our case demonstrates a true positive causal connection between PHPT and pancreatitis.

## CONCLUSION

A rare presentation of primary parathyroid adenoma is acute pancreatitis (AP).

It is highly recommended that imaging be done to check for any parathyroid proliferative disorders in patients with AP who have elevated serum calcium levels after excluding commonly recognized etiologies of pancreatitis. In addition to prevent AP problems, early identification and treatment can help stop AP from recurring.

For parathyroid adenoma, a parathyroidectomy is a safe, efficient, and permanent treatment.

### Acknowledgements

We sincerely thank the patient for their kind consent to share their case for the purpose of advancing medical knowledge and education through publication.

**Funding:** No funding was received from any organisation or institute for this case report.

**Conflict of interest:** The authors declared no conflict of interest in relation to this case report.

### Ethical consideration

Ethical approval was not required for this case report. However, informed consent was obtained from the patient and all measures were taken to protect their privacy and confidentiality.

## REFERENCES

1. Ouyang G, Pan G, Liu Q, et al. The global, regional, and national burden of pancreatitis in 195 countries and territories, 1990-2017: a systematic analysis for the global burden of disease study 2017. *BMC Med.* 2020; 18(1): 388. doi:10.1186/s12916-020-01859-5.
2. Yeh MW, Ituarte PH, Zhou HC, et al. Incidence and prevalence of primary hyperparathyroidism in a racially mixed population. *J Clin Endocrinol Metab.* 2013;98:1122-9.
3. Unveiling the hidden culprit: Parathyroid adenoma induced recurrent renal calculus and pancreatitis – A case report Aakash Kumar Pandit, Prajjwal Pokharel, Kabin Sapkota, Sanket Dhakal, Ram Narayan Kurmi, Mukesh Kumar Ranjan <https://doi.org/10.1002/ccr3.9248>.

4. Khan AA, Hanley DA, Rizzoli R, et al. Primary hyperparathyroidism: review and recommendations on evaluation, diagnosis, and management. A Canadian and international consensus. *Osteoporos Int*. 2017;28:1-19.
5. Diallo I, Fall CA, Ndiaye B, et al. Primary hyperparathyroidism and pancreatitis: a rare association with multiple facets. *Int Sch Res Notices* 2016;2016:7294274. DOI: 10.1155/2016/7294274.
6. Bist SS, Ahuja V, Agrawal V, et al. Recurrent acute pancreatitis: a diagnostic clue to primary hyperparathyroidism. *Iran J Med Sci* 2016;41(2):361-362.
7. Smith F, Cooke R. Acute fatal hyperparathyroidism. *Lancet*. 1940;236:650-1.
8. Pyrah LN, Hodgkinson A, Anderson CK. Primary hyperparathyroidism. *Br J Surg*. 1966;53:245-316.<sup>8</sup>
9. Prinz RA, Aranha G. The association of primary hyperparathyroidism and pancreatitis. *Am Surg*. 1985; 51(6): 325-329. <https://pubmed.ncbi.nlm.nih.gov/3994175/>
10. Carnaille B, Oudar C, Pattou F, Combemale F, Rocha J, Proye C. Pancreatitis and primary hyperparathyroidism: forty cases. *Aust N Z J Surg*. 1998; 68(2): 117-119. doi:10.1111/j.1445-2197.1998.tb04719.x.
11. Jacob JJ, John M, Thomas N, et al. Does hyperparathyroidism cause pancreatitis? A South Indian experience and a review of published work. *ANZ J Surg*. 2006;76:740-4.
12. Bess MA, Edis AJ, van Heerden JA. Hyperparathyroidism and pancreatitis. Chance or a causal association? *JAMA*. 1980; 243(3): 246-247. <https://jamanetwork.com/journals/jama/article-abstract/368364>.
13. Diallo I, Fall CA, Ndiaye B, et al. Primary hyperparathyroidism and pancreatitis: a rare Association with multiple facets. *Int Sch Res Notices*. 2016;2016:7294274.
14. Zander D, Bunch PM, Policeni B, et al. ACR appropriateness Criteria® parathyroid Adenoma. *J Am Coll Radiol*. 2021;18:S406-22. And Scholar[19]. Murad V, Barragán C, Rivera H. Ultrasound evaluation of the parathyroid glands. *Rev Colomb Radiol*. 2018;29:4861-6.
15. Ishii H, Mihai R, Watkinson JC, et al. Systematic review of cure and recurrence rates following minimally invasive parathyroidectomy. *BJS Open*. 2018;2:364-70.

## Erratum

### **A Comparative Study of Laparoscopic Appendectomy Versus Open Appendectomy**

Alankar<sup>1</sup>, Inderjeet<sup>2</sup>, Manohar L. Dawan<sup>3</sup>, Abhishek Chabra<sup>4</sup>, Sunder kishore<sup>5</sup>, Sanjay Lodha<sup>6</sup>

Published in

New Indian Journal of Surgery

Volume 15 Number 1, January - June 2024

DOI: <https://dx.doi.org/10.21088/nijs.0976.4747.15124.5>

### **A Comparative Study of Early Versus Delayed Ileostomy Closure Following Bowel Surgery**

Inderjeet<sup>1</sup>, Alankar Sharma<sup>2</sup>, Manohar L. Dawan<sup>3</sup>, Abhishek Chhabra<sup>4</sup>, Sunder kishore<sup>5</sup>, Sanjay Lodha<sup>6</sup>

Published in

New Indian Journal of Surgery

Volume 15 Number 1, January - June 2024

DOI: <https://dx.doi.org/10.21088/nijs.0976.4747.15124.6>

**The original published version of this Article contained errors in article type. The article was incorrectly categorized as a case report. The Correct article type is an original article.**

**Mistake is regretted**

**Editor-in-chief**

## Subject Index

Title	Page No
A Case Report of Corrosive Injury of Gastrointestinal Tract Managed with Pectoralis Major-Myocutaneous Patch Cover Over Pharyngo-Esophageal Anastomosis	27
A Comparative Study of Early Versus Delayed Ileostomy Closure Following Bowel Surgery	37
A Rare Case of Multiple Ileal Lipoma in a Young Male	71
A Rare Presentation of Thyroid Swelling (Epithelioid Angiosarcoma): A Case Report	67
A Study of Genitourinary Fistulas and its Implications	148
A comparative Study of Laparoscopic appendectomy Versus Open Appendectomy	33
Autologous Platelet-Rich Plasma Utilisation in Plastic Surgery as Adjunctive Burn Management Treatment	77
Clinical Presentation and Outcome of Adult Groin Hernia	101
Clinical Profile Analysis of Diabetic Foot	13
Endotrainer	63
Gossypiboma: A Surgeon's Nightmare: A Systematic Review and Case Report	19
Hyperparathyroidism Masquerading as Acute Pancreatitis	154
Investigating the Healing Potential of Topical Phenytoin for Therapeutic Treatment in Thermal Burns	59
Medical Management of Benign Prostate Hyperplasia and Its Outcome	111
Miracle Negative Pressure Wound Therapy (NPWT) or Vacuum Assisted Closure (VAC): For difficult and Complicated Wounds: An Observational Study	95
Perinatal Amoebic liver Abscess in 3rd Trimester Twin Pregnancy: A Case Report	158
Post-Operative Outcomes of Stapler Versus Open Hemorrhoidectomy: A Systematic Review	166
Role of Non cultured Keratinocyte Graft with Sucralfate in Second Degree Scald Burns	107
Study of Outcome of Diathermic Incision Cautery more than 5 cms in General and Urologic Surgery Operations	07
The Role of OrmeloXifene in the Management of Fibro-Adenosis/ Adenomas and Associated Mastalgia	141
Use of Three Layered Regenerative Scaffold Dressing in the Wound Bed Preparation of Second Degree Scald Burns	119

## Author Index

Name	Page No	Name	Page No
Abhishek Sharma	95	Nishant Visvas	77
Alankar Inderjeet	33	Padmalakshmi Bharathi Mohan	77
Alankar Sharma	37	Padmalaskhmi Bharathi Mohan	59
Amrutha J S	119	Prabh Simranpal	154
Amrutha J S	107	Pranav Bhatt	27
Anitha Kandi	101	Prashant Vanzare	27
Anitha Kandi	111	Rajan Jagad	27
Ankit	158	Ramprashanth M P	71
Arjun Chinnappa	166	Ramprashanth M.P.	19
Arnab Chattupadhyay	27	Ravi Kumar Chittoria	107
Ashishjot Kaur	154	Ravi Kumar Chittoria	119
Ashwin	67	Ravi Kumar Chittoria	59
Avinash Surwade	101	Ravi Kumar Chittoria	77
Avneet Singh Setia	154	Rishi Vyas	166
Basavaraj Bukkegar	71	Sadashiv Patil	63
Dharmraj Biradar	63	Safeera M.D.	19
Dumont	77	Sangamesh B T	71
Edunoori Prashanth	63	Sanjay P Dhangar	07
Inderjeet	37	Sarojini Jadhav	101
Jacob Antony Chakiath	59	Sarojini Jadhav	111
Jacob Antony Chakiath	77	Savita K.S.	13
Jameel Akther	67	Sheetal Patil	07
Jayanth Lavu	141	Shivakumar C R	71
K Nischal	148	Shruthirachita Malagatti	148
Kanav Gupta	59	Singh Setia	161
Kanav Gupta	77	Siva Subramaniyan S	107
Karthikeyan	59	Subhajit Kar	158
Ketan Karande	07	Sudarsan. S	67
Lalith Dasari	141	Sumit Salve	101
Manohar L. Dawan	37	Suyash Deshmukh	111
Manohar L. Dawan	33	Tanvi Arora	148
Naveen N.	19	Varun Gawda	111
Nidhi Shukla	27	Vinay H.G	19
Nikhilesh	63	Viswak M	119

## Guidelines for Authors

Manuscripts must be prepared in accordance with "Uniform requirements for Manuscripts submitted to Biomedical Journal" developed by international committee of medical Journal Editors

### Types of Manuscripts and Limits

Original articles: Up to 3000 words excluding references and abstract and up to 10 references.

Review articles: Up to 2500 words excluding references and abstract and up to 10 references.

Case reports: Up to 1000 words excluding references and abstract and up to 10 references.

### Online Submission of the Manuscripts

Articles can also be submitted online from [http://rfppl.co.in/customer\\_index.php](http://rfppl.co.in/customer_index.php).

1) First Page File: Prepare the title page, covering letter, acknowledgement, etc. using a word processor program. All information which can reveal your identity should be here. use text/rtf/doc/PDF files. Do not zip the files.

2) Article file: The main text of the article, beginning from Abstract till References (including tables) should be in this file. Do not include any information (such as acknowledgement, your name in page headers, etc.) in this file. Use text/rtf/doc/PDF files. Do not zip the files. Limit the file size to 400 Kb. Do not incorporate images in the file. If file size is large, graphs can be submitted as images separately without incorporating them in the article file to reduce the size of the file.

3) Images: Submit good quality color images. Each image should be less than 100 Kb in size. Size of the image can be reduced by decreasing the actual height and width of the images (keep up to 400 pixels or 3 inches). All image formats (jpeg, tiff, gif, bmp, png, eps etc.) are acceptable; jpeg is most suitable.

Legends: Legends for the Fig.s/images should be included at the end of the article file.

If the manuscript is submitted online, the contributors' form and copyright transfer form has to be submitted in original with the signatures of all the contributors within two weeks from submission. Hard copies of the images (3 sets), for articles submitted online, should be sent to the journal office at the time of submission of a revised manuscript. Editorial office: Red Flower Publication Pvt. Ltd., 48/41-42, DSIDC, Pocket-II, Mayur Vihar Phase-I, Delhi - 110 091, India, Phone: 91-11-79695648. E-mail: [author@rfppl.co.in](mailto:author@rfppl.co.in). Submission page: [http://rfppl.co.in/article\\_submission\\_system.php?mid=5](http://rfppl.co.in/article_submission_system.php?mid=5).

### Preparation of the Manuscript

The text of observational and experimental articles should be divided into sections with the headings: Introduction, Methods, Results, Discussion, References, Tables, Fig.s, Fig. legends, and Acknowledgment. Do not make subheadings in these sections.

### Title Page

The title page should carry

- 1) Type of manuscript (e.g. Original article, Review article, Case Report)
- 2) The title of the article should be concise and informative;
- 3) Running title or short title not more than 50 characters;
- 4) The name by which each contributor is known (Last name, First name and initials of middle name), with his or her highest academic degree(s) and institutional affiliation;
- 5) The name of the department(s) and institution(s) to which the work should be attributed;
- 6) The name, address, phone numbers, facsimile numbers and e-mail address of the contributor responsible for correspondence about the manuscript; should be mentioned.
- 7) The total number of pages, total number of photographs and word counts separately for abstract and for the text (excluding the references and abstract);
- 8) Source(s) of support in the form of grants, equipment, drugs, or all of these;
- 9) Acknowledgement, if any; and
- 10) If the manuscript was presented as part at a meeting, the organization, place, and exact date on which it was read.

### Abstract Page

The second page should carry the full title of the manuscript and an abstract (of no more than 150 words for case reports, brief reports and 250 words for original articles). The abstract should be structured and state the Context (Background), Aims, Settings and Design, Methods and Materials, Statistical analysis used, Results and Conclusions. Below the abstract should provide 3 to 10 keywords.

Introduction  
State the background of the study and purpose of the study and summarize the rationale for the study

or observation.

### Methods

The methods section should include only information that was available at the time the plan or protocol for the study was written such as study approach, design, type of sample, sample size, sampling technique, setting of the study, description of data collection tools and methods; all information obtained during the conduct of the study belongs in the Results section.

Reports of randomized Clinical trials should be based on the CONSORT Statement (<http://www.consort-statement.org>). When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000 (available at [http://www.wma.net/e/policy/17-c\\_e.html](http://www.wma.net/e/policy/17-c_e.html)).

### Results

Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra or supplementary materials and technical details can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

### Discussion

Include summary of key findings (primary outcome measures, secondary outcome measures, results as they relate to a prior hypothesis); Strengths and limitations of the study (study question, study design, data collection, analysis and interpretation); Interpretation and implications in the context of the totality of evidence (is there a systematic review to refer to, if not, could one be reasonably done here and now?, What this study adds to the available evidence, effects on patient care and health policy, possible mechanisms)? Controversies raised by this study; and Future research directions (for this particular research collaboration, underlying mechanisms, Clinical research). Do not repeat in detail data or other material given in the Introduction or the Results section.

### References

List references in alphabetical order. Each listed reference should be cited in text (not in alphabetic order), and each text citation should be listed in the References section. Identify references in text, tables, and legends by Arabic numerals in square bracket (e.g. [10]). Please refer to ICMJE Guidelines ([http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html)) for more examples.

#### Standard journal article

[1] Flink H, Tegelberg Å, Thörn M, Lagerlöf F. Effect of oral iron supplementation on unstimulated salivary flow rate: A randomized, double-blind, placebo-controlled trial. *J Oral Pathol Med* 2006; 35: 540-7.

[2] Twetman S, Axelsson S, Dahlgren H, Holm AK, Källestål C, Lagerlöf F, *et al.* Caries-preventive effect of fluoride toothpaste: A systematic review. *Acta Odontol Scand* 2003; 61: 347-55.

#### Article in supplement or special issue

[3] Fleischer W, Reimer K. Povidone-iodine antiseptics. State of the art. *Dermatology* 1997; 195 Suppl 2: 3-9.

#### Corporate (collective) author

[4] American Academy of Periodontology. Sonic and ultrasonic scalers in periodontics. *J Periodontol* 2000; 71: 1792-801.

#### Unpublished article

[5] Garoushi S, Lassila LV, Tezvergil A, Vallittu PK. Static and fatigue compression test for particulate filler composite resin with fiber-reinforced composite substructure. *Dent Mater* 2006.

#### Personal author(s)

[6] Hosmer D, Lemeshow S. Applied logistic regression, 2nd edn. New York: Wiley-Interscience; 2000.

#### Chapter in book

[7] Nauntofte B, Tenovou J, Lagerlöf F. Secretion and composition of saliva. In: Fejerskov O, Kidd EAM, editors. Dental caries: The disease and its Clinical management. Oxford: Blackwell Munksgaard; 2003. pp 7-27.

### No author given

[8] World Health Organization. Oral health surveys - basic methods, 4<sup>th</sup> edn. Geneva: World Health Organization; 1997.

### Reference from electronic media

[9] National Statistics Online – Trends in suicide by method in England and Wales, 1979–2001. [www.statistics.gov.uk/downloads/theme\\_health/HSQ20.pdf](http://www.statistics.gov.uk/downloads/theme_health/HSQ20.pdf) (accessed Jan 24, 2005): 7–18. Only verified references against the original documents should be cited. Authors are responsible for the accuracy and completeness of their references and for correct text citation. The number of reference should be kept limited to 20 in case of major communications and 10 for short communications.

More information about other reference types is available at [www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html), but observes some minor deviations (no full stop after journal title, no issue or date after volume, etc.).

### Tables

Tables should be self-explanatory and should not duplicate textual material.

Tables with more than 10 columns and 25 rows are not acceptable.

Table numbers should be in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.

Explain in footnotes all non-standard abbreviations that are used in each table.

For footnotes use the following symbols, in this sequence: \*, ¶, †, ‡, ††

### Illustrations (Fig.s)

Graphics files are welcome if supplied as Tiff, EPS, or PowerPoint files of minimum 1200x1600 pixel size. The minimum line weight for line art is 0.5 point for optimal printing.

When possible, please place symbol legends below the Fig. instead of the side.

Original color Fig.s can be printed in color at the editor's and publisher's discretion provided the author agrees to pay.

Type or print out legends (maximum 40 words, excluding the credit line) for illustrations using double spacing, with Arabic numerals corresponding to the illustrations.

### Sending a revised manuscript

While submitting a revised manuscript, contributors are requested to include, along with single copy of the final revised manuscript, a photocopy of the revised manuscript with the changes underlined in red and copy of the comments with the point-to-point clarification to each comment. The manuscript number should be written on each of these documents. If the manuscript is submitted online, the contributors' form and copyright transfer form has to be submitted in original with the signatures of all the contributors within two weeks of submission. Hard copies of images should be sent to the office of the journal. There is no need to send printed manuscript for articles submitted online.

### Reprints

Journal provides no free printed, reprints, however an author copy is sent to the main author and additional copies are available on payment (ask to the journal office).

### Copyrights

The whole of the literary matter in the journal is copyright and cannot be reproduced without the written permission.

### Declaration

A declaration should be submitted stating that the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under the present authorship has been published or is being considered for publication elsewhere and the authorship of this article will not be contested by any one whose name(s) is/are not listed here, and that the order of authorship as placed in the manuscript is final and accepted by the co-authors. Declarations should be signed by all the authors in the order in which they are mentioned in the original manuscript. Matters appearing in the Journal are covered by copyright but no objection will be made to their reproduction provided permission is obtained from the Editor prior to publication and due acknowledgment of the source is made. Approval of Ethics Committee

We need the Ethics committee approval letter from an Institutional ethical committee (IEC) or an institutional review board (IRB) to publish your Research article or author should submit a statement that the study does not require ethics

approval along with evidence. The evidence could either be consent from patients is available and there are no ethics issues in the paper or a letter from an IRB stating that the study in question does not require ethics approval.

### Abbreviations

Standard abbreviations should be used and be spelt out when first used in the text. Abbreviations should not be used in the title or abstract.

### Checklist

- Manuscript Title
- Covering letter: Signed by all contributors
- Previous publication/ presentations mentioned, Source of funding mentioned
- Conflicts of interest disclosed

### Authors

- Middle name initials provided.
- Author for correspondence, with e-mail address provided.
- Number of contributors restricted as per the instructions.
- Identity not revealed in paper except title page (e.g. name of the institute in Methods, citing previous study as 'our study')

### Presentation and Format

- Double spacing
- Margins 2.5 cm from all four sides
- Title page contains all the desired information. Running title provided (not more than 50 characters)
- Abstract page contains the full title of the manuscript
- Abstract provided: Structured abstract provided for an original article.
- Keywords provided (three or more)
- Introduction of 75-100 words
- Headings in title case (not ALL CAPITALS). References cited in square brackets
- References according to the journal's instructions

### Language and grammar

- Uniformly American English
- Abbreviations spelt out in full for the first time. Numerals from 1 to 10 spelt out
- Numerals at the beginning of the sentence spelt out

### Tables and Fig.s

- No repetition of data in tables and graphs and in text.
- Actual numbers from which graphs drawn, provided.
- Fig.s necessary and of good quality (color)
- Table and Fig. numbers in Arabic letters (not Roman).
- Labels pasted on back of the photographs (no names written)
- Fig. legends provided (not more than 40 words)
- Patients' privacy maintained, (if not permission taken)
- Credit note for borrowed Fig.s/tables provided
- Manuscript provided on a CDROM (with double spacing)

### Submitting the Manuscript

- Is the journal editor's contact information current?
- Is the cover letter included with the manuscript? Does the letter:
  1. Include the author's postal address, e-mail address, telephone number, and fax number for future correspondence?
  2. State that the manuscript is original, not previously published, and not under concurrent consideration elsewhere?
  3. Inform the journal editor of the existence of any similar published manuscripts written by the author?
  4. Mention any supplemental material you are submitting for the online version of your article. Contributors' Form (to be modified as applicable and one signed copy attached with the manuscript)

## Call for Editorial Board Members

As you are well aware that we are a medical and health sciences publishers; publishing peer-reviewed journals and books since 2004.

We are always looking for dedicated editorial board members for our journals. If you completed your master's degree and must have at least five years experience in teaching and having good publication records in journals and books.

If you are interested to be an editorial board member of the journal; please provide your complete resume and affiliation through e-mail (i.e. info@rfppl.co.in) or visit our website (i.e. www.rfppl.co.in) to register yourself online.

---

## Call for Publication of Conference Papers/Abstracts

We publish pre-conference or post-conference papers and abstracts in our journals, and deliver hard copy and giving online access in a timely fashion to the authors.

For more information, please contact:

For more information, please contact:  
A Lal  
Publication-in-charge  
Red Flower Publication Pvt. Ltd.  
48/41-42, DSIDC, Pocket-II  
Mayur Vihar Phase-I  
Delhi - 110 091 (India)  
Phone: 91-11-79695648  
E-mail: info@rfppl.co.in

---

---

## Free Announcements of your Conferences/Workshops/CMEs

This privilege to all Indian and other countries conferences organizing committee members to publish free announcements of your conferences/workshops. If you are interested, please send your matter in word formats and images or pictures in JPG/JPEG/Tiff formats through e-mail attachments to sales@rfppl.co.in.

### **Terms & Conditions to publish free announcements:**

1. Only conference organizers are eligible up to one full black and white page, but not applicable for the front, inside front, inside back and back cover, however, these pages are paid.
2. Only five pages in every issue are available for free announcements for different conferences.
3. This announcement will come in the next coming issue and no priority will be given.
4. All legal disputes subject to Delhi jurisdiction only.
5. The executive committee of the Red Flower Publication reserve the right to cancel, revise or modify terms and conditions any time without prior notice.

For more information, please contact:

A Lal

Publication-in-charge

**Red Flower Publication Pvt. Ltd.**

48/41-42, DSIDC, Pocket-II

Mayur Vihar Phase-I

Delhi - 110 091 (India)

Phone: 91-11-79695648

E-mail: info@rfppl.co.in

---

## Win Free Institutional Subscription!

Simply fill out this form and return scanned copy through e-mail or by post to us.

Name of the Institution \_\_\_\_\_

Name of the Principal/Chairman \_\_\_\_\_

Management (Trust/Society/Govt./Company) \_\_\_\_\_

Address 1 \_\_\_\_\_

Address 2 \_\_\_\_\_

Address 3 \_\_\_\_\_

City \_\_\_\_\_

Country \_\_\_\_\_

PIN Code \_\_\_\_\_

Mobile \_\_\_\_\_

Email \_\_\_\_\_

We are regular subscriber of Red Flower Publication journals.

Year of first subscription \_\_\_\_\_

List of ordered journals (if you subscribed more than 5 titles, please attach separate sheet)

### Ordered through

Name of the Vendor	Subscription Year	Direct/subs Yr

Name of the journal for which you wish to be free winner

### Terms & Conditions to win free institutional subscription

1. Only institutions can participate in this scheme
2. In group institutions only one institution would be winner
3. Only five institutions will be winner for each journal
4. An institution will be winner only for one journal
5. The free subscription will be valid for one year only (i.e. 1 Jan – 31 Dec)
6. This free subscription is not renewable, however, can be renewed with payment
7. Any institution can again participate after five years
8. All legal disputes subject to Delhi jurisdiction only
9. This scheme will be available to participate throughout year, but draw will be held in last week of August every year
10. The executive committee of the Red Flower Publication reserve the right to cancel, revise or modify terms and conditions any time without prior notice.

I confirm and certify that the above information is true and correct to the best of my knowledge and belief.

Place:

Signature with Seal

Date: