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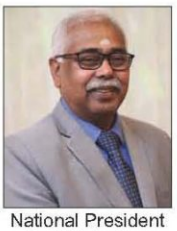
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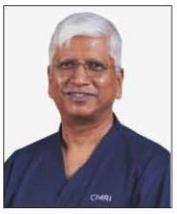
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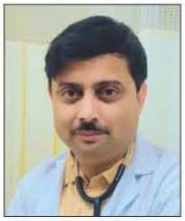
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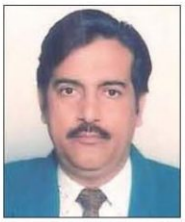
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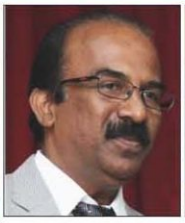
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BRIEF REPORT OF JIMA NATIONAL ASSEMBLY OF EDITORS OF MEDICAL JOURNALS (3rd Edition)

DR. SANJOY BANERJEE
Hony. Editor, JIMA (2023-2024) & Organising Secretary, 3RD NAEMJ

I am extremely happy to pen down the report as the **Hony. Editor, JIMA & Organising Secretary** of this prestigious **National Assembly of Editors of Medical Journals 3rd Edition** which was successfully organised on **28th July (Sunday)** at **The Park Hotels, 17, Park Street, Kolkata-700016** after **15 years.** As you know the first one was organised way back in **1985** and the second one was held on **29th November, 2009.**

I have been always of the opinion that such Editor's assembly should be organised frequently to upgrade the authors who are the backbone of any publication. When I was the Hony Secretary, I attempted it unsuccessfully because of the dreaded COVID PANDEMIC that started.

But, as the Hony Editor Elect, I was determined to organise it & started working for it. And when I took over as the Hony Editor, I immediately started giving it a shape. After initial discussion amongst us, the first meeting was called on 15/2/2024. We invited all the Past Hony. Editors and Hony. Secretaries of JIMA. Many of them turned up with their valuable suggestions. The first thing was to fix a date with the approval of IMA HQs, which we got. The ball started rolling.

Many hurdles came while organising this assembly. We crossed the hurdles together as **TEAM JIMA.** But what I feel that organising this type of assembly after 15 years is very difficult for any Hony. Editor of JIMA whose tenure is only one year. If it is not organised every year there is no budget for this assembly from supporting Pharma & allied industries, Hospitals & Diagnostic Centres. After taking charge as Hony. Editor, understanding his work and implementing it takes 6 months and the elections for the next Hony. Editor is in the air by then. If an assembly has to be organised it requires 2-3 months of preparation. My earnest appeal to IMA HQs to change the tenure of Hony. Editor for 2 years (One term) just like Hony. JIMA Secretary, JIMA by amendment of the Constitution. Otherwise, I don't think any Hony. Editor will venture to organise this type of assembly during his tenure in near future.

As many as **15 Scientific Sessions** of different specialities were there. I am indebted to all my colleagues who arranged the scientific session sponsors.

Many Editors of different medical journals across the country came and exchanged their views as well. There were **15 Scientific Display stalls** also as a feather to this assembly. There was an issue of high registration charges & relatively less attendance but we were ultimately successful to convince everybody and also to mention that **IMA Behala Branch** members came all-out in support of the Organising Secretary and stayed from morning till the end.

The topics and speakers are as follows respectively : Challenges in IVFin PCOS by Dr. Honey Qureshi; Autoimmunity by Dr. Mallika Ghosh; Intervention of Stroke & the Newer Era by Dr. Apratim Chatterjee; Arni in Heart Failure by Dr. Asesh Halder; Pathogenesis of Fever: Approach to a Case of PUO by Dr.Navneel Chakraborty & Dr. Oishi Ganguly; Managing Helicobacter Pylori The Indian Perspective; Moderator: Prof. Dr. Sanjoy Kumar Banerjee; Panelists: Dr. Subrata Pal, Dr. Saswata Chatterjee, & Dr. Shambo Samrat Samajdar; Two Peas in a Pod by Dr. Shambo Samrat Samajdar; Role of Robot in Complex GI Surgery by Dr. Udipta Ray; ECMO Cardiac and Pulmonary Rescue by Dr. Arpan Chakraborty; Ethics & Law in Medical Research & Practice by Prof. Dr. Ranjan Bhattacharyya; Role of Oncotype DX Breast Recurrence Score by Dr. Sanjit Agrawal; Exploring the Clinical Implications: How Genomics Shapes Human Health

by Sri. Krishnendu Menon; Insulin Co-Formulation in Management of Diabetes by Dr.Rudrajit Pal; Innovations in Cancer: Are we witnessing paradigm shifts; Over the last two Decades? - A Panel Discussion; Moderator: Dr. Amitabh Ray; Panelist: Prof (Dr) P K Maity, Prof (Dr) Partha Dasgupta, Prof (Dr) Subrata Chatterjee, Dr Abhishek Basu, Dr Sudip Das, Dr Jibak Bhattacharya which chaired by Prof (Dr) Subir Gangopadhyay.

I am thankful to **Dr.Tamonas Chaudhuri,** Past Hony. Editor of JIMA who came forward to organise a hands-on workshop, **'How to upgrade one's writing skills for Medical Journals',** which I feel the most attracting part of this assembly. The sessions were as follows:

How to write a Scientific Research Paper - A Step-By-Step Approach; Course theme "Common Pitfalls in Writing Various Components of the Scientific Paper"; Patron: Course Director: **Dr. Vikram Kate**, Puducherry; Overall Coordinator: **Dr.Tamonas Chaudhuri,** Kolkata.

How to Write a Scientific Paper - An Overview by **Dr. Vikram Kate**, Puducherry; Pitfalls in Writing Title, Abstract & Introduction by **Dr. Prasanth Ganesan,** Puducherry; Components of Patients & Methods including Study Design by **Dr. Vikas Menon,** Puducherry; Group Task I - Integrative and Problem-Based Discussion; Writing Results Comprehensively by **Dr. Kalayarasan R, Puducherry;** The Essential Components of the Discussion by **Dr. Vikas Menon,** Puducherry; References & Summation of Manuscript Writing by **Dr. Kalayarasan R,** Puducherry.Group Task II -Integrative and Problem-Based Discussion

Panel Discussion : Writing An Original Article-Do's and Don'ts Moderator: **Dr. Prasanth Ganesan,** Puducherry; Panelists : **Dr. Kalayarasan R, Vikas Menon, Vikram Kate,** Puducherry

A Short Paper Presentations was also there which was coordinated by **Dr. Ranjan Bhattacharyya & Dr. Prashanta Bhattacharyya,** Hony. Associate Editors JIMA. How To Secure Funded Research Projects from Government of India, ICMR, Dst., by **Prof. Ujjwal Kumar Neogi;** Publication Ethics & Plagiarism Check by **Prof. Dr. Tapas Kumar Bose;** Utility of Artificial Intelligence in Medical Research by **Dr. Abhishek Das;** Mastering Manuscript Submission: Navigating the Journey to Success by **Dr. Shambo Samrat Samajdar.** Then an Open Forum Editor's Meet, How to Upgrade Journal; Co-Ordinator: **Dr. Kajal Krishna Banik & Dr.Tamonas Choudhuri** was organised.

The Assembly was inaugurated by **Dr. R.V. Asokan,** National President of IMA. **Dr. Santanu Sen** Ex-MP, Past National President, Chairperson, Reception Committee, **Dr. Samarendra Kumar Basu,** Chairperson, Org. Com. **Dr. Sanjoy Banerjee,** Hony. Editor JIMA & Organising Secretary, **Dr. Sibabrata Banerjee,** Hony. Secretary, JIMA, **Dr. Kakali Sen,** Hony. Editor, Your Health of IMA and **Dr. Pradeep Nemani,** Jt. Secretary, IMA HQs (Kolkata) were on the dais. Thanks to **Dr. Ranjan Bhattacharyya, Dr. Prashanta Kumar Bharttacharyya,** Associate Editors of JIMA & **Dr. Minakshi Gangopadhyay,** Assistant Secretary, JIMA who managed the dias during inauguration.

National President, Dr. R.V. Asokan felicitated the Hony. Editors and Secretaries of JIMA. namely, **Dr. Surendra Daga, Hony. Editor, JIMA (2006-08); Dr. Kajal Krishna Banik, Hony. Editor, JIMA (2009); Dr. Swaraj Haldar, Hony. Editor, JIMA (2010); Dr. Subir Ganguly, Hony. Editor, JIMA (2012) & Hony. Secretary (1992-1994); Dr. Dilip Kumar Dutta, Hony. Editor (2017); Dr. Samarendra Kmar Basu, Hony. Editor (2018); Dr.Golokbihari Maji, Hony. Editor, JIMA (2019); Dr.Tamonas Chaudhuri, Hony. Editor, JIMA (2021); Dr. Sanjoy Banerjee,Hony. Editor, JIMA (2024) & Hony. Secretary (2019-20); Dr. Subhas Chakraborty, Hony. Secretary, JIMA (1996-98); Dr.Sibadatta Chaudhuri, Hony. Secretary, JIMA (2001-02); Dr. Asim Kumar Sarkar, Hony. Secretary, JIMA (2004-06); Dr. Santanu Sen, Hony. Secretary, JIMA (2015-16); Dr. Kakali Sen, Hony. Secretary, JIMA (2017-18) andDr.Sibabrata Banerjee, Hony. Secretary, JIMA (2023-24).**

The following Hony. Editors and Secretaries of JIMA were unable to be present at the felicitation ceremony and their mementoes and a Souvenir with a covering letter were delivered to them after the assembly. **Dr. Sudipto Roy, Hony. Editor, JIMA (1999-2002) & Hony. Secretary (2002-04); Dr. Prabir Kumar Sur, Hony. Editor, JIMA (2004); Dr. Ram Dayal Dubey, Hony. Editor, JIMA (2005) & Hony. Secretary (2008); Dr. Nemai C. Nath, Hony. Editor, JIMA (2011); Dr. Ashok Kumar Ghoshal, Hony. Editor (2013); Dr. Sudarsan Chakraborty, Hony. Editor, JIMA (2014); Dr. Debasish Mukherjee, Hony. Editor (2016); Dr. Jyotirmoy Pal, Hony. Editor, JIMA (2020) & Hony. Secretary (2021-22); Dr. Sujoy Ghosh, Hony. Editor, JIMA (2022); Dr. Nandini Chatterjee, Hony. Editor, JIMA (2023); Dr. Maya Rani Ghosh, Hony. Secretary, JIMA (2007); Dr. Iskandar Hossain, Hony. Secretary, JIMA (2009-10); Dr. Sarbari Dutta,Hony. Secretary, JIMA (2011-12)**

Dr. R.V. Asokan, National President in his maiden speech enlightened various issues related to JIMA and IMA. He said that once Gopal Krishna Gokhale ji said "What *Bengal thinks today*, *India thinks tomorrow*", and it applies even today. He said that Bengal must be united for the sake of National IMA. He said that JIMA is the face of IMA and it has been enriched by stalwarts like Sir Nilratan Sircar and many. He said such type of assembly should be organised frequently. He thanked and congratulated **Dr. Sanjoy Banerjee** for his hard work to make the assembly a grand success. He mentioned that **JIMA** now **indexed** in **SCOPUS & EMBASE** and will be indexed in **PUBMED** very soon. He also mentioned that when he was the Hony. Secretary General of IMA, **Dr. Santanu Sen** was the National President and he helped a lot to renew the Registration of IMA. Lastly, he thanked **Dr. Sanjoy Banerjee** for arranging his accommodation at the Bengal Club which is a pre-independence heritage and he was overwhelmed.

Dr. Santanu Sen, Chairman Reception Committee was very brief in his address and highlighted all round success of JIMA. He mentioned how he fought to keep JIMA in Kolkata when there was a ploy to shift the office to New Delhi. He also mentioned that IMA is registered in Kolkata since its inception and officially IMA House in Kolkata is the registered office as per society registration act. He also thanked the Organising Secretary for organising the assembly single handed. He also praised the full house for their co-operation.

Dr. Samarendra Kumar Basu, Chairman, Organising Committee welcomed all the delegates and dignitaries. He thanked all the members of the Organising Committee & staff for this stupendous achievement. He mentioned about the strategies to bring delegates early morning by Early Bird Gift, the JIMA Selfie Zone for amusements and the valedictory gift to hold delegates till the end the organising capability of the Organising Secretary.

Dr. Dilip Dutta, President, IMA Bengal Branch, praised the organising team for a grand success of the assembly.

Dr. Sanjoy Banerjee, *Organising Secretary & Editor, JIMA* : I am thankful to all the **Speakers, Panellists** and **Moderators;** I am also thankful to all the **Advertisers, Sponsors, Vendors and Well-wishers;** But I must mention specially **Dr. Sankar Sengupta, Dr. Anirban Dolui, Dr.Sibabrata Banerjee, Dr. Samarendra Kumar Basu, Dr. Sanjay Kumar Banerjee, Dr. Ranjan Bhattacharyya, Dr. Sekhar Chakraborty, Dr. Subir Gangopadhyay, Dr. Sujoy Ghosh, Dr. Swaraj Halder, Dr. Dilip Kumar Dutta, Dr.Bibartan Saha, Dr. Prashanta Kumar Bhattacharya** and **Dr. Santanu Sen** for their financial help towards organising the National Assembly of Editors of Medical Journals. I shall everremain indebted to you all for making this assembly a grand success.

I whole heartedly thank all our **JIMA Committee** and the **Organising Committee** colleagues for their support and co-operation.

I thank National President, **Dr. R.V. Asokan** to come to Kolkata to inaugurate the programme.

For the last few months, we worked hard to showcase this event a grand success. Any lapses in any point would be mine and the success will go to the whole organising team including the staff of JIMA. Special thanks to **Mr. Debabrata Chatterjee,** General Manager, JIMA, **Mr. Pranab Kumar Sahoo,** Accountant, **Mr. Mrinal Kanti Dey,** Editorial Department, **Ms. Paramita Chowdhuri** and **Ms. Ipshita Mukherjee** for their contribution. I must also mention **IMA Behala Branch Office & Staff** who also worked day & night for the success of this assembly.

I am indebted to my mentor my elder brother **Dr. Ketan Dhirajlal Desai** for his continuous support.

Long Live IMA!! Long Live JIMA!

Glimpses of 3rd JIMA National Assembly of Editors of Medical Journals

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Communications intended for publication should be sent to the Editor, Journal of the Indian Medical Association (JIMA). JIMA will consider manuscripts prepared in accordance with the **Vancouver style[1].**

Articles are considered for publication on condition that these are contributed solely to JIMA, that they have not been published previously in print and are not under consideration by another publication. In the selection of papers and in regard to priority of publication, the opinion of the Editor will be final & IMA members will be given prerogative. The Editor shall have the right to edit, condense, alter, rearrange or rewrite approved articles, before publication without reference to the authors concerned. **We Publish only online submitted articles through https://onlinejima.com**

Authorship : All persons designated as authors should **qualify for authorship.** Authorship credit should be based only on **significant contributions** to (a) conception and design, or analysisand interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final ap-proval of the version to be published. **Conditions (a), (b) and (c) must all be met.** Authors may include explanation of each author'scontribution separately.

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Illustrations — Graphs, charts, diagrams or pen drawings must be drawn by professional hands. Photographs should be supplied in resolution minimum 350 dpi and 5 inch wide. In case of microphotograph, stains used and magnification should be **mentioned.** Each illustration should have a minimum resolution of 350 dpi with proper labelling. All illustrations should be with suitable legends.

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Reference from Journal :

[1]Cogo A, Lensing AWA, Koopman MMW, Piovella F, Sivagusa S, Wells PS, *et al* —Compression ultrasonography for diagnostic management of patients with clinically suspected deep vein throm-bosis: prospective cohort study. *BMJ* 1998; **316:** 17-20.

Reference from Book :

[2]Handin RI — Bleeding and thrombosis. In: Wilson JD, Braunwald E, Isselbacher KJ, Petersdorf RG, Martin JB, Fauci AS, *et al* editors—Harrison's Principles of Internal Medicine. Vol 1. 12th ed. New York: Mc Graw Hill Inc, 1991: 348-53.

Reference from Electronic Media :

[3]National Statistics Online—Trends in suicide by method in England and Wales, 1979-2001. www.statistics.gov.uk/downloads/ theme_health/ HSQ 20.pdf (accessed Jan 24, 2005): 7-18.

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Editorial

Mental Health in Changing Scenario : Present Status and Future Direction

Mental Health Landscape has seen drastic changes over past decade with adoption of Mental Healthcare Act (2017). The National Mental Health Survey (NMHS) in India (2015-16) is a significant initiative aimed at assessing the mental health status of the population across the country. The NMHS was conducted to provide comprehensive data on the prevalence, patterns, and correlates of mental disorders in India. It aimed to gather information that could guide mental health policy and planning.The survey was conducted by the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, in collaboration with various state health departments and other stakeholders.The survey covered a broad spectrum of mental health issues, including common mental disorders like depression and anxiety, severe mental illnesses, substance use disorders, and suicidal behaviors.Despite its significance, challenges such as stigma, limited awareness, and resource constraints continue to affect mental health care in India. Moving forward, there is a need for sustained efforts to strengthen mental health systems and integrate services into primary healthcare[1].

Common Mental Disorders (CMDs) refer to a group of mental health conditions that are relatively widespread in the general population. These disorders typically affect mood, thinking, and behavior, and they can impair daily functioning and Quality of Life[2].

(1) **Depression** is characterized by persistent sadness, loss of interest or pleasure in activities once enjoyed, changes in appetite or sleep patterns, and feelings of worthlessness or guilt. Major depressive disorder is a common form of depression.

(2) **Anxiety Disorders :** These include conditions such as generalized anxiety disorder (excessive worry about various aspects of life), panic disorder (recurring panic attacks), social anxiety disorder (intense fear of social situations) and specific phobias (irrational fears of specific objects or situations).

(3) **Post-Traumatic Stress Disorder (PTSD) :** Develops after exposure to a traumatic event such as combat, assault, natural disaster, or other life-threatening events. Symptoms include intrusive memories, avoidance of reminders of the trauma, negative changes in mood and thinking, and increased arousal or reactivity.

(4) **Obsessive-Compulsive Disorder (OCD)** is characterized by recurrent, unwanted thoughts (obsessions) and/or repetitive behaviors or mental acts (compulsions). People with OCD may feel driven to perform rituals or routines to alleviate anxiety caused by obsessions.

(5) **Borderline Personality Disorder (BPD) :** Although categorized under personality disorders, BPD involves severe mood swings, unstable relationships, impulsivity,

and distorted self-image. It can lead to intense episodes of anger, depression, and anxiety.

(6) **Post-Traumatic Stress Disorder (PTSD) (Severe):** While PTSD can vary in severity, severe cases involve debilitating symptoms such as flashbacks, nightmares, severe anxiety, and emotional numbness. It often follows exposure to traumatic events such as combat, assault, or natural disasters.

(7) **Eating Disorders :** These include conditions such as anorexia nervosa (persistent restriction of food intake leading to dangerously low body weight), bulimia nervosa (episodes of binge-eating followed by compensatory behaviors like vomiting or excessive exercise), and binge-eating disorder (frequent episodes of consuming large quantities of food followed by distress).

Severe Mental Disorders (SMDs) are a category of mental health conditions that significantly impact a person's ability to function in daily life. These disorders often involve severe disturbances in thinking, emotions, and behaviors.They can be chronic and require ongoing treatment and support. Some examples of severe mental disorders include :

(1) **Schizophrenia :** A complex and chronic mental disorder characterized by disruptions in thought processes, perceptions, emotions, and behaviors. People with schizophrenia may experience hallucinations, delusions, disorganized thinking, and impaired social functioning.

(2) **Bipolar Disorder :** Also known as manic-depressive illness, bipolar disorder involves episodes of mania (extreme highs) and depression (extreme lows). These mood swings can be severe and disrupt relationships, work, and daily activities.

(3) **Schizoaffective Disorder :** A condition characterized by symptoms of schizophrenia, such as hallucinations or delusions, combined with mood disorder symptoms like mania or depression. Individuals with schizoaffective disorder may experience periods of psychosis and mood disturbances.

These disorders can vary in severity and may co-occur with each other or with other medical conditions. Early recognition, diagnosis, and treatment are crucial for managing these disorders effectively and improving outcomes for individuals affected by them. Treatment often includes a combination of psychotherapy, medication, and support services tailored to the specific needs of the individual.

The District Mental Health Programme (DMHP) is a centrally sponsored scheme launched in India in 1996 with Bellary district model of Karnataka, to provide accessible and affordable mental health services at the district level[3]. In West Bengal, Bankura district had been taken as pilot to implement this program. Here are the key aspects and objectives of the District Mental Health Program :

(1) Objectives : The primary goal of the DMHP is to provide mental health care services to the population at the district level, focusing on early detection, treatment, and rehabilitation of persons with mental illnesses.

(2) Implementation : The program is implemented through collaboration between the Ministry of Health and Family Welfare, state health departments, and district administrations. It operates under the National Mental Health Program (NMHP).

(3) Service Delivery : DMHP aims to integrate mental health services into primary health care settings. It includes initiatives such as screening camps, outreach programs, and training of primary health care workers to identify and manage common mental disorders.

(4) Infrastructure Development : The program supports the establishment and strengthening of mental health facilities, including district-level mental health clinics, psychiatric wings in general hospitals, and residential care facilities for severe mental illnesses.

(5) Human Resources Development : DMHP focuses on capacity building by training medical officers, psychologists, psychiatric social workers, and psychiatric nurses in evidence-based practices for mental health care.

(6) Community Participation : Community involvement is encouraged through awareness campaigns, involvement of local NGOs, and self-help groups to reduce stigma and promote mental health literacy.

(7) Monitoring and Evaluation : Regular monitoring and evaluation are conducted to assess the effectiveness of services provided under DMHP, improve service delivery, and ensure accountability.

(8) Expansion and Coverage : Over the years, the program has expanded to cover more districts across India, aiming to reach a larger population in need of mental health care services.

Overall, the District Mental Health Program plays a crucial role in addressing the mental health needs of the community at the grassroots level, promoting early intervention, reducing stigma, and improving access to essential mental health care services in India.

The National Mental Health Program (NMHP) in India is a comprehensive initiative aimed at addressing mental health issues across the country[4]. Here are the key components and objectives of the National Mental Health Program :

(1) Objectives :

- **Service Delivery :** To ensure the availability and accessibility of minimum mental health care for all.
- **Human Resources Development :** To develop human resources for mental health to provide mental health services.
- **Information, Education, and Communication (IEC) :** To promote mental health awareness and reduce stigma.
- **Research :** To undertake research in mental health.
- **Monitoring and Evaluation :** To monitor implementation and evaluate outcomes.

(2) Implementation :

- The program is implemented by the Ministry of Health and Family Welfare, Government of India, in collaboration with state health departments and other stakeholders.
- It operates through various components, including District Mental Health Program (DMHP), mental health clinics, and psychiatric wings in medical colleges and general hospitals.

(3) Service Delivery :

- NMHP aims to integrate mental health services into primary health care through the DMHP. This includes providing treatment for common mental disorders, severe mental illnesses, and substance use disorders.
- The program also supports the establishment of mental health facilities and the training of health care professionals in evidence-based practices.

(4) Human Resources Development :

- NMHP emphasizes capacity building by training medical officers, psychologists, psychiatric social workers, and nurses in mental health care.
- It encourages the recruitment and deployment of mental health professionals at various levels of health care delivery.

(5) Community Participation :

- NMHP promotes community involvement through awareness campaigns, advocacy programs, and the engagement of local NGOs and self-help groups to support persons with mental illnesses.

(6) Research and Evaluation :

- The program supports research initiatives to generate evidence for effective mental health interventions and policies.
- Monitoring and evaluation mechanisms are in place to assess the implementation of NMHP activities and their impact on mental health outcomes.

(7) Challenges and Future Directions :

- Challenges include stigma associated with mental illness, limited mental health infrastructure in rural areas, and the need for sustained funding and political commitment.
- Future directions include expanding coverage, improving quality of care, integrating mental health into broader health policies and addressing the mental health needs of vulnerable populations such as children, adolescents, and the elderly.

In summary, the National Mental Health Program in India is a crucial initiative aimed at promoting mental health, improving access to mental health care services and reducing the burden of mental illness on individuals and society.

A General Hospital Psychiatry Unit (GHPU) is a specialized department within a general hospital that provides psychiatric services to patients first started at R G Kar Medical College & Hospital, Kolkata in 1933 by Dr Girindra Sekhar Bose[5]. The GHPU offers comprehensive psychiatric care to patients who require treatment for various mental health disorders.It aims to integrate mental health services with general medical care, addressing both physical and mental health needs.Psychiatrists and mental health professionals assess patients for mental health disorders through interviews, observations, and sometimes psychological testing. A GHPU typically operates with a multidisciplinary team that may include psychiatrists, psychologists, psychiatric nurses, social workers, occupational therapists, and other mental health professionals.GHPU facilities include inpatient wards for short-term stays, outpatient clinics for follow-up care, and day treatment programs.The GHPU coordinates closely with other departments within the general hospital, such as emergency services, intensive care units, and medical/surgical wards. Many GHPU units are involved in education and research activities, training medical students, residents, and fellows in psychiatry, and conducting studies to advance knowledge and treatment options in mental health.

Investment in mental health is crucial for several reasons and it encompasses various forms of support, funding and resources allocated to improve mental health outcomes[6]. Here are some key aspects and reasons why investment in mental health is important:

(1) Improving Access to Services :

Investment allows for the expansion and enhancement of mental health services, including the establishment of community-based clinics, psychiatric facilities, and telehealth services. This helps bridge the gap in access to care, especially in underserved areas.

(2) Early Intervention and Prevention :

Funds directed towards mental health can support early intervention programs aimed at identifying and addressing mental health issues before they escalate. This includes screening programs, school-based interventions and workplace mental health initiatives.

(3) Integrated Care and Holistic Approach :

Investment promotes the integration of mental health services into primary health care settings, ensuring that individuals receive comprehensive care that addresses both their physical and mental health needs. This approach improves overall health outcomes and reduces healthcare costs associated with untreated mental illnesses.

(4) Research and Innovation :

Funding for mental health research fosters innovation in treatment methods, medication development, and understanding of mental health disorders. It supports studies on effective interventions, prevention strategies, and the impact of social determinants on mental health.

(5) Reducing Economic Burden :

Mental health conditions impose a significant economic burden on individuals, families, workplaces, and society as a whole. Investment in mental health can lead to cost savings by reducing productivity losses, healthcare expenditures related to untreated mental illnesses, and social welfare costs.

(6) Promoting Mental Health Literacy and Awareness :

Resources allocated to education and awareness campaigns help reduce stigma surrounding mental health issues. This encourages early help-seeking behavior and promotes a supportive environment for individuals living with mental health conditions.

(7) Addressing Vulnerable Populations :

Investment can target specific vulnerable populations such as children and adolescents, elderly individuals, marginalized communities, and those affected by trauma or substance use disorders. Tailored programs and services can meet their unique mental health needs.

(8) Policy and Advocacy :

Adequate funding supports advocacy efforts and policy initiatives aimed at improving mental health care delivery, expanding insurance coverage for mental health services, and advocating for mental health parity laws.

Investment in mental health is essential for building resilient communities, promoting overall well-being, and reducing the personal, social and economic impacts of mental health disorders. It requires a multi-sectoral approach involving governments, healthcare providers, researchers, advocates, and the community to achieve lasting improvements in mental health outcomes.

Future direction : The future of mental health holds promises and challenges across various dimensions:

(1) Technology Integration : Advances in technology like AI and virtual reality are reshaping mental health diagnostics, treatment, and accessibility. Telehealth and digital platforms offer convenience and reach, especially in remote or underserved areas.

(2) Personalized Medicine : Precision medicine approaches are becoming more prevalent, tailoring treatments based on genetic, environmental, and lifestyle factors. This could lead to more effective interventions with fewer side effects.

(3) Destigmatization and Awareness : Increasing awareness and efforts to reduce stigma around mental health are crucial. Education and advocacy campaigns can encourage early intervention and support.

(4) Integration with Physical Health : Recognizing the strong link between mental and physical health, healthcare systems are moving towards integrated care models that address both aspects comprehensively.

(5) Challenges : Despite progress, challenges like data privacy concerns, unequal access to technology and the need for trained professionals remain. Additionally, cultural attitudes and societal norms about mental health vary globally.

(6) Treatment Resistant : Continued research into novel therapies such as psychedelics for treatment-resistant conditions, and non-traditional approaches like mindfulness and art therapy, offer new avenues for healing.

(7) Policy and Funding : Adequate funding and supportive policies are essential for scaling effective mental health interventions and ensuring equitable access to care.

While technology and research are advancing mental health care, addressing stigma, enhancing accessibility, and integrating holistic approaches remain critical for shaping a positive future in mental health.

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Original Article

An Assessment of Knowledge and Attitude of Beneficiaries Attending Tertiary Care Hospital regarding Temporary Family Planning Methods and to Determine their Experienced Side Effects of Temporary Contraceptive Methods in Ahmedabad City, Gujarat, India

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Background : Despite the fact that contraception usage has increased over a period of time, there exist a Knowledge, Attitude and Practice-gap of Contraceptives.

Aims and Objectives : (1) To study the Knowledge and Attitude about temporary methods of contraception. (2) To determine the side effects of temporary family planning methods.

Material and Methods : This was a hospital based prospective study carried out at Tertiary Care Centre during the year 2020. Selection of participants (150) was done through stratified sampling those patients who had received temporary family planning services. The interview was taken of beneficiaries attending the Tertiary Care Centre.

Results : Majority of the women belonged to young age (70%). Most common source of information was a doctor at their antenatal clinic (50.67%). Women (82%) were aware of condoms, 70% of IUCD and only 31% aware of injectable contraception. Among users of Oral Contraceptive (OC) Pills, 40% had complaint of irregular bleeding, 36% over-weight, 30% nausea. Among IUCD users, 18% had problem of bleeding p/v, 6% patients had string problem like discomfort while intercourse and expulsion of IUCD (2%). Amenorrhea (72%) was side effects observed in Injection DMPA users.

Conclusion : Most of the participants were aware of various temporary methods except injectable. Women users were experienced mild side effects and no major complications.

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***Key words* : Family Planning Methods, Primipara, Irregular Bleeding, Amenorrhoea.**

Family planning is outlined by World Health Organization (WHO) as "a way of thinking and living that is adapted voluntarily, upon the basis of knowledge, attitudes and responsible decisions taken by person and couples, in objective of promotion of health and welfare of family group and this contribute effectively to the social development of the Nations".

Globally, India was the 1st Nation to launch national family planning programme in 1952 with the goal of reduction in the birth rate of extent necessary to stabilize the population at a level consistent with requirement of national economical vision. One of the important objectives of the programme is to space the knowledge of family planning methods and develop among the people an attitude favourable for adoption of contraceptive methods. The progress achieved in this sphere is normally assessed form the result of Knowledge, Attitude and Practice survey. Despite the fact that contraception usage has increased over a period of time, there exist a Knowledge, Attitude and Practice-gap. That is a gap between Knowledge, Attitude and Practice regarding contraception[1].

Editor's Comment :

- The use of temporary contraceptives is growing day by day due to fact of avoiding unwanted pregnancy.
- The successful outcome of family planning program can only be attained by increasing the awareness of various temporary contraceptives available.

Among the 1.9 billion reproductive age group females (15-49 years) globally in 2019, 1.1 billion have a need for family planning; of these, 842 million are using contraceptive methods and 270 million have an unmet need for contraception[2].

There has been a substantial decline in traditional methods by 2.1% which can be well correlated with the provision for quality family planning services. National Family Health Survey-3 data, 10.1% of female non-users reported that health workers had talked to

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their patients about FP methods. This has improved to 17.7% in National Family Health Survey-4[3].

In developing country like India, over population is an important concern. Despite development resulting from making contraceptive methods widely available in the country, there is poor acceptance of family planning methods. This was either due to ignorance or fear of complications using them[4].

Inadequate Knowledge, Attitude and Practice about contraception method and incomplete or enormous information about their use or where to procure them are the main reason for not accepting formula planning.

Aims and Objectives

- To study the Knowledge and Attitude about temporary methods of contraception.
- To describe the factors associated with acceptability of temporary contraceptive methods in women according to their socio-demographic and obstetrics characteristics and future pregnancy desire.
- To determine the side effects of temporary methods of contraception [Oral Contraceptive (OC) Pills, Injection DMPA, Intra Uterine Contraceptive Device].

Materials and Methods

This was a hospital based prospective study carried out in the Department of Obstetrics and Gynaecology at tertiary care institute during the year 2020. Selection of participants (150) was done through stratified sampling those patients who had received temporary family planning services. [Oral Contraceptive (OC) Pills (50), Injection DMPA (50) and Copper T (50)]. The interview was taken of 150 patients attending the tertiary care centre through pre-tested and pre-structured questionnaire. That includes socio-demographic information, parity status, complication developed following use of temporary family planning methods.

Inclusion Criteria :

Women belonging to the age group of 20-40 years, women of any parity delivered vaginally, by caesarean section or aborted, desired to have any contraceptive method, no infection, Haemoglobin ≥8g/dl.

Exclusion Criteria :

Women with significant medical disorders like Diabetes Mellitus, Heart Diseases, Severe Anaemia, Coagulation Disorders, having active STD or other lower genital tract infection or high risk for STD, women with mental disorders, having HIV and not on anti-retroviral therapy, known uterine abnormalities-bicornuate, septate uterus, fever during labour and delivery or immediate postabortion period, An allergy to copper, women with age <20 and >40, women not willing to respond even after requesting and ensuring confidentiality.

Observations

In present study, majority of the women belonged to the age group of 20-29 years (70%) which is the peak reproductive age group. Less acceptance among women with increasing age suggest their preference for permanent method of contraception. Majority of the subject in the study group were housewives (74%). Temporary contraceptive methods are very safe and easy to administer. These are the reasons for higher acceptance among housewives. Majority of participants were from urban area (68%).

In current study of the 150 women, 32.67% women were illiterate and 42.67% women possessed primary education, 14% women possessed secondary education and up to 10.66% women possessed higher secondary level and above. Hence, higher the literacy, higher the awareness and acceptance of contraceptive methods.

Majority of the subjects belong to class IV (upper lower) (46%), class II (upper middle) (19.33%) and class III(lower middle) (14.67%) socio-economic class. Requirement of less follow-up, its reversibility and feasibility in using them may be the reason for higher acceptance among middle and lower socio-economic class (Table 1).

Contraceptive acceptance is more among Hindu community (82.7%). Location of hospital in which study was carried out having more Hindu community and religious restrictions in Muslim community may be the reason for this result.

Table1— *Socio-demographic characteristic of the participants (n=150)*

	No of patients (%)
Locality :	
Urban	102 (68%)
Rural	48 (32%)
Age (in Years) :	
<20	5 (3.33%)
20-29	105 (70%)
30-39	40 (26.67%)
>40	0 (0%)
Occupation :	
Housewife	111(74%)
Labourer	26(17.33%)
Employed	13(8.67%)
Education :	
Illiterate	49(32.67%)
Primary	64(42.67%)
Secondary	21(14%)
Higher Secondary & Above	16(10.66%)
Socio-economic status (Modified kuppuswamy socio-economic scale 2020)[36]:	
I	3(2%)
II	29(19.33%)
III	22(14.67%)
IV	69(46%)
V	27(18%)
Religion :	
Hindu	124(82.67%)
Muslim	25(16.67%)
Christian	1 (0.66%)

Table 2 —*Awareness about different temporary Contraceptive Methods (n=150)*

Contraceptive Methods	Percentage (%)
Condom	123 (82%)
Intra Uterine Contraceptive Devices (IUCD)	105 (70%)
Hormonal Pills	93 (62%)
Emergency Contraceptives	63 (42%)
Injectables	48 (31%)
Implant	09(6%)

Table 2 showed that 82% of the women were aware of condoms, 70% were aware of IUCD while only 31% of women were aware of injectable contraception.

Table 3 shows women who are utilizing contraceptive methods are primipara (32.67%) and 2nd para (43.33%) which may be because of its easy reversibility.

In present study majority of the patients had a doctor at their antenatal clinic as their source of information (50.67%). After introduction of Government schemes like Janani Suraksha Yojana (JSY) & Janani Shishu Surksha Karykram (JSSK), majority of the deliveries are conducted in institutions, which is giving more opportunity to counsel and motivate patients to adopt contraceptive methods. Other sources of information are relatives, media, husbands, etc (Table 4).

In present study 40% women had complaint of irregular bleeding, 36% women had complaint of over-weight, 30% women had nausea. These side effects are attributed to oestrogen content of the OC pills. As low dose OC pills were prescribed to the patients, in this study group above mentioned side effects are seen commonly (Fig 1).

As shown in the Fig 2, 18% women had problem of bleeding p/v. It may be because of subclinical endometritis or PID. Three patients (6%) had string problem like discomfort while having intercourse and irritation. One patient (2%) had complaint of expulsion of IUCD (Fig 2).

In current study, most common side effects observed in Injection DMPA users was amenorrhea in 72%. This is because of the chronic effect of High progesterone and decreased oestrogen on endometrium causing thinning of the endometrium. Second most common side effect observed was weight gain (34%) (Fig 3).

Discussion

In present study, 70% women were in the peak reproductive age group. In current study of the 150 women, 32.67% women were illiterate. Majority of the subjects belong to class IV (upper lower) (46%). Majority of the patients had a doctor at their antenatal

Table 3 — *Parity wise distribution of the beneficiaries (n=150)*

Parity status	No of Patients and Percentage
Primi para	49(32.67%)
2nd para	65(43.33%)
3rd para	31(20.67%)
>3rd para	5 (3.33%)

Table 4 — *Source of information/motivation for Contraceptive Methods (n=150)*

Source	No of patients and Percentage
Health personnel	76(50.67%)
Husband	31(20.67%)
Relative / Social circle	20(13.33%)
Media	14(9.33%)
Others	9(6%)

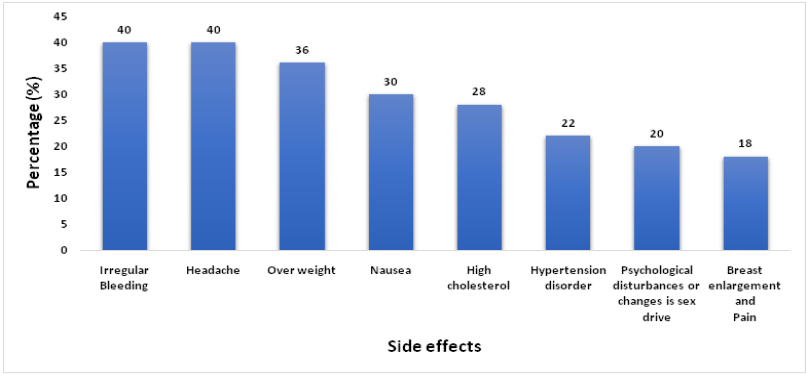

Fig 1 — Side effects of OC pills (n=50)

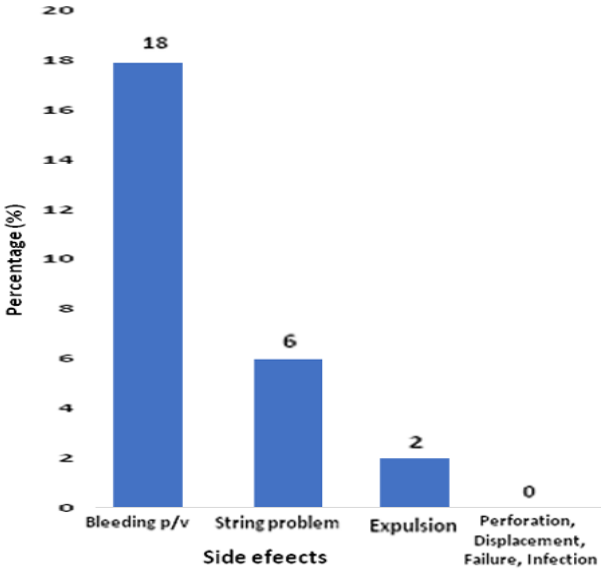

Fig 2 — Complications of IUCDs (n=50)

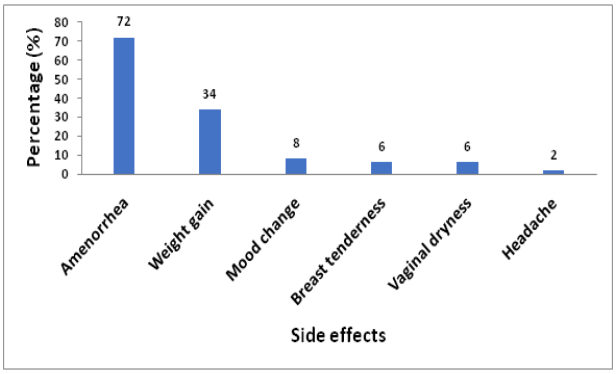

Fig 3 — Side effects of DMPA injections (n=50)

clinic as their source of information (50.67%). Most women who are utilizing contraceptive methods are primipara (32.67%) and 2nd para (43.33%) which may be because of its easy reversibility. Among users of OC pills, 40% women had complaint of irregular bleeding, 36% over-weight, 30% had nausea. Among IUCD users, 18% women had problem of bleeding p/v, 6% patients had string problem like discomfort while having intercourse and irritation. And 2% patient had complaint of expulsion of IUCD. In present study, most common side effects observed in Injection DMPA users was amenorrhea in 72%.

In other similar research study, the prevalence of temporary contraception usage varies very little by geographic address (urban area or rural area) and educational status, and have positive correlation with high socio-economic status. Females belonging to highest wealth quintile are more likely to use contraceptive methods than other females and Scheduled Tribe (ST) female are less likely to use Family Planning Methods than most other female. Consistent with son preference, which too play a major factor for acceptance of contraception[5].

Other research study showed that the overall proper Knowledge, Attitude and Practice of female towards contraception was 42.3%, 58.8% and 50.4% respectively. The average age of patients was 29.7± 6.4. Two hundred forty six (64.6%) and 133 (34.9%) were house wife's and farmers respectively by their occupation. Almost all patients, two-third (65.4%) were married, 24.9% were divorced by their marital status. All (100%) patients ever heard about contraceptive methods. The major sources of information were from health care workers (57.5%) and radio (41.5%). Regarding perceived adverse effects of usage of Family Planning, 13.1%, 24.9%, 9.7% and 52.2% of participants were responded heavy blood loss, irregular bleeding, missed menstrual cycle and abdominal cramps respectively were mentioned as common side effects. Almost 88.5% of the beneficiaries ever talked on contraceptive related problems with their spouse and wants to use it in the subsequently. About 24.5% of the patients self-reported that they believed that contraceptives exposes to infertility.Three fourth (75.3%) beneficiaries ever used any of the contraceptive methods. The various types of Family Planning Methods were oral contraceptive pills (7.4%) and injectable contraceptives (77.2%)[6].

Ninety eight percent of the female had heard about family planning methods and only very few (2%) were unaware about the same. About 54.4% of women received information about fFamily Planning Methods form mass media. 44.6% women were not using any contraceptive method, but were willing to adopt contraception in future and over 98% women thought that contraception was helpful to them and 93.2% reported that they would like to motivate their friends, colleagues and relatives to use the contraceptive methods. Of 215 women who had used contraceptives, 85% were satisfied with contraceptives that they had used in the past and 62% were still using contraceptives[7].

Knowledge of contraception was maximum for Sterilization 99%, Abstinence 98%, Barrier 97.4%; and less for OCPs, safe period and LAM. Para1 and 2 had better knowledge of Oral Contraceptive Pills, Intrauterine Contraceptive Devices and Depot-Medroxy-Progesterone Acetate (DMPA) than multipara who know more about permanent methods (100%). Most of the beneficiaries obtained information from mass media (54.4%). 68% obtained Family Planning Services from Government facility. Majority (60.8%) had positive attitude. 22.4% women discussed contraception with their husband. 55.6% women used some method of contraception, barrier (66.1%) being most common. 71.8% women had myths or other barriers to use contraceptives[8].

Major information sources about contraceptive methods were Health Workers (68.88%), Husband (68.46%), Television (42.06%). The leading motivators for family planning in women were Health Professionals in 66.9% participants[9]. Forty eight percentage of the females received information about contraceptives from Health Care Workers[10].

Women explained their perceptions of how the heating effects of contraceptives could cause unwanted side effects including menstrual irregularities, weight gain and weakness, leading to disease[11].

Various complications like gain in weight, irregular and painful menses with excessive blood loss exists as adverse effects of various control mechanism[12].

Conclusion

Temporary contraceptive methods have few side effects and with no major complications. Beside the role of contraceptive, there are different minor and major side effects associated with. There is a need of proper promotion and follow up on as well as information on contraceptives focusing particularly on its side effects. The successful outcome of family planning programs can only be attained by increasing the awareness of various temporary contraceptives available. Contraceptive methods play a vital role in preventing unwanted births and proper gap in between two successive pregnancy.

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Original Article

Impact of Psychological Intervention on the Quality of Life of Primary Care Givers of Patients with Cancer : Preliminary Report in City based Cancer Hospital, India

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Background and Aim : Caring for an individual with cancer can lead to significant stress, anxiety and feelings of sadness among primary caregivers, ultimately impacting their overall psychological and physical well-being. The aim of this research was to assess if cancer primary caregivers who underwent Psychological Interventions (PI) observed enhancements in their Quality of Life by decreasing levels of depression and anxiety.

Materials and Methods : A single-centre randomized control trial was conducted among 53 adult primary caregivers aged ≥18 years of age to ≤65 years and those involved with their patients' actual care not less than 12 hours per day, between April, 2023 to August, 2023. All participants went through the assessment of QoL and Depression and Anxiety levels by using validated tools. Participants were randomly assigned into two groups : Group-A (N=31), participants receiving psychological support and Group-B (N=22), who did not receive any psychological support.The intervention comprised five sessions. Following department protocol participants were followed-up based on 21,42, 63, 84 and 105 days. Participants completed primary outcomes (Anxiety, Depression and Quality of Life) before one of each session to see the impact of each session. To identify the impact of PI, descriptive statistics were calculated as the Mean±Standard deviation of the score of validated tools based on primary outcomes.

Results : A total of 53, female caregivers (61%) were more than male individuals (39%). About 60.57% of the caregivers reported severe hampering of their QoL. The data showed significant improvements in outcomes measured from pre to post and from post-to-follow-up as compared to Group-B counterparts (p<0.005). Group-A had statistically significant improvements in QoL in 120 days' follow-uptime, compared with Group-B, p=<0.01.

Conclusion : Under challenging circumstances during the period of cancer treatment, PI is a useful intervention for standing continuous psychological support as it is associated with better Quality of Life for primary caregivers. Further research examining factors influencing the outcomes of psychological intervention will be justified.

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Key words **: Cancer, Primary Caregivers, Quality of Life, Depression and Anxiety.**

Cancer is a life-threatening illness that is stressful not only to the patients but also to the caregivers in terms of how it might be experienced. During this lengthy treatment period, which frequently lasts for months or years, the patient and their Primary Caregivers spends more time at the cancer centre than at home. There are significant changes in the daily routines of both parties and they need to work very hard to adapt to the demands of this life-threatening disease. The family feels obligated to work together to support the patient after learning that a family member has cancer[9].

As is clear, daily practice reflecting the rise in cancer cases in India over the past ten years, the emotional anguish that it causes the family members, and the difficulty in coping with the diagnosis of their loved ones The patient's primary caregiver is responsible for making decisions, monitoring changes in the patient's condition, giving hands-on care, adjusting care as needed, gaining access to resources, negotiating with the healthcare system, providing emotional support, and frequently securing funding for

Editor's Comment :

- Psychological counseling is an essential resource for primary non-medical caregivers of cancer patients. It addresses the emotional and practical challenges of care giving, promotes mental health and fosters a supportive community. By prioritizing the well being of caregivers, we can enhance the quality of care for cancer patients and ensure that caregivers are able to sustain their vital roles over the long term.

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the treatment. The primary carer has a difficult responsibility to complete both physically and emotionally: juggling the care of the cancer patient with his or her own daily routine[20]. Since ancient times, providing care has been valued as a worthwhile experience, but the effects on the carers themselves are frequently disregarded. According to the Quality of Life in LifeThreatening Illness-Family Carer Version (QoLLTI-F) assessment, half of the carers in a recent study on the Quality of Life (QoL) of carers had a bad quality of life. The statistical results showed that characteristics like gender, religion, location, financial burden, lung cancer stage and kind, disability and patient depression had a substantial impact on the carers' Quality of Life.

The Quality of Life of the patient's primary caregivers, a group that is frequently disregarded, is a very important concern that has been addressed by the widespread usage of this questionnaire and its translation into many languages. The Turkish translation of the English CQOLC yielded results that were comparable to those of our study, suggesting that there were some concerns that were shared by families of cancer patients. It was also administered alongside the World Health Organisation Quality of Life Short Version (WHO-QoL-BREF) to breast and Gynaecological cancer patients and validated to the German version[6]. It demonstrated good reliability for burden, disruptiveness, and financial concerns but low reliability for positive adaptation. Utilising the same CQOLC scale, similar studies were carried out in Korea and the United Arab Emirates, with comparable results on demographic comparisons[6,15].

Previously many researchers in India have already discussed about depression, death anxiety and stress in cancer caregiver[3,17,10] along with the burden the caregivers have to go through[16]. Keeping these psychological issues in mind, researchers have discussed about psychosocial intervention for the cancer caregivers' better Quality of Life[19,5,8].

After interacting with cancer caregivers, the most common psychological issues seen were anxiety (about losing loved ones), overprotectiveness, feeling of failure to give best their loves ones who has cancer and depression. Therefore, keeping all this factors in mind we have developed a psychosocial intervention in West Bengal for cancer caregivers for the first time. As the concept of psychosocial intervention is still new in West Bengal, we were unable to refer to previous state-wise researches about effect of psychological intervention on caregivers' Quality of Life (QoL).

The objective of this study was to evaluate the impact of Psychological Interventions (PIs) on the quality of life of cancer primary caregivers, specifically in terms of reducing their levels of depression and anxiety.

Materials and Methods

Study Design :

This study was a randomized controlled trial conducted at a tertiary cancer hospital in Eastern India after receiving approval from the institutional review board. Out of 149 cancer patients' primary caregiver between April, 2023 to August, 2023, only 66 participants were enrolled in the study after fulfilling eligibility criteria. Participants were randomly assigned by using computer generated random number to either the Group-A (N=34), participants receiving Psychological Intervention (PI) and Group-B (N=32), did not receive any PI. Sample size was calculated based on power 80% and alpha 0.05 and few patients previously agreed to take part in study and refused later. Hence, we omitted those participants leading to sample size- Group-A=33 and Group-B=29. These participants were screened using the Mini International Neuro-psychiatric Interview (MINI) and those with the diagnosis of first episode depression and anxiety (mild or moderate severity) as per International Classification of Diseases – 10th edition (ICD 10) criteria, as confirmed by an experienced clinical psychologist were included in the study. Those participants who received a diagnosis other than depression and anxiety [Group=A (N = 2) and Group=B (N=7)] were excluded.

Eligibility Criteria :

Inclusion criteria :

(1) Diagnosed cancer patients and undergoing active cancer treatment

(2) No evidence of previous psychiatric illness

(3) Currently not enrolled in another PI study or psychiatric support

(4) Age more than 18 years

(5) Able to understand, read and speak the Bengali language. (Response from patients with oral cancer who were unable to verbalize was recorded with help of caregiver/ proxy)

Exclusion Criteria :

(1) Caregiver not staying with the patient for not less than 12 hours per day.

(2) Those unable to complete the questionnaires

Experimental Group —

After initial screening, participants fulfilling eligibility criteria were enrolled and explained about the study protocol in face-to-face form. Informed written consent was obtained and recorded in an official document form.

Each participant was asked to complete the baseline questionnaire (Bengali translated version for each study tool was already validated and easily available): demographic characteristics, Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Caregiver Quality of Life Index (CQoL-C). All these questionnaires measured various dimensions of depression, anxiety, and Quality of Life respectively. The psychologist messaged all the patients as a reminder one day before of each session and no reply from the patients was translated to the number of drop-outs in the study. We also noted the cause of the refusal to participate in the study. This information helped to determine the acceptability of the psychological support as well as document the major barriers to participation.

Control Group —

In this group, they did not receive psychosocial support on a regular basis. At first, clinical psychologists assessed the psychological factors at baseline by using a standardised questionnaire. Then it was reassessed twice in a month with a 15-day' gap and continued up to 120 days.

Psychological Intervention :

This type of psychological support based on over-the-phone communication consisted of five sessions, each lasting 30-35 minutes. Before starting the psychological sessions, the first clinical psychologist assessed the psychological issues at baseline by using the standardised questionnaires. Again, psychologists used it before one day of each session to see the impact of each session. The department protocol for medical assessment was based on 21, 42, 63, 84, and 105 days. So, we followed the same pattern to make it easier.

Covered Areas of Psychological Intervention —

The intervention programme, held at a board room in the Oncology Unit of the Hospital, was coordinated by the coordinator. It comprised five face-to-face sessions (once a week for a month) delivered by experienced Psychologist. Each session was 40-45 minutes in length; a presentation of interactive content followed by questions and discussion. Each session had a specific theme: 1. Knowledge 2. Anxiety management 3. Activities of daily life 4. Bonding with patient 5. Develop social interaction (Table 1)

Table 1 — *Psychological Intervention-Covered areas*

No of Session	Content
Session 1 (21 days)	In this first session, the content of the intervention was explained, an evaluation was made of essential information about respective cancer, from which the patient is suffering.
Session 2 (42 days)	Discuss the role of caregiver during critical management of the patient
Session 3 (63 days)	Advice on communication between caregiver and patient (interactive daily activities) and Dealing with the emotional aspect of caring his or her patients (not to show overloaded sympathy which makes a feeling of burden to patients)
Session 4 (84 days)	Self-care: its importance and strategies to promote self-care (develop social interaction)
Session 5 (105 days)	Discuss and explain the common symptoms of the patients during the whole curse of planned treatment and dealing with the patients' emotional changes.

Data Collection :

Socio-demographic data were collected from both groups followed by structured interviews.

Instruments —

Structured Proforma : A structured proforma was developed to assess the Socio-demographic and clinical details of the study subjects.

Mini International Neuropsychiatry Inventory (MINI):

MINI is a short structured diagnostic interview, developed jointly by Psychiatrists and Clinicians in the United States and Europe, for DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association - IVth Edition) and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, it is easy to administer[18].

Caregiver Quality of Life Index : The CQoL-C is a self-administered rating scale designed to assess QoL issues in family caregivers of patients with cancer. It had 35 QoL-specific items, each of which was graded from 0 to 4 on the Likert scale, where "0" denoted "Not at all," "1" denoted "A little bit," "2" denoted "Somewhat," "3" denoted "Quite a bit," and "4" denoted "Very much." The maximum total score for the instrument is 140. All 35 things were added together for a final score, which was taken into consideration for analysis[20]. Three separate translators (2 with medical background and one with a master's degree in Bengali) translated the scale into Bengali and the final, approved version was utilised to gather the data. The caregivers were personally interviewed for the data collection. Test-rest reliability was 0.95 and internal consistency was 0.90. The instrument has good divergent validity. The instrument is also responsive to changes in the health state of the patient, as measured by the ECOG-PSR (r=0.45).

Beck Depression Inventory (BDI) :

The original English version of BDI II consists of 21

items to measure the severity of depression. Each item is a list of four statements arranged in ascending order of severity about a particular symptom of depression which could be rated from 0 (symptom not present) to 3 (symptom strongly present), with resulting summary scores ranging from 0 to 63. The time reference for the response set has 2 weeks. The severity rating guidelines and cut-off scores suggested by the authors for total scores of patients diagnosed with major depression are 0-13 minimal; 14-19 mild; 20-28 moderate; and 29-63 severe. In the translation and validation process, a validated Bengali version of BDI II was produced to measure depression and its severity among the Bengali population[12].

Beck Anxiety Inventory (BAI) :

This scale is a self-report measure of anxiety. It consists of 21 items. Internal consistency for the BAI = (Cronbach's α=0.92) Test-retest reliability (1 week) for the BAI = 0.75. The severity rating guidelines and cut-off score suggested by the authors for total scores of patients diagnosed with anxiety are 0–21 low; 22-35 moderate, and 36 and above potentially concerning levels of anxiety[7].

Consent form :

Informed verbal consent was obtained from all participants and recorded in audio format.

Statistical analysis :

Descriptive statistics were used to summarize participants' demographic and clinical characteristics of all the participants. Socio-demographic and BAI, BDI, CQoL-C scores were categorized according to two participated groups. Chi-square was applied to observe comparability according to two cancer groups. The overall mean values of each scale at baseline/day on 21,42, 63, 84, 105 and 120 days of psychological support course were calculated for both groups. Repeated measure was used to define significance of telephone based psychological support among metastatic cancer patients through psychological assessment score before, during and after participation. Independent "t" test was used to define the association between impact of telephone based psychological support and emergency visit.

Results

Demographic Information :

Table 2 depicts the baseline demographic and clinical characteristics of the study participants. The majority of them belonged to middle-class socio-economic status (1000 to 2000 Indian rupees per capita per month). Both the study groups were comparable at baseline.

Table 2 — *Prevalence of demographic and clinico-pathological details among participants*

Demographic details	Group A (N=81)	Group B (N=72)	p-value
Age	52.23±2.05	51.07±2.19	1.13
Gender :			
Male	49%	53%	1.12
Female	51%	47%	
Residence :			
Rural	54%	51%	1.11
Urban	46%	49%	
Relationship status :			
Living with spouse	74%	65%	1.14
Living without spouse	26%	35%	
Education :			
Illiterate	9%	6.5%	
Primary Education	17%	20.1%	
Secondary Education	41%	36.1%	
More than secondary education	33%	37.3%	0.098
Occupation :			
Engaged with work	49%	50.4%	
Unemployed	35%	39%	1.13
Home maker	16%	10.6%	
Family Income :			
≥500	13%	11%	
1000-2000	49%	56%	0.07
>2000	38%	33%	
Clinico Pathological (Diagnosis) :			
Head and Neck Cancer	20%	16.5%	
Gynaecological Cancer	22%	17.6%	1.01
GI and Thoracic cancer	3.5%	10.2%	
Ortho-oncology	15.5%	17.1%	
Treatment History :			1.42
Standard care Only	53%	54%	
Standard care with Palliative care	31%	30.2%	
Palliative care Only	16%	15.8%	
Psychological Variable :			
Depression	43±1.13	44.2±1.07	1.32
Anxiety	18±1.02	19±1.22	
QoL	55.7±1.11	56±1.14	

In the Group-A, the mean age of participants was 52.23±2.05 years. 51% were female primary caregivers, 54% were residing in a rural area, 74% were living with their spouse and 41% received up to secondary education, 49% were working. Distribution of participants according to the cancer site: from head and neck (20%), from gyn-oncology (22%), from gastrointestinal tract (3.5%) and from ortho-oncology (15.5%). Their mean baseline levels were: for depression- 43±1.13; for anxiety- 18±1.02 and for QoL-55.7±1.11.

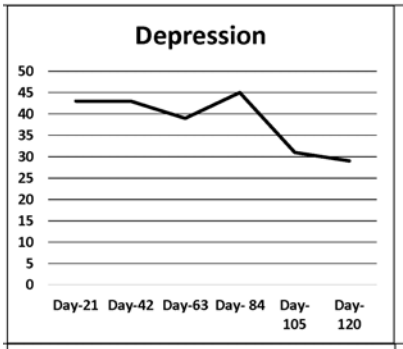
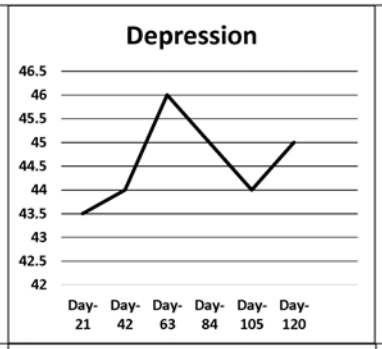
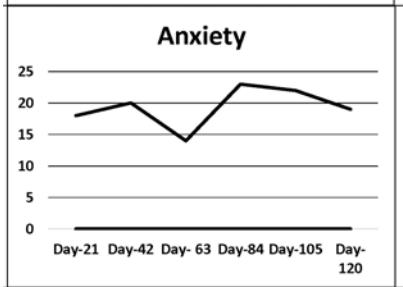
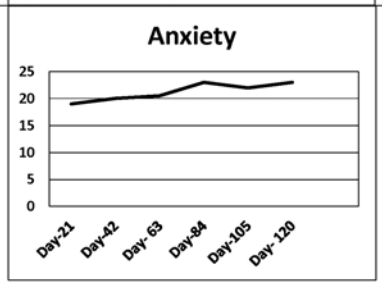
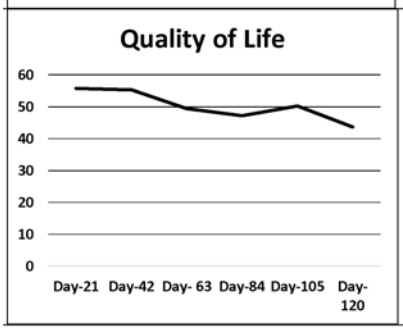
In the control group, the mean age of participants was 51.07±2.19 years. 53% were female caregivers, 51% were residing in a rural area, 65% were living with their spouse and 36.1% received secondary education, 39% were unemployed. Distribution of

participants according to the cancer site: from head and neck (16.5%), from gyn-oncology (17.6%), from gastrointestinal tract (10.2%) and from ortho-oncology (17.1%). Their mean baseline levels were: for depression - 44.2±1.07; for anxiety- 19±1.22, and for psychological well-being- 56±1.14.

All groups were comparable in terms of socio-demographic, clinico-pathological and psychological variables.

Mixed model results demonstrated that overall symptom severity for each individual psychological factors- depression, anxiety and QoL (P<0.001) and progressively improved over the course of treatment. Statistically significant change in mean score has been observed over different study time points. We observed slight increase in mean scores- depression [44.2 *versus* 43 *versus* 39 *versus* 45 *versus* 31 *versus* 29]; anxiety [18 *versus* 20 *versus* 14 *versus* 23 vs 22 *versus* 19] and QoL [55.7 *versus* 55.3 *versus* 49.4 *versus* 50.2 *versus* 43.6] among Group-A. (Table 3)

Table 3 — *Distribution of psychological issues among participants during the time frame*

Experimental Group	Control Group	p-Value
		<0.01*
		<0.01*
		<0.01*

Discussion

The obtained results suggest that the implementation of a psychological intervention in primary caregivers enhanced their QoL and reducing their psychological issues-anxiety and depression. A repeated measure analysis conducted revealed that psychological issues and overall QoL reported significant differences in scores over the time frames between the Group-A and Group-B. Supporting our results, similar studies that conducted intervention programmes and discussed positive significant impact of a psychoeducation intervention on the QOL of primary caregivers as well as and its dimensions across the time points[4,1,14,2]. Following studies measured caregivers'QoL using CQOLC, but different psycho-educational intervention programmes were evaluated[1]; administered the Caring for the Caregiver Programme (CCP) among family caregivers of patients with advanced cancer[2]. Another study had worked among family caregivers of women with breast cancer using COPE (creativity, optimism, planning, and expert information) and result was same there[11]. The present study results had contradicted from those of using the COPE intervention programme, who reported a significant decline in caregiver QoL[13] and who conducted FOCUS programme for 134 dyads (only breast cancer patients and their family caregivers). Following the results, there were no significant difference in the dyads' QoL across the three time points (from baseline to 6 months)[13].

In respect to the psychological intervention in the first session, we provided the primary caregivers- patient psychological care-related information and answers to their concerns.After this session, we went to take the assessment on the caregiver's Quality of Life, following the test score report their Quality of Life had not statistically significantly improved, but according to their feedback they have understood the importance of psychology in

oncology and they have become more aware of their own psychological issues. Regarding the psychological intervention during the second session, we provided caregivers with information on how to manage cancer patients during their critical condition. The motto of this session is to give psychological support to help caregivers respond effectively to critical challenges, thereby helping them manage their anxiety and depression. Upon reassessing the caregiver's Quality of Life, the obtained score report indicated that the QoL of the caregiver has improved moderately comparing with last session.In relation to the psychological intervention during the third session, we provided caregivers with advice on how to interact with the patient and keep them engaged in family decisions. The primary caregiver requires mental support as they tend to become over protective towards the patient due to the fear of losing them. For the wellbeing of the patient's mental health, the primary caregiver's mental wellbeing should be prioritised as well. Proper support from the caregiver can often keep the patient happy and give them hope which in turn can help the caregiver too. After reassessing the caregiver's Quality of Life, the report states that the QoL of the caregiver has improved significantly.With respect to the psychological intervention in the fourth session, we provided the caregiver with ways to develop social interaction skills and knowledge about the patient's diagnosis and treatment. We also advised them to join peer support groups if possible. After reassessing the caregiver's quality of life, the report states that the QoL of the caregiver does not significantly improve due to the unavailability of peer support group or cancer support group according to diagnosis in West Bengal. For the last psychological intervention session, the psychologist discusses about the patient's mental health journey from the beginning of the cancer diagnosis till the duration of standard care treatment. The psychologist also discusses about the various psychological issues that come up, such as, fear of death, feeling of financial burden, unable to accept present situation of the disease, believing that cancer is the result of their own "karma". After the final reassessment of psychological issues, the reports state that, unfortunately the Quality of Life does not significantly improve due to the caregivers becoming puzzled whether to take care of their physical health or mental health.

The most important session during the whole Psychosocial Intervention was the third session, as it showed a very positive impact on the primary caregiver's QoL. This is due to the psychologist's advice given to the primary caregiver, through which they take care of the patient by including them in family decisions, having regular family meals and including them in small household chores. It reduces the patients feeling of being a 'family burden', which in turn reflects on their health and behaviour, while also decreasing the caregiver's psychological issues, anxiety and depression, manifesting through the caregiver's QoL.

The concept of Psychology in the field of Oncology is still new in West Bengal, therefore, there is not much research to refer to, but as per patients' family member's responses, along with the primary treatment they do take part in taking care of the patient's and their own psychological wellbeing.

Conclusion

In conclusion, our current randomized controlled trial supports the use of psychological interventions for primary caregivers of cancer patients, which might be highly acceptable and effective in improving their QoL and psychological outcomes in India. Future studies will expand the sample pool, apply to primary caregivers of patients with different cancer types and investigate the cost-effectiveness of such psychological interventions.

Disclosure Statement :

No potential conflicts of interest were reported by the authors.

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Original Article

Risk Factors for Early Re-bleed following Endoscopic Variceal Band Ligation and Assessing Utility of Dedicated Score (BICAP Score) to Identify High Risk Groups

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Background : Endoscopic Variceal Band Ligation (EVBL) is a universally accepted and approved treatment for bleeding esophageal varices. Re-bleed is the most common complication following EVBL. Ours is a prospective study analyzing risk factors for Early Re-bleed (ERB) and for creating a laboratory based BICAP score (Bilirubin, INR, Creatinine, Albumin, Platelet) for detecting high-risk groups for re-bleed.

Materials and Methods : The study period was between March, 2021 to March, 2022 when 111 patients underwent EVBL in our department. Patients were followed by telephone or direct visits weekly for 6 weeks. ERB was defined by active variceal hemorrhage presenting as hematemesis in a patient following EVBL within 6 weeks. Endoscopy was done for all patients after re-bleed to confirm.

Results : Among 111 patients, 26 patients developed ERB with an incidence of 23.4%. ERB was higher in emergency EVBL than elective (29.3% *versus* 6.9%, p=0.014). Platelet count of < 50,000 and INR > 2.0 were associated with high ERB risk (52.4%, p>0.002) and (60%, p = 0.001). Overt encephalopathy was associated with 42.3% risk of ERB (p = 0.009). Usage of high number of bands (>6) were associated with increased risk of ERB (56.3%, p>0.001). Child Pugh C patients had high risk of ERB (37.5%, p = 0.001). BICAP score >7 was associated with increased risk of ERB (80%, p = 0.002).

Conclusion : Child-Pugh score and BICAP score both can predict high risk groups for ERB, but BICAP score is a dedicated score and can be used even in non-cirrhotic patients. BICAP score is found to have high sensitivity in detecting patients with high risk for early Re-bleed.

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Key words **: Endoscopic Variceal Band Ligation, Early Re-bleed, BICAP Score, Child-Pugh Score.**

Variceal bleeding especially from esophageal varices is the most devastating complication of portal hypertension and is always a medical emergency. This complication is associated with a mortality rate of 24%[1] and leads to further complications such as ascites, spontaneous bacterial peritonitis, hepatic encephalopathy and hepatorenal syndrome. Following stabilisation upper GI Endoscopy is mandated early to assess and take action to prevent further bleeding. Endoscopic Variceal Band Ligation (EVBL) is the most accepted and used technique to ligate the large esophageal varices which are the most common cause of variceal bleed[2].

Re-bleed is one of the life-threatening complications of EVBL and can lead to significant morbidity and mortality. Many studies have identified causes for the high risk of re-bleed. Re-bleed can be classified into very early re-bleed which occurs within 5 days, Early Re-bleed (ERB) which occurs between 7th day and 6 weeks and late re-bleed, which occurs beyond 6 weeks[3].

Editor's Comment :

- BICAP score is useful in predicting high risk groups with increased risk for early re-bleed.
- A larger study is needed to validate its utility, especially for comparison with other indices like MELD score.

Our study focuses on ERB and the factors affecting it in our patients. We included both cirrhotic and non-cirrhotic causes of portal hypertension and subsequently variceal bleed or high-risk esophageal varices. In our study, we also used Child- Pugh score, MELD score and our own newly created BICAP score and assessed their utility in identifying high risk patients for ERB.

Materials and Methods

Study Design :

This was a case-control study that took place in our Department of Medical Gastroenterology and

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hepatology, Tirunelveli Medical College, Tirunelveli from March, 2021 to March, 2022. The Tirunelveli Medical College Scientific and Advisory Committee and Institutional Ethics Committee approved the study.

Study Participation :

111 patients who underwent EVBL were included in the study. Cases were patients who had early re-bleed and controls were patients without re-bleed. Inclusion criteria were patients between age group 18 to 70 years, who underwent emergency or elective EVBL. Patients with common etiologies of portal hypertension including ethanol, chronic viral hepatitis, NAFLD, EHPVO and PSVD (pre-hepatic) were included in the study. Exclusion criteria were Pregnant and lactating mothers, patients with other causes of upper GI bleeding like gastric or duodenal ulcers, gastric varices and patients with upper GI malignancies.

All patients gave informed consent and our Institute's Ethics Committee approved the study.

Study Intervention :

All the criteria fulfilled patients had blood work done including Complete Blood Counts, liver and renal biochemistry, viral screening tests for Hepatitis B,C and ultrasound abdomen during their course in the hospital. During EVBL the grading of the varices (Japanese classification) as well as number of bands applied were noted. The patients were kept on follow-up for 6 weeks either by hospital visits or through telephone for history of any re-bleed. Patients with re-bleed underwent urgent endoscopy.

Outcome Measures :

The primary objective was identification of all the risk factors for ERB. The secondary objective was using the Child – Pugh score, MELD score and BICAP score as means to detect patients with high risk of ERB.

Statistical Analysis :

Data were analysed with SPSS version 24. Quantitative variables were expressed as median and interquartile range and qualitative variables as frequency and percentage. The association of categorical variables was analysed by Chi-square test. A p-value of <0.05 was considered statistically significant.

Results

Among 111 patients who underwent EVBL, 26 patients developed early Re-bleed with an incidence rate of 23.4%. Early Re-bleed was highest in age less than 40-year-old (40%) probably because of increased re-bleed in pre-hepatic cases which are mostly young age population. Low Platelet Count <50,000 and elevated PT-INR >2.0 were associated with 52.4% and 60% cases of ERB (p = 0.002 and 0.001 respectively). 29.3% patients in emergency EVL had re-bleed compared to only 6.9% with elective EVL (p = 0.014). 43.2% of patients with overt encephalopathy had ERB compared to 17.6% in covert group (p = 0.009). In patients who had more than 6 bands applied, 56.3% of them developed an ERB (p = 0.001).

MELD score of more than 20 had higher ERB, but it was not found to be statistically significant. Child–Pugh score C category patients had 37.5% of them developing an ERB and this was found to be statistically significant. BICAP score was calculated for all patients and categorized into 3 groups ≤3 (low), 4-6 (mid) and 7-10 (high). 80% of patients with high BICAP score (7-10) had ERB while only 14.9% in low BICAP score (≤3) group (p = 0.002) (Tables 1-4).

Discussion

The study had higher than expected incidence of Early Re-bleed (ERB) cases (23.4%). The previous studies with early Re-bleed incidence was between 4.8% and 20.54%[4-6]. We believe the high re-bleed cases is due to higher number of emergency cases in the study. Many of these cases had elevated bilirubin or low platelets or high PT-INR which put them at increased risk of an ERB.

Majority of patients with early re-bleed were young patients in our study and this finding was also found by Grothaus, *et al*[7] in his study. The reason for this finding in our study is probably because of a greater number of young patients especially with pre-hepatic portal hypertension and alcoholics with severe alcoholic hepatitis both are high risks for early Re-bleed. Our study did not find a correlation between early Re-bleed among men and women and this finding was also published by Xu, *et al*[8] showing gender did not have a significant outcome in early re-bleed. Emergency EVBL was associated with more risk of Re-bleed in our study compared to elective cases and this observation was also noted by Petrasch, *et al*[9]. Very low platelet count was associated with higher risk of re-bleed in our study and this finding was mentioned by MS Faisal, *et al*[10].

Table 1 — *BICAP Score*

	0	1	2
Bilirubin	<3mg/dl	3-5mg/dl	>5mg/dl
INR	<1.5	1.5- 2.0	>2.0
Creatinine	<1mg/dl	1-1.5 mg/dl	>1.5mg/dl
Albumin	>3.5g/dl	2.8 – 3.5 g/dl	< 2.8g/dl
Platelet count	>1.5 L	50,000 to 1.5L	<50,000
	Max score is 10		

Table 2 — *Patient baseline Characteristics*

	Total (n=111)	Re-bleed (n=26)	No Re-bleed (n=85)
Age - median (IQR)	49(42-58)	45(35-51)	50(43-61)
Sex - female- n(%)	29(26.1)	6(23.1)	23(27.1)
Platelet count (10^3) -median (IQR)	98(56-149)	60(31.75-98)	107(77.5-163.5)
Bilirubin - median (IQR)	1.2(0.8-3.8)	2.35(1.25-5.95)	1(0.75-3.15)
Albumin - median (IQR)	3.2(3-3.8)	3.05(2.5-3.8)	3.3(3-4)
Creatinine - median (IQR)	0.8(0.7-1.1)	0.85(0.675-1.125)	0.8(0.7-1.1)
INR - median (IQR)	1.3(1.1-1.67)	1.77(1.1675-1.9075)	1.28(1.1-1.54)
MELD score - median (IQR)	11(9-19)	17(9.75-23.25)	11(8-17)
Child Pugh score - median (IQR)	8(6-9)	9(6-10.25)	7(6-9)
BICAP score - median (IQR)	3(2-5)	4(3 - 6)	3(2-4)
UGI bleed - n(%)	82(73.9)	24(92.3)	58(68.2)
Ascites - n(%)	51(45.9)	16(61.5)	35(41.2)
Hepatic encephalopathy Grade>2 - n(%)	19(17.1)	11(42.3)	8(9.4)
Grade of varices>2 - n(%)	88(79.3)	22(84.6)	66(77.6)
Red signs+ - n(%)	80(72.1)	19(73.1)	61(71.8)
Number of bands >4 - n(%)	59(53.1)	12(46.1)	47(55.3)

Table 3 — *Etiology Statistical Analysis*

		Early Re-bleed (ERB) N-26	No-Re-bleed N-85	P-value
Age : years	<40	8(40%)	12(60%)	
	40-60	17(25%)	51(75%)	0.020
	>60	1 (4.3%)	22 (95.7%)	
Sex :	Male	20(24.1%)	63(75.9%)	
	Female	6(21.4)	22(78.6%)	0.773
Etiology :	Alcohol	8(16%)	42(84%)	
	NAFLD	3(10%)	42(90%)	
	Pre-hepatic	10(47.6%)	11(52.4%)	0.002
	Others	5(50%)	5(50%)	
EVBL:	Emergency	24(29.3%)	58(70.7%)	
	Elective	2(6.9%)	27(93.7%)	0.014
Blood transfusion	Restrictive	14(28%)	36(72%)	
	Liberal	10(29.4%)	26(70.6%)	0.888
Platelet count:/mm^3	<50,000	11(52.4%)	10(47.6%)	
	50,000 to 1.5 L	12(18.4%)	54(81.8%)	0.002
	>1.5L	3(12.5%)	21(87.5%)	
Bilirubin mg/dl	<3	15(19.5%)	62(80.5%)	
	3-5	4(28.6%)	10(71.4%)	0.306
	>5	7(35%)	13(65%)	
Albumin g/dl	<2.8	8(34.8%)	15(65.2%)	
	2.8-3.5	9(18.4%)	40(81.6%)	0.308
	>3.5	9(23.15%)	30(76.9%)	
INR	<1.5	8(11.8%)	60(88.1%)	
	1.5-2.0	15(39.5%)	23(60.5%)	0.001
	>2.0	3(60%)	29(40%)	
Creatinine mg/dl	<1.0	16(22.2%)	56(77.8%)	
	1.0-1.5	6(20.7%)	23(79.3%)	0.425
	>1.5	4(40%)	6(60%)	
Ascites	Present	17(15.5%)	35(84.5%)	
	Absent	9(23.6%)	49(76.4%)	0.034
Hepatic Encephalo-pathy	Present	11(42.3%)	15(57.7%)	
	Absent	15(17.6%)	70(82.4%)	0.009
Grade of varices	Grade 2	1(7.1%)	13(92.9%)	
	Grade 3	25(25.8%)	72(74.2%)	0.124
Number of bands	≤3	0(0%)	17(100%)	
	4-6	17(21.8%)	61(78.2%)	0.001
	>6	9(56.3%)	7(43.8%)	

In study by Mostafa and Mohammad, SBP and ascites was associated with high risk of re-bleed but in our study, due to reasons not clear re-bleed was more in patients without ascites. In our study we made a comparison between increased risk of re-bleed among patients who received restricted transfusion and who received liberal transfusion. Our observations are that there is no statistically significant difference between risk of re-bleed in restrictive and liberal transfusion groups. Current recommendations are however for restrictive blood transfusion targeting a hemoglobin of 7-8 g/dl which in turn prevents wastage and decreases chance of recurrent bleed. Renal insufficiency is an independent risk factor for early Re-bleed and in our study in those with creatinine more than 1.5, Re-bleed was higher although it did not show statistical significance. In our study overt hepatic encephalopathy (West haven 2 and above) patients had higher risk of rebleed (43%).

In our study there was an observation that re-bleed was higher in patients who had received a greater number of EVL bands probably because of increased risk of band ulcers this observation was also explained by Petrasch, *et al*[9]. Comparing MELD score to risk of re-bleed, previous study Bambha, *et al*[11] suggested that rebleed is higher in MELD more than 18 and in our study, re-bleed was higher in MELD more than 15. In previous study by Wipassakornwarawuth, *et al*[12] Child Pugh class C was associated with increased ERB and this was seen in our study where the re-bleed was highest in Child C patients. The BICAP score which is laboratory value-based score of Bilirubin, INR,

Table 4 — *MELD, Child-Pugh class, BICAP score data analysis*

		Early Re-bleed (ERB) N-26	No-Re-bleed N-85	P-value
MELD	<10	6(14.6%)	35(85.4%)	
	10-15	6(20.7%)	23(79.3%)	0.105
	>15	14(34.1%)	27(65.9%)	
Child-Pugh Class	Class A	0(0%)	28(100%)	
	Class B	4(14.3%)	24(85.7%)	0.001
	Class C	12(37.5%)	20(62.5%)	
BICAP Score	≤3 (Low)	10(14.9%)	57(85.1%)	
	4-6 (Mid)	12(30.8%)	27(69.2%)	0.002
	7-10 (High)	4(80%)	1(20%)	

creatinine, albumin and platelet count was found to be as good as Child Pugh score in predicting patients with ERB risk. In an inpatient study of mortality in post variceal bleed patients Krige, *et al*[13] observed that both MELD and Child-Pugh scores were poor measurements of mortality and recommended modified scores for better prediction of mortality[13]. The incidence of ERB was more in patients with high BICAP score. There needs to be more recruitment of patients with high BICAP score for assessing the utility of the score further.

BICAP score in our study was calculated using the laboratory values at the time of presentation, so when it is used as a predictor of ERB, it actually does not take into account the fact an EVBL procedure was done. Also, endoscopic findings and number of bands applied were not included in the score. So, there is a scope for extended BICAP score with endoscopic findings like grade of varices, length of the varices and number of bands applied. Having a dedicated score like BICAP score for identifying individuals with a high risk of re-bleed has the advantage that it can be used across all etiologies of a variceal bleed. BICAP score will be needed to be studied extensively for its applicability in very early Re-bleed, early Re-bleed as well as delayed onset Re-bleed. It is a simple score and easy to use and reproduce. We believe that the BICAP score could be used as a tool of predicting or identifying high-risk patients for early re-bleed.

Conflict of Interest : The authors declared there was no conflict of interest

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Original Article

Effects of Prophylactic Retention Sutures on Closure of Laparotomy Wound in High-risk Patients in a Tertiary Care Hospital

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Wound dehiscence is the postoperative separation of musculo-aponeurotic layers. It occurs in up to 4.5-8% laparotomies, usually on 7th-10th postoperative day. It carries a mortality rate of up to 15-20%. Retention Sutures are interrupted sutures placed across wound before formal fascial closure through rubber / latex bolsters and knotted in mattress fashion. The objective of this research was to study the effects of using Prophylactic Retention Sutures on wound complications, specifically on wound dehiscence and surgical site infections. The relevance of the study was to determine whether retention suture can be used prophylactically to prevent wound dehiscence, thus avoiding several complications, reducing health-care cost, providing better quality of life with a shorter hospital stay. The study was an observational, descriptive study with cross-sectional design. We performed the data collection from 1st March, 2021 till 28th February, 2022. The sample size was 65, which included all patients undergoing emergency laparotomy in NRS Hospital having any of the 17 high-risk factors. The data was checked for consistency and completeness and analyzed using SPSS version 20. Proportions were analyzed using Chi-square test. Four patients (6.2%) had wound dehiscence despite retention sutures and 29 (44.6%) had surgical site infection. Association of obesity with wound dehiscence and chronic cough, diabetes, jaundice and malignancy with surgical site infection were statistically significant. The outcome of Prophylactic Retention Suture on wound dehiscence (6.2%) is not statistically significant as opposed to the rate of wound dehiscence without it (4.5-8%). Hence, the use of Retention Sutures is left to the discretion of the operating surgeon.

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Key words **: Wound Dehiscence, Retention Suture, Prophylactic, Burst Abdomen, Surgical Site Infection.**

Laparotomy wound repair has several sequelae like seroma / hematoma formation, Surgical Site Infection (SSI), Evisceration, Wound Dehiscence (WD) (WD), and incisional hernia. Wound Dehiscence is the most serious one among all these in the acute setting. Dehiscence of abdominal wounds most commonly occurs between 7 to 10 days postoperatively but can occur up to 3 months after surgery[1].

Wound dehiscence refers to postoperative separation of the abdominal musculo-aponeurotic layers[1]. Abdominal fascial dehiscence occurs in up to 3.5-4% of patients following a laparotomy, which are associated with significant morbidity and mortality[1]. The mortality rate following a Wound Dehiscence can be as high as 15-20%[2].

Retention sutures are interrupted sutures placed across the wound prior to formal fascial closure, using non-absorbable monofilament sutures, through skin and fascia approximately 2 cm from the wound margins at intervals of 2-3 centimeters.The sutures are threaded through rubber / latex tubing bolsters or commercially available plastic bolsters and knotted at the skin level[2]. The rubber or latex tubings are placed in order to prevent the sutures in high tension to cut through the skin and subcutaneous tissue.

Editor's Comment :

- Retention suture application is widely prevalent currently in the form of treatment for wound dehiscence, and even though it has proven benefit of preventing wound dehiscence primarily, the adverse effects of the procedure limits its usage prophylactically, and is to be kept at the discretion of the surgeon.

WD increases the healthcare cost for the patient by increasing hospital stay as well as by increasing the demand for equipment and accessories needed to repair it.Use of biological or synthetic meshes to repair these wounds is a very well-known and good technique. But the downsides remain that biological meshes are very costly and have low availability in our setup, whereas, use of synthetic meshes is not feasible in infected wounds, which is one of the primary factors for wound dehiscence (Figs 1&2).

Materials and Methods

The objective of the study was to determine the effects of using Retention Sutures prophylactically on wound complications in high-risk patients, specifically

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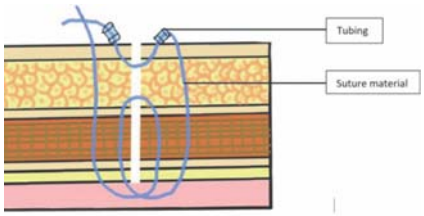

Fig 1 — Application of Retention Sutures using bolsters

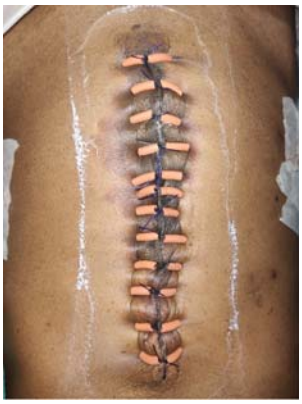
Fig 2 — Postoperative image of repair of burst abdomen by application of retention sutures using bolsters

on wound dehiscence and SSI. This was an institution based observational descriptive study with cross-sectional design. The study was conducted from 1st March, 2021 to 28th February, 2022 in Nil Ratan Sircar Medical College and Hospital (NRSMC&H), Kolkata. The sample size was 65, which included all the patients undergoing emergency laparotomy through midline incision, who have been applied Retention Sutures based on the presence of any of the 12 high-risk factors —

(1) Chronic cough – intermittent cough of >8 weeks duration, without phlegm[3]

(2) Hemodynamic instability – Systolic blood pressure < 100 mm of Hg[4,7], Pulse rate > 100 / min[1,4]

(3) Malnutrition – Serum Albumin < 3.0 g/dl[2]

(4) Diabetes mellitus.

(5) Obesity– BMI > 30 kg/m2[5]

(6) Ascites (Imaging or intra-operative finding)

(7) Jaundice– Total serum bilirubin > 2 mg/dL[6]

(8) Immunocompromised / immunosuppression (Use of corticosteroids[5], chemotherapeutic agents[7], diabetes mellitus, AIDS[4,8]).

(9) Intra-abdominal abscess or sepsis[1,2,5,7,9].

(10) Smoking and tobacco use – a person who has smoked 100 cigarettes in his lifetime[10]

(11) Connective tissue disorders – Ehler -Danlos syndrome, Marfan syndrome[1,2,9], ICD-9-CM codes for rheumatoid arthritis 714.0, systemic lupus erythematosus 710.0, scleroderma 710.1, mixed connective tissue disease 710.9, Sjogrens syndrome 710.3 and myositis 710.3[5]

(12) Disseminated malignancy

Approval of the Institutional Ethics Committee was obtained and consents were taken in English, translated to the patient's vernacular. Patients were followed up till their hospital stay or till removal of sutures for incidence of WD, and up to 30 days for SSI. The collected data were checked for consistency and completeness and analyzed using SPSS version 20. Descriptive analysis was done in the form of proportion for categorical variables and mean or median for continuous variables. The difference between proportions was analyzed using Chi square test; p value of less than 0.05 was considered statistically significant.

Observations and Results

In our study, we found that 4 of our patients out of 65 (06.2%), developed WD. In 29 patients (44.6%) had developed SSI after application of prophylactic retention suture. Most of the patients in our sample had multiple comorbidities, the distribution of which is summarized in Tables 1 & 2.

Table 1 — *Distribution and association of WD according to presence of risk factors. *(a) = number of patients with the risk factor, % out of n (n=65). **(b) = % of (a)*

Presence of risk factors [a, (%)*]	Wound Dehiscence [b, (%)**]		χ^2 value, df, p value
	Absent	Present	
Chronic cough [14, 21.5%]	14 (100)	-	1.170, 1, 0.279
Hemodynamic instability [23, 35.4%]	20 (87)	03 (13)	2.926, 1, 0.087
Malnutrition [18, 27.7%]	17 (94.4)	01 (5.6)	0.015, 1, 0.901
Diabetes mellitus [24, 36.9%]	22 (91.7)	02 (8.3)	0.313, 1, 0.576
Obesity [24, 36.9%]	20 (83.3)	04 (16.7)	7.281, 1, 0.007
Ascites [11, 16.9%]	10 (90.9)	01 (9.1)	0.198, 1, 0.657
Jaundice [09, 13.8%]	08 (88.9)	01 (11.1)	0.445, 1, 0.505
Immunocompromised [04, 06.2%]	04 (100)	-	0.279, 1, 0.597
Intra-abdominal abscess or sepsis [12, 18.5%]	11 (91.7)	01 (8.3)	0.121, 1, 0.728
Smoking [22, 33.8%]	20 (90.9)	02 (9.1)	0.497, 1, 0.481
Connective tissue disorders [02, 03.1%]	02 (100)	-	0.135, 1, 0.713
Disseminated malignant disease [19, 29.2%]	17 (89.5)	02 (10.5)	0.889, 1, 0.346

Table 2 — *Distribution and association of SSI according to presence of risk factors. *(a) = number of patients with the risk factor, % out of n (n=65). **(b) = % of (a)*

Presence of risk factors [a, (%)*]	SSI [b, (%)**]		χ^2 value, df, p value
	Absent	Present	
Chronic cough [14, 21.5%]	11 (78.6)	03 (21.4)	3.882, 1, 0.049
Hemodynamic instability [23, 35.4%]	16 (69.6)	07 (30.4)	2.897, 1, 0.089
Malnutrition [18, 27.7%]	11 (61.1)	07 (38.9)	0.330, 1, 0.565
Diabetes mellitus [24, 36.9%]	-	24 (100)	47.233, 1, <0.001
Obesity [24, 36.9%]	13 (54.2)	11 (43.9)	0.023, 1, 0.880
Ascites [11, 16.9%]	07 (63.6)	04 (36.4)	0.365, 1, 0.546
Jaundice [09, 13.8%]	08 (88.9)	01 (11.1)	4.746, 1, 0.029
Immunocompromised [04, 06.2%]	02 (50)	02 (50)	0.050, 1, 0.823
Intra-abdominal abscess or sepsis [12, 18.5%]	04 (33.3)	08 (66.7)	2.896, 1, 0.089
Smoking [22, 33.8%]	12 (54.5)	10 (45.5)	0.009, 1, 0.922
Connective tissue disorders [02, 03.1%]	01 (50)	01 (50)	0.024, 1, 0.876
Disseminated malignant disease [19, 29.2%]	15 (78.9)	04 (21.1)	6.032, 1, 0.014

Discussion

In our study, among all the risk factors, only obesity (p = 0.007) was found to be statistically associated with WD and chronic cough, diabetes mellitus, jaundice and malignancy were found to be statistically associated with SSI (p = 0.049, 0.001, 0.029, 0.014).

A comparative study of technique of retention suture by Chatterjee S, *et al* (2021) observed that wound dehiscence occurred in 3 (5.8%) patients in short stitch group whereas 8 (15%) patients in long stitch group developed wound dehiscence[11]. Another comparative study of intervention in patients with risk factors by Khorgami Z, *et al* (2013) found that 147 patients were followed in the intervention group and 148 patients in the control group. WD occurred in 6 patients (4%) in the intervention group and 20 control patients (13.3%) (P = 0.007)[8]. This is comparable to the occurrence of WD in our study and falls in the general range of rate of WD following laparotomy.

A comparative study on SSI due to Retention Sutures by Mandal, *et al* (2020) reported that 19.4% of the patients in the study group developed SSIs, compared with 13 (34.2%) in the control group. Three (8.3%) and two (5.6%) patients in the study group developed superficial wound dehiscence and deep wound infections (burst abdomen), respectively, compared to 8 (21.1%) and 4 (10.5%) in the control group, respectively[12]. The rate of SSI was much higher (44.6%) in our study after application of prophylactic retention suture. In a study by Ito, *et al* (2018)[6], diabetes mellitus, surgical wound classification, large incision and Retention Suture were associated with Surgical Site Infections (SSI) in multivariate analysis. In subgroup analysis, SSI risk factors were analysed in each surgical wound classification. Only in surgical wound classification class II and III did Retention Suture significantly reduce the risk of SSI [odds ratio = 0.100 (0.012-0.837), P = 0.034]. In class IV, however, half of the patients developed SSI, regardless of Retention Suture. The present data suggest that prophylactic retention suture reduces SSI for surgical wound classification class II or III. For class IV operations, however, other methods to prevent SSI are necessary.

Conclusions and Recommendation

The use of Retention Sutures is left to the discretion of the operating surgeon, but it is likely to be beneficial only for patients with a high risk of developing wound problems. It's important to educate patients about wound care and any concerns like Surgical Site Infection, pain, that may arise. Following abdominal surgery, many surgeons impose activity limits in order to prevent the failure of the fascial closure.

Different surgical techniques for closing the wound should be carefully considered. Suture materials are of great importance in providing sufficient strength and influencing adverse events. Some authors have proposed the application of thick or Retention Sutures as a preventive strategy to eliminate or reduce the occurrence of wound dehiscence. Retention sutures have already been shown to reduce the rate of wound dehiscence after surgery and their use has also been suggested as a treatment choice for managing fascial dehiscence, however, due to the subsequent pain, postoperative discomfort and skin maceration, routine application of this technique has not been accepted. Considering the controversies involved in using this method for the prevention of abdominal wound dehiscence, my study included only patients at a high risk for developing Wound Dehiscence who would benefit the most from prophylactic retention sutures.

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Original Article

A Cross Sectional Study of Socio-cultural and Clinical Determinants of Health-related Quality of Life in Indian Patients with Epilepsy

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Background : Health-related Quality of Life (HRQoL) is a vital component of adherence to treatment in patients with epilepsy. The present study was conducted to determine the level of HRQoL in patients with epilepsy attending the Outpatient Department of our hospital.

Materials and Methods : This cross-sectional study was done by the Neurology Department of tertiary-level care Municipal Hospital in Mumbai from January, 2021 to December, 2021. Inclusion criteria included patients with a confirmed diagnosis of epilepsy, age 18 and older, receiving anti-epileptic drugs, and the ability to provide written consent. The QOLIE-31 questionnaire and a study proforma were administered to the patients.

Results : 248 patients were included in the study. The QOLIE-31 overall score ranged from 17.4 to 78.6, and the average overall score was 66. It was observed that mean QOLIE-31 score was significantly lower (poorer QoL) in patients aged more than 40 years (58.6±8.4 *versus* 72.4±13.5, p-value <0.05), female patients (51.4±8.6 *versus* 69.5±7.5, p-value <0.05), married (51.1±7.8 *versus* 68.4±9.4, p-value <0.05), epilepsy for more than 10 years (59.4±9.4 *versus* 71.6±10.6, p-value <0.05), and those on polytherapy (57.5±10.8 *versus* 72.5±9.6, p-value <0.05).

Conclusions : Older age, female gender, being married, higher seizure frequency, longer duration of epilepsy, and polytherapy were the factors associated with significantly lower QoL.

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Key words **: Epilepsy, Health-related Quality of Life, Socio-cultural and Clinical Determinants.**

Epilepsy is a chronic neurological non-communicable condition that is characterized by a predisposition to repeated epileptic seizures. It affects around five million people all over the globe every single year. Epilepsy is expected to be diagnosed in around 49 out of every 1,00,000 people living in nations with high incomes each year. This rate may reach 139 per 1,00,000 people in countries that have a low or moderate income[1].

Because of the burden of polypharmacy, increased socio-economic expenses, lower employment rates, and lower income, epilepsy patients have much greater rates of health-related Quality of Life (HRQoL) impacts than healthy people[2].

As a consequence of this, health-related Quality of Life, also known as HRQoL, is an essential component for better epilepsy treatment results. When compared to other chronic conditions, such as cancer, diabetes, and cardiovascular disease, epilepsy lags far behind in terms of the amount of research that has been conducted to evaluate the quality-of-life improvements associated with successful treatment.[3] There have been very few studies on the QoL in epilepsy assessed using QOLIE-31 questionnaire carried out in India. Research in this field will discover variables impacting QoL and may lead to solutions that improve the care of epilepsy patients. As a result, the current research was carried out to evaluate the QoL of epilepsy patients who presented themselves at our hospital.

Editor's Comment :

- This article underscores the profound impact of epilepsy on Quality of Life, highlighting the challenges faced by individuals with this condition. It reveals how seizure frequency, medication side effects of polytherapy and social stigma collectively affect emotional well-being, daily functioning, and overall satisfaction with life. Addressing these issues requires a holistic approach that includes medical treatment, psychological support, and social integration.

Materials and Methods

Study Design and Sample Population :

This cross-sectional study was performed on the epileptic patients attending the outpatient clinic of Department of Neurology, Lokmanya Tilak Municipal Medical College, Mumbai, from January, 2021 till December, 2021. Inclusion criteria included having medical records with confirmed diagnosis of epilepsy based on ILAE diagnostic criteria 2017, passing at

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least 1 year from the onset of the disease, age 18 and older, receiving anti-epileptic drugs, and the ability to provide written consent. In order to meet the criteria for exclusion, patients must be at least 80 years old, have non-epileptic seizures, acute symptomatic seizures, inappropriate psychiatric disorders, and provide personal agreement without being solicited. Before any patients were enrolled in the study, it was given the go-ahead by the Institutional Ethics Committee.

Data Collection and Data Analysis :

In this study we used the Hindi version of QOLIE-31 questionnaire and a checklist proforma which contained demographic variables (age, sex, employment status, marital status) and information about the disease (the nature of the episodes, duration of disease, number of episodes per month, familial history of epilepsy). The seizures were classified according to the 2017 ILAE criteria[4]. The QOLIE-31 questionnaire is a self-administered, widely used measure of HRQoL in Epilepsy. It contains 31 questions and seven multi-item scales[5]. The QOLIE-31 questionnaire includes questions designed to assess overall HRQoL perception and additional seizure-related areas: seizure worry, emotional well-being, energy/fatigue, cognitive functioning, medication effects, social functioning, as well as an overall score. The QOLIE-31 scale responses are assigned numeric values ranging from 1 to 100, with higher scores indicating a higher HRQoL[6]. The QOLIE-31 questionnaire was translated into Hindi, then back-translated and tested in a pilot study to ensure its accuracy. Patients' responses to each query are mapped to multiple-choice response options. Scores range from 0 to 100, with higher scores indicating a higher QoL[7]. Calculated scores are 'T' scores. After fulfilling the inclusion and exclusion criteria, patients with Epilepsy entered the study with informed consent.

The data were compiled and entered in SPSS version 23 for statistical analysis. Categorical data were described as frequency distribution and quantitative data as means. To assess the association of mean QOLIE-31 overall score and patient variables, independent t test was used, considering p value < 0.05 as statistically significant.

Results

This study the total number of participants were 248. The age range of patients was 18-77 with a mean age of 34.6±8.9 years. There were 102(41%) female and 146(59%) male participants. Demographic features of patients are shown in Table 1 and clinical features are listed in Table 2. Statistical data about clinical features show that 42 (17%) had focal onset seizures and 206(83%) had generalized onset seizures. A positive familial history of epilepsy was seen in 42(17%) of patients. 55 (22%) patients the duration of epilepsy was more than 10 years. 61(25%) patients had less than 1 episode, 154(62%) had more than 1 episode per month whereas 33(13%) patients were seizure free for more than 1 year. In the present study, 154(62%) of all patients were on polytherapy and 94 (38%) on monotherapy. In this study, the QOLIE-31 overall score ranged from 17.4 to 78.6 and the average overall score was 66 (SD = 11).

Table 3 shows descriptive statistics about the QOLIE-31 score with its subscales separately, highest mean score being for emotional wellbeing subscale. In Table 4, the association of various patient related parameters and mean QOLIE-31 score was assessed.

Table 1 — *Baseline characteristics of the patients included in the study*

Variables		Frequency	Percent
Age groups (years)	18 to 20	57	23%
	21 to 40	76	31%
	41 to 60	68	27%
	61 to 80	47	19%
Gender	Female	102	41%
	Male	146	59%
	Married	167	67%
Education	Illiterate	80	32%
	Till primary	46	19%
	Till secondary	57	23%
	Till graduation	65	26%
Family history of epilepsy		42	17%
Employment	Unemployed	78	31%
	Employed	170	69%

Table 2 — *Clinical characteristics of the patients included in the study*

Variables	Frequency	Percent
Types of Seizures		
Focal Onset	42	17%
With preserved awareness	20	8%
With Impaired awareness	22	9%
Generalized Onset	206	83%
Tonic-clonic	156	63%
Tonic	26	10%
Atonic	15	6%
Myoclonic	9	4%
Duration of Epilepsy		
≤ 5 years	74	30%
5 to 10 years	119	48%
>10 years	55	22%
Number of seizure episodes per month		
<1	61	25%
>1	154	62%
Seizure free for 1 year	33	13%
Medication		
Monotherapy	94	38%
Polytherapy	154	62%

Table 3 — *Mean subscale scores of QOLIE-31*

Subscales of QOLIE-31	Mean ± SD
Seizure worry	55.6 ± 13.05
Quality of Life	66.7 ± 14.1
Emotional well being	71.4 ± 14.2
Energy / Fatigue	65.4 ± 10.6
Cognitive	66.8 ± 11.2
Medication effect	69.3 ± 14.2
Social function	64.6 ± 14.3
Overall Score	65.7 ± 10.5

Table 4 — *Association of different patient variables and mean overall QOLIE-31 score*

Patient variables		N	Mean ± SD	p-value*
Age	<40 years	133	72.4 ± 13.5	<0.05
	>40 years	115	58.6 ± 8.4	
Gender	Male	146	69.5 ± 7.5	<0.05
	Female	102	61.4 ± 8.6	
Education	Illiterate	80	66.5 ± 12.5	0.45
	Literate	168	61.8 ± 14.1	
Marital status	Married	167	51.1 ± 7.8	<0.05
	Unmarried	81	68.4 ± 9.4	
Employment	Unemployed	78	69.5 ± 10.5	0.15
	Employed	170	66.8 ± 8.1	
Family history of Epilepsy	Yes	42	65.5 ± 7.5	0.09
	No	206	68.8 ± 12.1	
Duration of Epilepsy	<10 years	193	71.6 ± 10.6	<0.05
	>10 years	55	59.4 ± 9.4	
Seizure per month	>1 per month	154	64.7 ± 8.9	<0.05
	<1 per month	94	69.3 ± 10.4	
Medication	Monotherapy	94	72.5 ± 9.6	<0.05
	Polytherapy	154	57.5 ± 10.8	

**Analyzed using independent 't' test*

It was observed that mean QOLIE-31 score was significantly lower (poorer QOL) in patients aged more than 40 years (58.6 ± 8.4 *versus* 72.4 ± 13.5, p-value <0.05), female patients (61.4 ± 8.6 *versus* 69.5 ± 7.5, p-value <0.05), married (51.1 ± 7.8 *versus* 68.4 ± 9.4, p-value <0.05),epilepsy for more than 10 years (59.4 ± 9.4 *versus* 71.6 ± 10.6, p value < 0.05) and those on polytherapy (57.5 ± 10.8 *versus* 72.5 ± 9.6, p-value <0.05). Education level, employment status, family history of Epilepsy and seizure frequency were not significantly associated with poorer QoL.

Discussion

The current research found that participants had a mean overall score of 65.7, with the emotional wellbeing subscale yielding the highest score. A higher mean total score on the QOLIE-31 (68.9) was obtained in research that was conducted in Malaysia[8]. A higher score, according to the findings of our research, indicates a higher quality of medical treatment. The distribution of scores on the various QOLIE-31 subscales in our research followed a pattern that was somewhat comparable to the studies carried out in Africa[9] and Malaysia[8]. In the course of our research, we discovered that the emotional well-being subscale scored the highest, while the seizure concern subscale scored the lowest. results from other nations may not be applicable to the circumstances in one's own country because of differences in beliefs, cultures and other socio-economic variables.

We found that younger patients had a higher QoL overall. The age group of less than 30 years often contains students or young people, who, since they are still under their parents' care, are likely to get better medical attention. As people become older, the stigma that society places on them in respect to work chances and social life may become more apparent, which is one reason for the decline in QoL. Multiple more research came to the same conclusion about the connection between Epilepsy patients' ages and their QoL[10].

We observed that female epilepsy patients had a worse quality of life. Studies conducted in India found that females with epilepsy reported lower levels of social support and higher levels of social isolation compared to their male counterparts who also suffered from the condition[11]. A research that was conducted in Europe found that female responders with epilepsy had lower levels of energy, as well as worse levels of physical functioning, mental health, and overall health.[12] The social structure of patriarchy, in which men are seen as the dominant figures of authority, lies at the heart of the organization of a significant portion of Indian society.

In the present research, it was discovered that having a quality of life that was currently married was connected with having a lower QoL. A recent research that was conducted in India found that those who were married and had Epilepsy had considerably lower levels of energy, weariness, and emotional well-being[13]. People diagnosed with Epilepsy have a much reduced likelihood of getting married compared to the general population as a whole[14]. People diagnosed with epilepsy in Asian nations have also been shown to have a higher than average risk of divorce[15]. This may be the case since many people who are single are young and, as a result, have a high QoL.

It has also been shown that having Epilepsy for a longer period of time is a predictor for a worse QoL as a result of more difficulties and limitations[16]. In addition, the length of time that a patient has had epilepsy was shown to have a substantial connection with QoL. According to Herodes, *et al*, patients with epilepsy who had shorter durations of the condition had lower ratings, with shorter durations also having substantial implications on energy, mental well-being, and

physiological discomfort[17].

According to the findings of our research, patients who received monotherapy had a higher QoL compared to individuals who received polytherapy. In a study that Thomas and his colleagues conducted found similar results[18]. This might be attributable to the fact that patients receiving polytherapy have more severe and complex diseases than individuals not receiving polytherapy.

According to the findings of a research carried out by Herodes and colleagues, higher seizure frequency had a significant impact on QoL. Additionally, Strauss believed that a longer period of life free of seizures is the key to improving QoL in epileptics[19]. In the current research, there was a tendency toward a lower QoL with an increasing frequency of seizures; however, this association did not reach statistical significance.

The current research has a few limitations. To begin, this was a study conducted in a single location, which means that the findings of our research may not be applicable to other regions of the world. Second, since it was cross-sectional research, it was not possible to determine whether or not there was a temporal trend in the patient characteristics or the QoL ratings.

Conclusion

Our research makes it clear that the QoL of persons who have Epilepsy is affected by a wide variety of different parameters. The following characteristics were shown to be substantially linked with a worse Quality of Life (QoL): greater age, female gender, being married, higher seizure frequency, longer duration of epilepsy and polytherapy.

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Original Article

Current Spectrum of HIV Associated Ophthalmic Diseases among the Patients Enrolled for Antiretroviral Therapy and its Correlation with CD4-T Cell Count — A Cross Sectional Study

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Background : Various studies have demonstrated 40-45% of HIV patients have Ophthalmic Manifestations. Previous prevalence estimates done within populations selected based on symptoms or ophthalmological referral. This study aims to analyze the prevalence and nature of HIV-related eye involvement in all newly diagnosed HIV patients, before commencing Anti Retro-viral Therapy (ART).

Materials and Methods : This cross-sectional study was done on 271 newly diagnosed HIV-infected patients. Based on a typical ocular lesion with systemic infection the diagnosis of ocular HIV was done. All data were analyzed on SPSS.

Results : Ocular manifestations found in 33.6% of HIV patients. The majority were male (53%) and 14.3% of patients had low vision. The most common involvement was posterior segment (48%). We have found a large number of patients with Ophthalmic Manifestations were asymptomatic (46.2%). Increased chances of HIV ophthalmopathy are observed with increasing severity of HIV infection as evidenced by 74.1% and 91.7% of patients of stage 3 and stage 4 respectively having ocular involvement. The percentage of eye involvement is gradually increasing with decreasing CD4-T Cell Count that is 34.7% of patients of 200 to 500/µL CD4 count and 77.1% patients of less than 200/µL CD4-T Cell Count have ocular involvement.

Conclusion : Multi-disciplinary approach with proper Ophthalmological evaluation is a must for patients with advanced immune deficiency as manifested by WHO clinical stages 3 or 4 and lower CD4 counts.

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Key words **: HIV, Ophthalmic Manifestation, Anti Retro-viral Therapy, CD4-T Cell Count.**

Human Immuno-deficiency Virus (HIV) causes multisystem involvement but the ophthalmic disease does affect 70-80% of the patients with HIV infection sometime during the natural history of their infection. Various studies have demonstrated that 40-45% of HIV-infected patients do have some Ophthalmic Manifestations when they are examined by an ophthalmologist[1,2]. There is a wide spectrum of HIV-associated Ophthalmopathy, which ranges from adnexal disorder to posterior segment involvement, including the optic nerve. These ocular manifestations can be sometimes the presenting signs of a systemic infection in an otherwise asymptomatic individual. The severity of ophthalmic involvement of HIV increases as Immuno-competency decrease which is measured by CD4-T Cell Counts[3].This study aims to conduct an epidemiological study to evaluate the prevalence and nature of HIV-related eye disease, in all newly diagnosed HIV-infected patients, before commencing Anti Retro-viral Therapy (ART) and its relationship with CD4-T Cell Count.

Editor's Comment :

- Ophthalmic screening examination must be prioritized for all HIV positive patients before initiation of ART to halt the potentially blinding complications. As ophthalmic manifestations are still not very uncommon even in present scenario where ART is initiated irrespective of CD4-T cell count.

Materials and Methods

This observational cross-sectional study was conducted over 12 months with 271 newly diagnosed HIV-positive patients, who are candidates for ART,

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attending in ART clinics of a Tertiary Care Centre.

Sampling :

All newly diagnosed HIV positive patients, satisfying the inclusion and exclusion criteria were taken for the study. With proper permission from the In-charge of the ART clinic, all patients are requested to be sent to the Department of Ophthalmology for eye examination before starting ART.

Inclusion Criteria :

All newly diagnosed HIV-positive patients satisfying the criteria for initiating ART [All HIV positive patients, irrespective of CD4-T Cell Counts and clinical staging of HIV, are the candidate for ART, according to recent NACO guidelines[4,5]], attending the ART clinics irrespective of the presence or absences of visual symptoms are included for the study.

Exclusion Criteria :

Patients who already started ART (Old cases), have not satisfied the criteria for initiation of ART, have not given the consent for examination, have other immuno-suppressive diseases that can cause a similar types of ocular manifestations ie, uncontrolled diabetes, on Immuno-suppressive drugs etc. were excluded from the study.

Tools and Techniques :

Demographic and medical information was obtained by a combination of direct questioning by the ART clinic counsellor and a review of the medical case notes. Data obtained include present CD4 count, WHO clinical stage and duration since HIV diagnosis. Then a detailed history and comprehensive ophthalmic examination were done. Relevant systemic investigations were done for the diagnosis of ocular diseases.

Statistical Analysis :

Collected data were compiled in SPSS (Statistical Packages for Social Sciences) version 20 and checked for completeness. Descriptive and inferential statistics were used to analyze and present it. Normally distributed data from continuous variables were presented in the form of mean (±SD) and the data from discrete variables were presented in the form of frequency and proportion. Independent sample t-test was performed for normally distributed data from continuous variables and Chi square test was done for normally distributed data from discrete variables. A P-value of <0.05 was considered significant.

Ethical Issues :

Ethical clearance was taken from Institutional Ethics Committee and informed consent was taken from all participants before including them in the study if they diagnosed with any ophthalmic disease, have been treated accordingly or referred to a higher center after consultation with the In-Charge of the ART clinic.

Result

In this study, we have examined both eyes of total 271 newly diagnosed HIV-positive patients, who are candidates for ART. Among them, 33.6% have Ophthalmological Manifestations (91 out of 271 patients). Among our study population, male to female ratio was 1.1:1 but 40.3 % of male patients have Ophthalmological Manifestations whereas only 26% of female patients have Ophthalmological Manifestations. Our study shows there are significant chances of developing Ophthalmological Manifestation among male patients (Table 1).

Among our study populations, the majority (133 patients out of 271 ie, 49 %) of the patients are staying at home (they are either housewives or students), 27% of patients are skilled labor and 24% of patients are unskilled labor. But disease frequency is more among skilled labor (43.8%) than unskilled labor (35.4%) and at the home group (27.1%) which is statistically significant (p-value 0.048). Our study showed, the majority of the patients (65.3%) came from rural areas than urban areas (34.7%). But urban populations have more ophthalmic manifestation (41.5%) than rural populations (29.4%) which is also statistically significant (ie, df-1, p-value 0.045).

In this study, the mean age of the study population is 33 years; Standard Deviation is 12 years ranging from 5 years to 68 years. We have found most of the patients belong to the 31-45 age group (52.8%) but the maximum disease frequency was noted (52.2%) in 46-60 years of age followed by 31-45 years of age (36.4%). In the box plot, we have found that median age is higher among those who have Ophthalmic Manifestations in comparison to the patients without the same (p=0.004) (Fig 1).The mean body weight of the patients with or without Ophthalmological Manifestations are 49, which according to the box plot retains the null hypothesis (p-value 0.996) showing there is no significant correlation between the body weight of the patients and the development of Ophthalmological Manifestations (Fig 2).

In this study, we have found 17.4 % of patients

Table 1 — *Distribution of Ophthalmic Manifestation across Sex (n=271)*

Sex	Ophthalmological Manifestation		Total	p value
	Absent	Present		
Male	86(59.7%)	58(40.3%)	144(100%)(53%)	
Female	94(74.0%)	33(26.0%)	127(100%)(47%)	0.013
Total	180(66.4%)	91(33.6%)	271(100%)(100.0%)	

have binocular involvement, 16.2 % have uniocular involvement and the majority of the study population has no ocular involvement (66.4%). Among total of 91 patients with ocular involvement most commonly involved structure is the posterior segment (48%), followed by the anterior segment (31%) and adnexa (30%) but 9 % of patients have multiple structures involved.

Table 2 — *Eye involvement pattern among the categories of vision (n=271)*

Visual Acuity	Eye Involvement			Total	p value
	None	One eye	Both eye		
Normal	180 (70.8%)	41(16.2%)	33(13%)	254 (100%)(93.7%)	0.000
Low vision	0	3 (23%)	10 (77%)	13 (100%)(4.8%)	
Blind	0	0	4 (100%)	4 (100%)(1.5%)	
Total	180 (66.4%)	44 (16.2%)	47 (17.4%)	271 (100%)(100%)	

The majority (81.3%) of the patient with HIV-related ocular disease (N=91) have a normal vision at the time of diagnosis but 14.3 % of patient have low vision and only 4 patients out of 91 are blind. Among the patients with normal vision, 16.2% patients have uniocular involvement and 13% have binocular involvement. We have also found, 10 out of 13 (77%) of low vision patients and all 4 blind patients have both eye involvement, so vision significantly depends on eye involvement (p-value 0.000)(Table 2).

In our study we have found, out of 91 patients with ocular involvement 53.8% (49 out of 91) patients have ocular symptoms, among them most frequent symptoms are low vision (46.9%) followed by redness (30.6%), watering (18.6%) and pain (18.4%) and 22.4 % patients have multiple symptoms. But many patients with Ophthalmic Manifestation are Asymptomatic (46.2%).

In our study majority (74.9%) of the patients belongs to stage-1 followed by 10.7% in stage-2, 10% in stage-3 and 4.4 % of patients belong to stage-4. But only 24.1% of stage -1 patients have ocular manifestation whereas 74.1 % and 91.7 % patient of stage 3 and 4 respectively have ocular manifestations. So we have found that the chances of the development of Ophthalmological Manifestation is increasing with increasing severity of HIV infection which is also statistically significant (p-value 0.000)(Fig 3).

In this study, we have found that 12% of the study population have associated co-morbidity like Tuberculosis and Thalassemia. We have also found that the patients with co-morbidity have more chances of developing eye diseases 75% (ie, 24 out of 32 patients) which is statistically significant (p value-0.000).

We have found,45.8 % of patients have a CD4 count within 200-500/µL,41.3 % patients have a CD4 count of more than 500/µL and only 12.9 % patients have a CD4 count less than 200/µL. Among them 18.8 % of patients of more than 500/µL CD 4 count have eye involvement, while the percentage of eye involvement is gradually increasing with decreasing CD4 count (ie, 34.7% of patients of 200 to 500/µL CD4 count and 77.1% patients of less than 200/µL CD4 count have ocular involvement), which also is statistically significant (p-value 0.000)(Fig 4).

We have also found that patients with CD4 count of more than 500/µL have 7.1 % adnexal and posterior segment involvement each and 3.6 % anterior segment involvement. Patients with CD4 count 200-500/µL have 11.3 % of the posterior segment and anterior segment each and 10.5% have adnexal involvement. But patients with CD4 count less than 200/µL have 42.9 % posterior segment,17.1% anterior segment, 8.6% adnexal with posterior segment and 5.7 % anterior with posterior segment involved. So chances of posterior segment involvement is increasing with decreasing CD 4 count which is statistically significant (p-value 0.000)(Table 3).

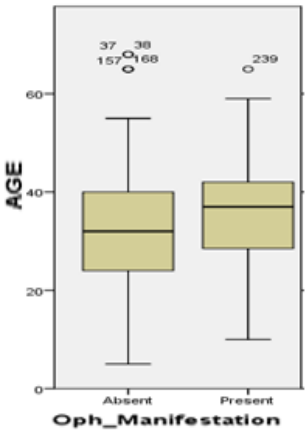

Fig 1 — Box plot showing median age of patients with or without Ophthalmic Manifestations

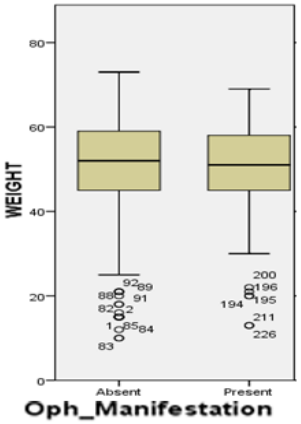

Fig 2 — Box plot shows distribution of weight of patients with Ophthalmic Manifestations (n=271)

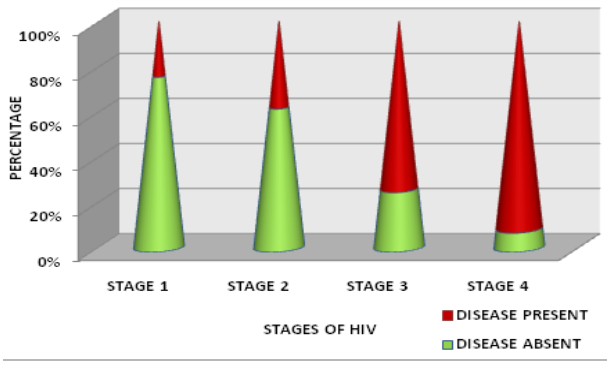

Fig 3 — Composite bar diagram showing distribution of Ophthalmic Manifestations with stages of HIV

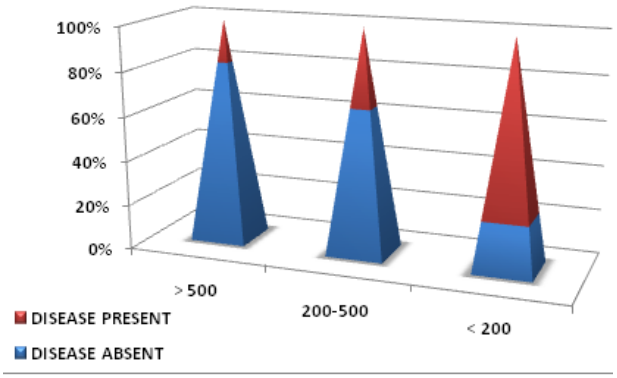

Fig 4 — Composite bar diagram shows Frequency of ophthalmological manifestation and degree of immunodeficiency (n=271)

In our study, posterior segment diseases are most frequent (44%), followed by anterior segment diseases (31%), adnexal diseases (30%) and neuro-ophthalmological manifestations (6.6%). Overall, the most common disease is Retinal micro-vasculopathy 30.8% (28 out of 91), followed by anterior uveitis (9.9%), Keratoconjunctivitis sicca (9.9%) and blepharitis (8.8%). We have found, blepharitis (8.8%), conjunctivitis (5.5%) and molluscum contagiosum (5.5%) are frequent in adnexal diseases. Keratoconjunctivitis sicca (9.9%), anterior uveitis (9.9%) and keratitis (7.7%) are common in anterior segment disease. Retinal micro vasculopathy (30.8%), tubercular chorioretinitis (5.5%) and CMV Retinitis (3.3%) are common in posterior segment disease and optic atrophy (4.4%) is commonly found in neuro-ophthalmological manifestations. We found some patients have multiple segment involvement and again some have multiple diseases in the same segment at presentation in the study group (Table 4).

Table 4 — *Distribution of different ophthalmic manifestations (n=91)*

Structure Involved / Diseases	No of Patients	Total
Adnexa :		
Blepharitis	08 (8.8%)	27(30%)
Conjunctivitis	05 (5.5 %)	
Molluscum Contagiosum	05 (5.5 %)	
Conjunctival Microvasculopathy	04 (4.4 %)	
Lid Abscess	02 (2.2 %)	
Trichomegaly	01(1.1 %)	
EOM Palsy	02 (2.2%)	
Anterior Segment :		
Anterior Uveitis	09 (9.9 %)	28(31%)
KCS	09 (9.9%)	
Keratitis	07 (7.7%)	
Corneal Ulcer	03 (3.3%)	
Posterior Segment :		
Retinal Microvasculopathy	28 (30.8 %)	40(44%)
Tubercular Chorioretinitis	05 (5.5%)	
CMV Retinitis	03 (3.3 %)	
Vetritis	02 (2.2%)	
PORN	01 (1.1%)	
Toxoplasma Retinitis	01 (1.1%)	
Neuro Ophthalmology :		
Optic Atrophy	04 (4.4 %)	06(6.6%)
Retro-Bulbar Neuritis	02 (2.2%)	
Total	101	101

Discussion

In this study, we have examined both eyes of total of 271 HIV-positive patients and evaluated the frequency of ophthalmological manifestations among them, regardless of the presence of ocular symptoms. Over one-third of our study populations have ophthalmological manifestation at the time of ocular screening. The estimated prevalence of HIV-related eye diseases in India is reported to be between 8-45 % with a study population ranging from 100-112 participants[1,2,6-8]. But we have found the overall frequency of ocular manifestations is 33.6% in our study population. A similar study was conducted in Mumbai, India where the overall prevalence of HIV-associated ocular disease was 17.5%, and 23.4% among those have CD4 counts <200 cells/μL[6]. We have screened patients at initiation of ART irrespective of CD4 cell count and symptoms. Nowadays ART has been initiated for all HIV-positive patients irrespective of CD4 T cell count , so the ocular involvement pattern is expected to be changing in India.

The majority of the patients (65.3%) came from a rural area but the urban population has more ophthalmic manifestation (41.5% of total urban populations). We have also found the majority of the patients (49%) are staying at home but disease frequency is more among skilled labor (43.8%). We have also found that the median age is higher among those who have Ophthalmic Manifestations in comparison to the patients without the same and the chances of developing ophthalmological manifestation among males is higher in comparison with females. But no difference was found across religion and marital status of study populations. Pathai S,

Table 3 — *Distribution of different structure involvementin co-relation with CD4 count (n=271)*

CD4 Counts (/μL)	Adnexa	Adnexa Anterior segment	Adnexa Posterior segment	Anterior segment	Anterior Posterior segment	Posterior segment	No Involv-ment	Total	p-value
> 500	8(7.1%)	0	0	4(3.6%)	1(0.9%)	8 (7.1%)	91	112(100%)	
200-500	13(10.5%)	1(0.8%)	1(0.8%)	14(11.3%)	0	14(11.3%)	81	124(100%)	0.00
< 200	1(2.9%)	0	3(8.6%)	6(17.1%)	2(5.7%)	15(42.9%)	8	35(100%)	
Total	22	1	4	24	3	37	180	271	

et al[6] showed there were no significant differences between the two groups in gender, age, marital status or occupation. But we have not found any study which showed an association between age, sex, occupation and residence-wise significance of Ophthalmic Manifestations, so further study needed.

In this study, we have found 17.4% of patients have binocular involvement. 16.2% have uniocular involvement and the majority of the study population have no ocular involvement (66.4%). Our study showed, the majority of the HIV-positive patients (81.3%) who have ocular involvement presented with normal vision at the time of screening but 14.3 % patients have low vision and only 4 patients out of 91 (4.4%) are blind. We have found that 77% of low vision patients and all 4 (100%) blind patients have both eye involvement. Our finding is similar with a study done by Listo BN, *et al*[9] and Pathai S, *et al*[6]. Diminution of vision is rarely complained of by patients suffering from HIV infections because of the good vision in the better eye. So visual acuity cannot be taken as an indication of Ophthalmic Manifestations.

The most common involved structure is the posterior segment 48 %, followed by the anterior segment 31% and adnexa 30% but 9% of patients have dual structure involved. This finding is corroborative with the study done by Joshi Purushottam, *et al*[10] who also revealed that among ocular findings posterior segment lesions (32%) were most common and 9.7% of the cases had anterior segment involvement.

We have found, a large no of patients with Ophthalmic Manifestations are asymptomatic (46.2%). The most frequent symptom is Dim vision (46.9%). A similar finding was noted in the study done by Pathai S, *et al*[6] where there is reporting of ocular symptoms was low (<10%) in groups of patients with and without ocular disease and 92.3% of patients are asymptomatic even though they have some form of HIV related Ophthalmic Manifestations. This may reflect that patients with HIV may not seek treatment for ocular conditions due to the absence of any symptoms.

In the present study, we have found that 12% of the study population have associated co-morbidity and most of them have tuberculosis. Listo BN, *et al*[9] showed, a number of HIV patients with TB were also noted to have ocular manifestations but this was not statistically significant. But we have found,the patients with co-morbidity have more chances of developing Ocular Manifestations (75%) which is statistically significant. This is because different types of Tuberculosis are the major co-morbidity found in our study and the occurrence of Tuberculosis is more in WHO clinical stages 3 and 4.Including our study, different studies shows clinical stage 3 and 4 are associated with more chance of developing ocular manifestations[9,6,11]. This is the probable explanation for this significant association between co-morbidity and the Ocular Manifestations.

In our study, only 24.1% of stage 1 patients have Ocular Manifestation whereas 74.1% and 91.7% patients of Stage-3 and Stage-4 respectively have ocular involvement. This relation is statistically significant and suggestive of the increasing chance of the development of ophthalmological manifestation with advanced staging of HIV infection. This finding is corroborative by a study done by Listo BN, *et al* showing that patients in stage 4 had the highest prevalence of ocular manifestations (95.7%) followed by patients in stage 3 (91.5%). The least prevalence was noted in stage 1(66.7%)[9]. Also in the study of Pathai S, *et al*[6] it is shown that the prevalence of ophthalmic lesions associated with HIV was significantly higher in patients with WHO clinical stages 3 or 4. Those patients with advanced WHO clinical staging of HIV were nine times more likely to have ocular involvement. Similarly, it is reported by Jabs DA, *et al*[11]. that the severity of HIV related eye diseases increases with advanced staging.

CD4-T lymphocyte counts have previously been said to be a reliable predictor of ocular complications of HIV infections[12]. Our study showed the percentage of eye involvement is gradually increasing with decreasing CD4 count which is statistically significant. A similar finding was shown by Pathai S, *et al*[6] that prevalence of ophthalmic lesions associated with HIV was significantly higher in patients with CD4 counts between 0-100 cells/μL. They found those with CD4 counts <100 cells/μL were six times more likely to have an ocular HIV-related lesion. Another study shows there was a significant association between current CD4 count of 0-100/μL, 101-200/μL and 500+/μL and Ocular Manifestations[7]. Our finding that 77.1% patients of less than 200/μL CD4 count have ocular involvement, is comparable with the result of the study by Pathai S, *et al*[6], in which 76.9% of patients with ocular manifestations of HIV had CD4 counts <200 cells/îL[6]. Bekele, *et al*[13] shown that Ocular Manifestation was common in patients with a CD4-T cell count of <200 cells/μl. These findings are similar to other studies conducted in India[13] and Senegal[14]. Thus CD4 count and WHO clinical stage may be important predictors of the presence of HIV-related eye disease in an ART-naïve population.

We have found, the majority of the patients with

adnexal and anterior segment lesion have CD4 count of more than 200/µL and most of the patients with posterior segment involvement have CD4 counts of less than 200/µL. A study done by Pratik Y Gogri, *et al*[15] also showed that posterior segment lesions has a significant association with low CD4-count and most of the posterior segment lesions (72%) had CD4 count less than 200 cell/mm^3, corroborative with our study. So the chance of posterior segment involvement is increasing with decreasing CD4 count.

In our study, posterior segment diseases are most frequent (44%) followed by anterior segment diseases (31%), adnexal diseases (30%) and neuro-ophthalmological manifestations (6.6 %). This finding is similar to the study by Joshi Purushottam, *et al*[10], in which, posterior segment lesions (32%) were the most common.

Among the posterior segment diseases (44%), Retinal micro-vasculopathy (30.8 %) is most common, followed by tubercular chorioretinitis (5.5%) and CMV retinitis (3.3 %).

Similar findings were also shown in studies conducted by Joshi Purushottam, *et al*[10]. and Pratik Y, *et al*[15]. But Biswas J, *et al*[7] showed a slightly different pattern where CMV retinopathy was more common. In most of the studies, increased frequency of CMV retinitis was noted as they have taken symptomatic patients with lower CD4 counts.

Among anterior segment diseases (31%) we have found, Kerato-conjunctivitis sicca (9.9%), anterior uveitis (9.9%) and keratitis (7.7%) are common. Blepharitis (8.8%), conjunctivitis (5.5%) and molluscum contagiosum (5.5%) are frequent in adnexal diseases and we have also found conjunctival microvasculopathy in 4.4%. Pratik Y, *et al*[15] showed similar findings as our study. We have also found Kerato-conjunctivitis Sicca (9.9%) is as common as anterior uveitis among anterior segment findings which is corroborating with Liesegang TJ, *et al*[16] which shows Keratoconjunctivitis sicca or dry eye occurs in 20-38.8% of HIV positive hosts in the later stages of AIDS.

We have found, Neuro-ophthalmological Manifestations (6.6 %) of which Optic atrophy (4.4%) is commonly found. This frequency of Neuro-ophthalmic manifestations was lower than that reported by Pratik Y, *et al*[15] (10%) Assefa, *et al*[17] (9.6%), Sudharshan, *et al*[18] (8.9%) and Biswas J, *et al*[7] (9.3%). This may be due to that in the past most of the Indian studies were done among HIV-positive patients with eye symptoms and low CD4 counts but in this study, we have taken HIV-positive patients irrespective of ocular symptoms and CD4 counts before initiation of ART as per NACO guideline.

Conclission

In India, current practice at several ART centers is to refer patients to Ophthalmologists only after complaints of ocular symptoms or abnormal ocular signs are noted by the Physicians. Our study emphasizes the need for routine baseline ocular screening examination before initiation of ART. For conditions like TB Chorioretinitis and CMV Retinitis where the lesion is mostly peripherally located within Retina, the patient may not experience a significant reduction in visual acuity but it is the utmost importance to carry out routine baseline ocular screening for all HIV-positive patients especially with an advanced degree of immuno-deficiency to halt disease progression and potentially blinding complications due to immune reconstitution once ART is commenced. The severity of Ocular Manifestations in HIV/AIDS in the form of visual impairment was higher in patients with low CD4- counts and advanced stages of HIV. So, when HIV infected patient comes to an ART Clinic multidisciplinary approach with proper ophthalmological evaluation is a must.

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Original Article

To Determine the Prevalence Pattern of Aeroallergens in Patients of Bronchial Asthma and Allergic Rhinitis Reporting to a Tertiary Care Centre in North India

Kamran Chaudhary[1], Manas Kamal Sen[2], Amrita Swati[3], Ruchi Sachdeva[4], Avinash Kumar[3]

Background : Allergens have been associated with diseases such as Bronchial Asthma (BA) and Allergic Rhinitis (AR) which are of most concern, among the patients visiting the chest physicians. Exposure to various aeroallergens has direct impact on pathogenesis as well as outcome of BA and AR.

Materials and Methods : It is a prospective study in which a cohort of 20 patients were assessed who were diagnosed as a case of BA or AR clinically or by pulmonary function test. These patients were subjected to skin prick test after taking written and informed consent.

Results : Most common allergen were Suaeda fruticosa, Mucormucedo, House Fly, Locust, House Dust, Buffalo Dander, Cat Dander and Silk.

Conclusion : The study concludes that most of patients of BA and AR had polysensitization. Majority of patients were female and belonged to the younger age group, 20-29 years followed by 0-19 age group. The patients who were found to be allergic should be educated regarding avoidance of allergens help in reduction of symptoms and morbidity and increasing the overall health status.

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***Key words* : Aeroallergens, Asthma, Rhinitis, Polysensitization.**

Allergens have been associated with diseases such as Asthma and Allergic Rhinitis (AR) which are two of the most common pathologies of pulmonolgy. Exposure to various aeroallergens has direct impact on pathogenesis as well as outcome of Asthma and AR. Both asthma and AR frequently co-exist and are now thought to be a continuum of inflammation involving one common airway[1]. Asthma may be characterized by recurrent episodes of wheezing, breathlessness chest tightness and coughing particularly in morning and night[2]. Asthma is characterized by widespread narrowing of the bronchial airways which changes its severity over short periods of time either spontaneously or under treatment. Allergic rhinitis is an inflammatory condition of nasal mucosa characterized by the symptoms of pruritus, sneeze, discharge, and stuffiness induced by an Immunoglobulin-E (IgE) – mediated response[4]. Common risk factors for Asthma and AR include allergens such as house dust mite, animals with fur, Cockroaches, Pollens, Moulds, Chemical irritants, Tobacco smoke which contains more than 1000 different components have been suggested to cause allergy. Allergens responsible for respiratory allergies (Asthma & AR) are found to be different from place to place as echoed in various Indian and international studies[5-7]. This study was done in tertiary care hospital in north India to find out the major prevailing aeroallergens leading to respiratory distress.

Editor's Comment :

- Skin prick testing, when performed by experienced tester is a simple and rapid test to identify atopic status.
- Relevance of allergen exposure and its relation to symptoms must be confirmed by patients history.
- Most Common age of presentation of allergic rhinitis and bronchial asthma is 20-29 years with significantly positive family history.

Aims and Objectives

To determine the prevalence pattern of aeroallergens in patients of Asthma and Allergic Rhinitis reporting to Tertiary Care Centre in North India

Inclusion Criteria :

(1) Patients with :

(a) Allergic rhinitis/ Allergic Rhinoconjunctivitis/ Allergic Rhinosinusitis, (b) Asthma.

(2) Age group : 18 years and above.

Exclusion Criteria :

(1) Nonspecific skin rash without allergic/atopic characteristics.

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(2) Chronic urticaria in the absence of allergic features on history

(3) Specific food allergies and intolerance

(4) Assessment of the effectiveness of allergen immunotherapy

(5) Chronic fatigue without allergic features

(6) Psychiatrically unstable patients

(7) Severe and unstable asthma

(8) Pregnancy (because of the small risk of anaphylaxis with hypotension and uterine contractions)

(9) Babies, infants and children

(10) Patients on Beta Blocker

Materials and Methods

It was a prospective study in which a cohort of 20 patients were assessed who were diagnosed as a case of Asthma or Allergic rhinitis clinically or by pulmonary function test. Diagnosis of Asthma was made based on variable respiratory symptoms and confirmed variable airflow restriction. Allergic Rhinitis was diagnosed based on clinical symptoms and skin prick tests.

These patients were subjected to skin prick test after taking written and informed consent.

Concentration of allergens used were :

- Pollens - 1:10
- Fungi - 1:10
- Insects - 1:10
- Dusts - 1:10
- Dander - 1:10
- Fabric and Feathers - 1:10
- House Dust Mite - 1: 100 (A mixture of D Farinae and Pteronyssinus in ratio 3:1)

Results

(1) Sex Distribution

Male : 35% ; Female : 65%

Table 1 — *Age Distribution*

Age Group	Male	Female	Total	Percentage
0-19	0	4	4	20%
20-29	2	5	7	35%
30-39	3	3	6	30%
40-49	0	0	0	0%
50-59	1	1	2	10%
60 and Above	1	0	1	5%
Total	7	13	20	

Table 2 — *Allergenicity to Pollens (Total – 47)*

Age group	Positive	Negative	P Value
0-19	29 (61.7%)	18 (38.2%)	0.02
20-29	45 (95.7%)	2 (4.2%)	<0.001
30-39	46 (97.8%)	1 (2.1%)	<0.001
40-49	0	0	0
50-59	27 (57.4%)	20 (42.5%)	0.14
60 and above	12 (25.5%)	35 (74.4%)	<0.001

MC - Suaedafruticosa

Table 3 — *Allergenicity to Fungi (Total – 18)*

Age group	Positive	Negative	P Value
0-19	17 (94.4%)	1 (5.5%)	<0.001
20-29	16 (88.8%)	2 (11.1%)	<0.001
30-39	16 (88.8%)	2 (11.1%)	<0.001
40-49	0	0	0
50-59	9 (50%)	9 (50%)	1
60 and above	2 (11.1%)	16 (88.8%)	<0.001

MC - Mucormucedo

Table 4 — *Allergenicity to Insects (Total – 15)*

Age group	Positive	Negative	P Value
0-19	14 (93.3%)	1 (6.6%)	<0.001
20-29	15 (100%)	0	0
30-39	15 (100%)	0	0
40-49	0	0	0
50-59	15 (100%)	0	0
60 and above	4 (26.6%)	11 (73.3%)	0.008

MC - House Fly, Locust (Female)

Table 5 — *Allergenicity to Dusts (Total – 11)*

Age group	Positive	Negative	P Value
0-19	9 (81.8%)	2 (18.1%)	0.003
20-29	11 (100%)	0	0
30-39	9 (81.8%)	2 (18.1%)	0.003
40-49	0	0	0
50-59	7 (63.6%)	4 (36.3%)	0.20
60 and above	5 (45.4%)	6 (54.5%)	0.67

MC - Grain Dust Bajra, House Dust

Table 6 — *Allergenicity to Dander (Total – 6)*

Age group	Positive	Negative	P Value
0-19	6 (100%)	0	0
20-29	6 (100%)	0	0
30-39	1 (16.6%)	5 (83.3%)	0.02
40-49	0	0	0
50-59	4 (66.6%)	2 (33.3%)	0.25
60 and above	2 (33.3%)	4 (66.6%)	0.25

MC - Buffalo Dander, Cat Dander

Table 7 — *Allergenicity to Fabrics and Feathers (Total – 6)*

Age group	Positive	Negative	P Value
0-19	3 (50%)	3 (50%)	1
20-29	5 (83.3%)	1 (16.6%)	0.02
30-39	4 (66.6%)	2 (33.3%)	0.25
40-49	0	0	0
50-59	0	0	0
60 and above	2 (33.3%)	4 (66.6%)	0.25

MC - Silk (Raw)

The above results conclude to the following findings:

(1) Maximum number of patients according to sex having allergenicity were females which was statistically significant.

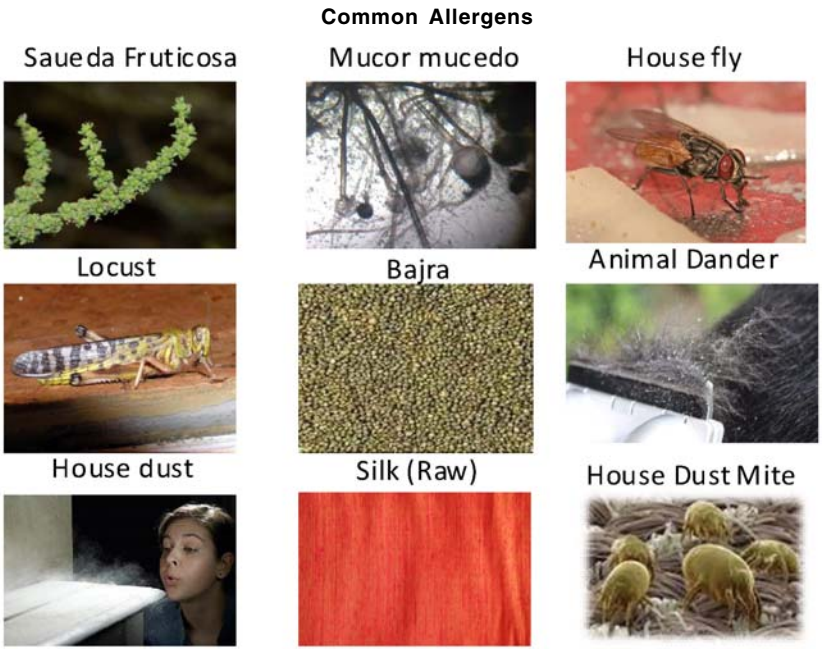
(2) The maximum load of allergenicity to pollens was found in age group 20-29 years (p value <0.001 significant) and the most common allergens was Sueda fruticosa.

(3) The maximum load of allergenicity to fungi was found in age group 0-19 years (p value <0.001 significant) and the most common allergens was Mucor mucedo.

(4) The maximum load of allergenicity to insects was found in age group 20-29 years and 30-39 (p value 0) and the most common allergens were house fly and locust (female).

(5) The maximum load of allergenicity to dusts was found in age group 20-29 years (p value) and the most common allergens were Grain Dust Bajra, House Dust.

(6) The maximum load of allergenicity to dander was found in age group 0-19 years and 20-29 (p value 0) and the most common allergens were Buffalo Dander, Cat Dander.



(7) The maximum load of allergenicity to fabrics and feathers was found in age group 20-29 years (p value 0.02) and the most common allergens was Silk (Raw).

Discussion

In the age group 20-30 years maximum number of the patients had Asthma followed by mixed disease and allergic rhinitis.

Our result has been in accordance with some other studies, where nasobronchial allergy has been found to be at its peak in age group 20-30 years as stated by Kumar R, *et al* and Singhal P, *et al* in Delhi.. similar results were observed by Rasool R, *et al*[7] and Sritipsukho P[8].

Maximum number of patients with symptoms having seasonal variation had asthma, followed by allergic rhinitis and mixed disease.

In this study it was observed that the major bulk of the patient had age of onset of nasobronchial disease between 15-20 years (28.57%) and least in 1-5 years (3.57%) and 5-10 years (3.57%).

Majority of the patients had positive family history with more predominance of paternal family history.

In our study majority of the patients (n=38; 67.86%) belonged to the urban class. Similar results were seen in most of the other studies.

In our study it was observed that maximum patients (n=32; 57.14%) of nasobronchial allergies owned pets which was statistically significant. Most of the patients (75%) that owned pets had Asthma.

In another study done by Gruchalla RS[9], *et al* in Dallas showed that nearly 34.4% of the nasobronchial allergic patients owned pets and most of them had moderate to severe asthma.

In our study the most prevalent aeroallergen among patients with nasobronchial allergy was House dust mite (71.43%), followed by insects (65.71%), followed by pollens and dusts (39.13% respectively), followed by fungi (30.16%), followed by dander (27.38%) and least by fabrics and feathers (26.19%). A significant correlation among all the groups of allergen was seen.

In our study house dust mite (71.43%) was found to be the most prevalent allergen among patients with nasobronchial allergies.

This was in accordance with the observation made by Hendrick DJ[10], *et al* (1975) which showed that house dust mite was the most prevalent allergen (82%). Most of the other studies found dust mites to be the most common aeroallergens in asthma and allergic rhinitis.

The insect group was the second most prevalent (65.71%) aeroallergen among the patients with nasobronchial allergy

House fly (78.57%) was the most prevalent insect followed by Ants, Honey Bee, Locust (female) and Mosquito. Mosquito showed highest positivity (67.86%) with skin prick test.

The next most prevalent aeroallergen was pollens (39.13%). Among pollens the highest prevalent allergen was Suaeda fruticosa (71.43%), followed by Gynandropis gynadra (67.85%), Cynodon dactylon (57.14%), Cassia occidentalis (53.57%). Among them

markedly positive reaction were seen by Cassia occidentalis and Cratava nurvala (35.71% respectively).

The next most prevalent group of aeroallergen in our study was dusts (39.13%). Among the dust group, the most prevalent allergens were Grain dust bajra and house dust (53.57% respectively), followed by Grain dust rice (50%), Grain dust Jowar (42.85%). Among the Dust group the highest positivity was seen with Grain dust bajra (46.43%).

The other common allergens were animal dander, fabric and feathers.

Conclusion

The study concludes that most of the allergic patients belong to female gender.

The frequency of allergenicity was maximum in youger age groups and maximum in 20-29yrs followed by 0-19 years.

Most of the patients had polysensitisation.

The most common allergens causing allergic respiratory diseases concluded from study are Suaeda fruticosa, Mucor mucedo, House fly, Locust (Female), Grain Dust Bajra, House Dust, Buffalo Dander, Cat Dander and Silk (Raw).

The patients who were found to be allergic should be educated regarding avoidance of allergens help in reduction of symptoms and morbidity and increasing the overall health status.

Sensitization is an important precursor of clinical allergic disease and further studies to unravel the complex gene-environment interactions of aeroallergen sensitization in different environments are needed.

Limitation of the study : The sample size used for bronchial asthma was small

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Original Article

Efficacy and Safety of Parenteral Human Placental Extract and Oral Azithromycin Versus Oral Azithromycin Alone in Chronic and Recurrent Pelvic Inflammatory Disease : An Open-Label Randomized Controlled Trial in Indian Patients

Purna Chandra Mahapatra[1], Amita Pandey[2], Niranjan M Mayadeo[3], Jyotsna S Dwivedi[4], Isukapalli Vani[5], Veena Venkatesh[6], Monjori Mitra[7]

Background : Treatment of Pelvic Inflammatory Disease (PID) is challenging due to symptom recurrence with broad-spectrum antimicrobials. Placental therapy combines antimicrobial with antibiofilm actions, in addition to other benefits.

Aims and Objectives : To compare the efficacy and safety of parenteral Human Placental Extract (HPA) and Oral Azithromycin (AZ) *versus* AZ monotherapy in chronic and recurrent PID.

Materials and Methods : This prospective, multicenter, open-label study was conducted in 60 consenting eligible subjects having PID. Subjects were randomly allocated to receive either 2ml intramuscular HPA injection once daily for 2 weeks plus 1g oral AZ once daily for 1 week or only 1g oral AZ once daily for 1 week. The primary endpoint was treatment response based on the Clinical Global Impression (CGI) scale at 2 and 12 weeks. Relapse/recurrence rate at 12 weeks was a secondary endpoint. Incidence of Adverse Events (AEs) was the safety endpoint.

Results : A significantly higher proportion of subjects in HPA+AZ showed 'excellent' response at 2 weeks compared to those in AZ (75.86% *versus* 50.00%; p=0.046); this significant benefit of HPA+AZ over AZ was sustained till 12 weeks (79.31% *versus* 38.46%; p=0.002). Subjects in HPA+AZ had fewer symptom relapses than those in AZ (17.24% *versus* 23.08%; p=0.589). Improvement in PID signs and symptoms was also evident. Mild AEs in 10.00% subjects in each arm resolved by study end.

Conclusion : This study showed that subjects treated with a combination of HPA and AZ responded better compared to those treated with AZ alone with respect to symptom alleviation of chronic PID.

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***Key words* : Pelvic Inflammatory Disease, Human Placental Extract, Azithromycin, Randomized Controlled Trial.**

Pelvic Inflammatory Disease (PID) is one of the most prevalent gynecological disorders in women of reproductive age. It is an inflammatory condition in which the upper reproductive tract (endometrium, fallopian tubes, ovaries, pelvic peritoneum and adjacent pelvic structures) is infected, often by multiple ascending microbes from the lower genital tract (vagina and cervix) to the uterine cavity; lymphatic or hematogenous routes of infection are rare. Untreated PID causes severe morbidity and complications such as chronic pelvic pain and intra-abdominal infections in addition to infertility, ectopic pregnancy and preterm labor that are of global concern due to their effects on reproductive health[1-5]. These also increase the risk of psychiatric disorders leading to decrease in Quality

Editor's Comment :

- Human placental extract has antimicrobial, antibiofilm, and repair properties. Its concomitant administration with antibiotic showed benefits over antibiotic monotherapy in symptom alleviation of chronic/recurrent pelvic inflammatory disease, a prevalent gynecological disorder that may cause infertility. Relapses were also comparatively fewer with the combinatorial treatment, although study in a larger cohort is required to substantiate the same.

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of Life (QoL)[6]. The age-standardized rate of global prevalence of PID and ectopic pregnancy was 53.19 and 342.44 per 1,00,000, respectively in 2019[1-5]. The rate of association between PID and infertility was 9%-85% worldwide with a low perception prevalence[7].

PID manifests as acute, chronic, or subclinical infection; it is often underdiagnosed due to the wide variation in nature/severity of symptoms. Diagnosis is primarily based on comprehensive history and clinical and physical examinations[5,8]. Due to its polymicrobial etiology, broad-spectrum antimicrobials are commonly used for management[5]. However, a challenge is symptom recurrence despite conventional treatments[8]. Biofilms provide a protective niche to microorganisms thus enabling them to thrive in the presence of antimicrobials. Such biofilm-producing pathogens increase the risk of PID[9] and limit the success of treatment modalities.

Placental therapy has been successfully utilized in multiple indications including PID, chiefly because Human Placental Extract (HPA) exhibits antimicrobial and antibiofilm properties in addition to facilitating tissue repair/regeneration, wound healing, debridement, pain relief, immunomodulation, anti-inflammation and cellular proliferation.These properties are attributed to a composition rich in biomolecules such as Polydeoxyribonucleotide (PDRN), Nicotinamide Adenine Dinucleotide Phosphate Hydrogen (NADPH), ubiquitin-like peptide, corticotropin-releasing hormone (CRH)-like peptide, growth factors and glutamate[10-12].

Earlier studies have reported better management of PID using HPA with conventional therapy[13], antimicrobial therapy[14], or doxycycline[15,16] compared to monotherapy of these. HPA resulted in lower recurrence and prevented long-term sequelae. Compared to antimicrobials such as Azithromycin (AZ), complete remission was evident in a higher proportion of PID patients treated with HPA for 12 weeks[17]. Although HPA has long been considered as an alternative modality for PID treatment, there are only a few studies supporting its use in recurrent PID. The current study evaluated the efficacy and safety of combinatorial treatment with HPA and AZ *versus* AZ monotherapy in women having chronic and recurrent PID.

Materials and Methods

This prospective, multicenter, open-label study was conducted at four sites in India between September, 2022 and September, 2023. Patients were enrolled after obtaining written informed consent and written approvals from Ethics Committees of study sites. The study was conducted in accordance with the Indian Council for Medical Research (ICMR), New Drugs and Clinical Trials (NDCT) rules 2019 and Indian Good Clinical Practice (GCP) guidelines for clinical research (CTRI/2022/09/045480; registered on 13 September 2022).

Eligible subjects were 18- to 45-year-old women with lower abdominal/pelvic pain and cervical motion or pelvic tenderness or adnexal tenderness based on historical ultrasonography, diagnosed with recurrent PID persisting despite antibiotic treatment within past 6 weeks, having a history of infertility and willingness to receive Intramuscular (IM) injections. Post-menopausal women, pregnant/lactating mothers, participation in any other clinical trial in the past month, active treatment or evidence of active tuberculosis/ Sexually Transmitted Disease (STD), unlikelihood to comply with trial protocol,or known endometriosis or hepatic/renal impairment or any other debilitating systemic condition, which, as per the Investigator, would deem the patient unfit to participate, were exclusion criteria.

Considering 48% difference in complete symptom remission rate between treatment arms at 12 weeks[17] and accounting for 40% drop out, a sample size of 60 (30 in each arm) was computed to achieve 90% power with 5% level of significance. Subjects were randomly and equally allocated (based on a computer-generated randomization list) to receive either 2ml IM HPA injection once daily for 2 weeks plus 1g oral AZ once daily for 1 week after meals or only 1g oral AZ once daily for 1 week after meals. After treatment initiation, subjects were followed up at 1, 2 and 12 weeks (window period: ±3 days at 1 and 2 weeks; ±7 days at 12 weeks).

The primary endpoint was the number and proportion of subjects whose response was excellent, good and poor on the Clinical Global Impression (CGI) scale at 2 and 12 weeks, wherein a subject was classified as 'excellent' if majority of presenting symptoms resolved, 'good' if majority of presenting symptoms remained unresolved but adequately controlled and 'poor' if there was minimal improvement or worsening of presenting symptoms. Relapse/recurrence rate of symptoms at 12 weeks was the secondary endpoint. Safety was assessed based on incidence of Adverse Events (AEs). Subjects were also monitored for improvement in the following symptoms: pain in the lower abdomen or pelvis, abnormal vaginal discharge, dysmenorrhea, pain in the upper right abdomen, painful sexual intercourse, fever and chills, menstrual irregularity, abnormal menstrual bleeding and painful urination.

Gynecological/bimanual pelvic examination was performed for signs of PID including presence of vaginal discharge, cervical motion or pelvic tenderness, adnexal tenderness, uterine tenderness and restricted mobility of uterus.

All statistical analyses were based on the International Council for Harmonization E9 document 'Statistical Principles for Clinical Trials' and performed using SPSS version 28.0.1.1. Independent t-test was used to compare demographic characteristics and Pearson's chi-square test to compare treatment responses; $p<0.05$ was considered statistically significant.

Results

A total of 60 PID patients were screened and enrolled, with 30 in each treatment arm. Baseline demographic characteristics were comparable between the arms (Table 1). A total of 5 subjects were lost to follow-up and 55/60 (91.67%) subjects completed the study (per protocol or PP population): 29 in HPA+AZ and 26 in AZ (Fig 1). Pain in the lower abdomen or pelvis (96.36% PP subjects) was the most common symptom at baseline. Among the signs of PID, presence of vaginal discharge was the most common (87.27% PP subjects) at baseline.

On the CGI scale, a significantly higher proportion of subjects in HPA+AZ, compared to AZ, had 'excellent' response at 2 weeks (75.86% *versus* 50.00%; p=0.046). This significant treatment response of HPA+AZ over AZ was sustained till 12 weeks (79.31% *versus* 38.46%; p=0.002). On the other hand, a significantly higher proportion of subjects in AZ, compared to HPA+AZ, had 'poor' response at 12 weeks (Fig 2). Recurrence rate was lower in HPA+AZ (17.24%) than AZ (23.08%; p=0.589). By 12 weeks, all subjects showed improvement in fever and chills. Also, improvement was seen in menstrual irregularity, painful urination and presence of vaginal discharge in all subjects in HPA+AZ and in pain in the upper right abdomen, abnormal menstrual bleeding and restricted mobility of uterus in all subjects in AZ (Table 2).

Mild AEs were reported by 6/60 (10.00%) subjects (HPA+AZ, 3; AZ, 3). AEs included fever, headache, urinary tract infection, abdominal pain, lower abdominal pain and muscle inflammation. All patients with AEs recovered. No clinically or statistically significant changes were observed in body temperature and blood pressure.

Discussion

PID poses significant physical, mental and healthcare burden, particularly due to its long-term detrimental effects on reproductive health. The concerns are further amplified due to symptom recurrence[1,6,7]; possible causes, among others, include biofilm formation and incomplete infection clearance upon conventional treatments. Due to its antibiofilm properties, HPA might be used to combat such difficult-to-treat deep-seated infections[9,18].

In the current study, a significantly higher proportion of subjects had 'excellent' response to symptoms upon treatment with HPA+AZ compared to AZ monotherapy. Recurrence rate was comparatively lower with HPA+AZ. Signs and symptoms improved in concordance with earlier reports[13,14] and improvement persisted even after completion of treatment. A marked reduction in PID symptoms was reported in 27%-59% subjects treated with HPA and antimicrobial[14]. In the current study, up to 74% subjects showed improvement in individual symptoms with HPA+AZ;

Table 1 — *Demographic characteristics of subjects at baseline*

	HPA+AZ (n=30)	AZ (n=30)	p-value
Age (years) :			
Mean ± SD	32.18±7.63	33.22±5.78	0.556
Median (min, max)	33.20 (18.20, 43.82)	32.63 (23.16, 44.59)	
Height (cm) :			
Mean ± SD	151.70±6.34	152.85±8.05	0.542
Median (min, max)	151.50 (138.50, 168)	153.50 (124.96, 168)	
Weight (kg) :			
Mean ± SD	57.58±10.10	61.66±10.56	0.132
Median (min, max)	58 (38, 80)	60.95 (39.26, 85)	

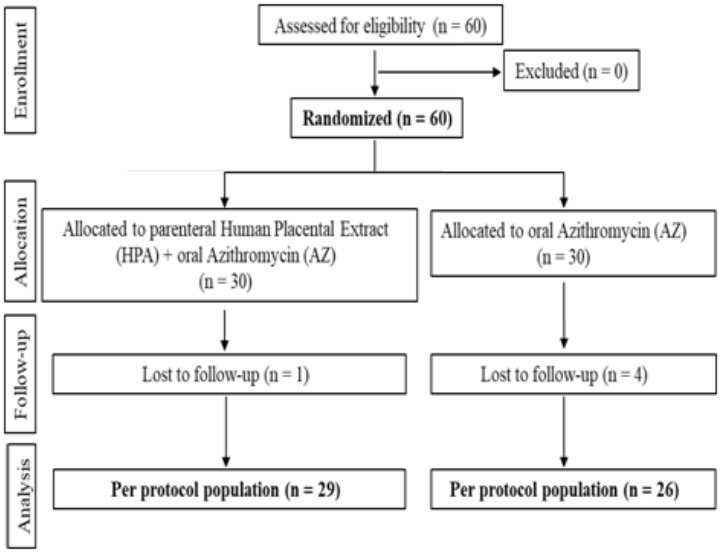

Fig 1 — Subject Disposition

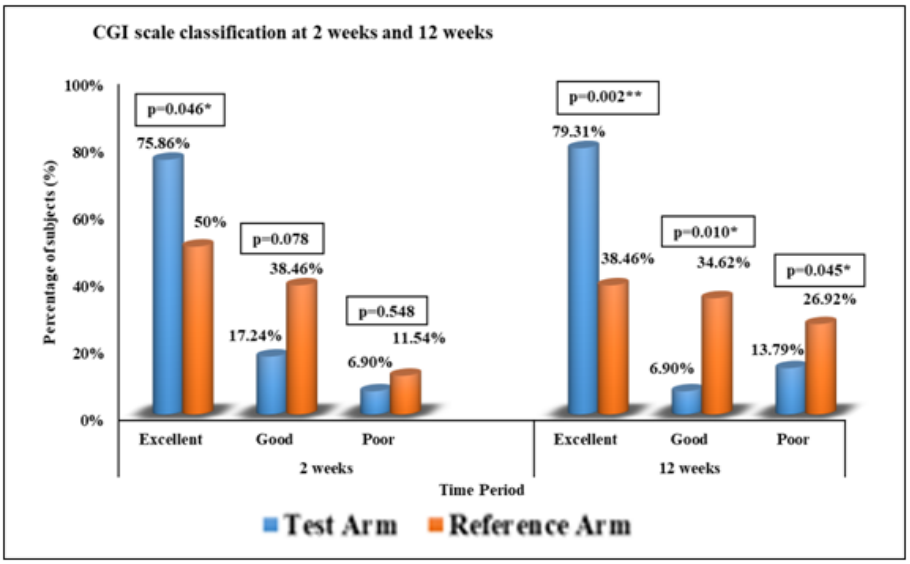

Fig 2 — Treatment response based on Clinical Global Impression (CGI) scale

improvement rates at 12 weeks were higher than those reported in an earlier study with HPA alone[17]. Notably, significant improvement was observed in the current study upon treatment with HPA+AZ for 2 weeks in patients who had been on antibiotic treatment prior to enrollment. HPA+AZ was also found to have a good safety profile. Taken together, combinatorial treatment with HPA and antimicrobial might be more effective than monotherapy, as has been reported earlier[15]. Overall, the current study corroborates existing literature on effective and safe use of this combination in PID management.

This study evaluated multiple efficacy measures including early improvement at 1 week, sustained improvement at 2 and 12 weeks and recurrence at 12 weeks. Recruitment from geographically-distributed regions across India enabled assessment of culturally diverse women from different backgrounds. However, this study is limited by its small sample size and the lack of information on causes of PID. Identification of the causative organisms in a future study would enable efficacy evaluation of HPA+AZ against specific pathogens.This is especially important because novel pathogens pose considerable challenges in PID management[8] and data on strain-specific prevalence is limited. In earlier studies, HPA was shown to cause a significant reduction in biofilm-forming ability of infectious organisms by inhibiting/decreasing bacterial motility, pyocyanin and pyoverdine, extracellular matrix of biofilm and cell surface hydrophobicity. Further studies are required to explore the efficacy of HPA+AZ in PID caused by biofilm-producing pathogens, to investigate

Table 2 — *Improvement in symptoms and signs of PID*

	HPA+AZ				AZ			
	Baseline, n	1 week, n (%)	2 weeks, n (%)	12 weeks, n (%)	Baseline, n	1 week, n (%)	2 weeks, n (%)	12 weeks, n (%)
Clinical symptoms of PID :								
Pain in the lower abdomen or pelvis	27	22 (81.48%)	23 (85.19%)	20 (74.07%)	26	22 (84.62%)	22 (84.62%)	20 (76.92%)
Abnormal vaginal discharge	26	22 (84.62%)	24 (92.31%)	24 (92.31%)	22	18 (81.82%)	19 (86.36%)	19 (86.36%)
Dysmenorrhea	22	13 (59.09%)	16 (72.73%)	19 (86.36%)	17	10 (58.82%)	10 (58.82%)	11 (64.71%)
Pain in the upper right abdomen	21	18 (85.71%)	19 (90.48%)	20 (95.24%)	17	15 (88.24%)	16 (94.12%)	17 (100.00%)
Painful sexual intercourse	9	5 (55.56%)	8 (88.89%)	8 (88.89%)	7	3 (42.86%)	4 (57.14%)	4 (57.14%)
Fever and chills	8	7 (87.5%)	8 (100.00%)	8 (100.00%)	3	1 (33.33%)	1 (33.33%)	3 (100.00%)
Abnormal menstrual bleeding	7	3 (42.86%)	5 (71.43%)	6 (85.71%)	3	1 (33.33%)	2 (66.67%)	3 (100.00%)
Menstrual irregularity	6	1 (16.67%)	6 (100.00%)	6 (100.00%)	5	0 (0%)	1 (20.00%)	3 (60.00%)
Painful urination	3	2 (66.67%)	3 (100.00%)	3 (100.00%)	4	3 (75.00%)	4 (100.00%)	3 (75.00%)
Gynaecological / Bimanual Pelvic Examination :								
Presence of vaginal discharge	25	21 (84.00%)	24 (96.00%)	25 (100.00%)	23	18 (78.26%)	19 (82.61%)	19 (82.61%)
Cervical motion or pelvic tenderness	24	18 (75.00%)	19 (79.17%)	20 (83.33%)	20	17 (85.00%)	18 (90.00%)	19 (95.00%)
Adnexal tenderness	20	15 (75.00%)	14 (70.00%)	17 (85.00%)	16	15 (93.75%)	15 (93.75%)	15 (93.75%)
Uterine tenderness	9	7 (77.78%)	8 (88.89%)	8 (88.89%)	6	4 (66.67%)	5 (83.33%)	5 (83.33%)
Restricted mobility of uterus	4	4 (100.00%)	4 (100.00%)	2 (50.00%)	1	1 (100.00%)	1 (100.00%)	1 (100.00%)

NOTE : Percentages are computed based on the number of symptomatic subjects at baseline.

possible association of the antibiofilm property of HPA with in vivo outcomes, and to identify the HPA component(s) responsible for its action[12]. A longer follow-up period in a larger cohort to assess recurrence rate and pregnancy outcome in PID patients with infertility would be useful too. Comparison between patients on different doses of antibiotic would also be worthwhile to investigate if the antibiotic dose can be lowered when co-administered with HPA.

Conclusion

This study showed that a combination of HPA and AZ is effective and safe for mitigation of signs and symptoms of chronic and recurrent PID; it results in excellent patient response at as early as 2 weeks with sustained effect and low recurrence and AE rate till 12 weeks.

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Conflict of Interest : VV is an employee of Albert David Limited. The other authors declare no conflict of interest.

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Original Article

A Cross Sectional Study on Factors Associated with Patients being MIS-3 on Anti-retroviral Therapy Registered at a Nodal Centre — Goa Medical College

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Background : Anti-retroviral Therapy (ART) has helped in improving lives of PLHA. But, NACP suggest a high adherence to ART is necessary for effective treatment of PLHA. Goa has a high loss to follow up and and MIS-3 patients hence we conducted this study to understand the reasons behind it.

Aims and Objectives : (a) To study the demographic and Socio-economic profiles of the MIS-3 patients. (b) To study the Knowledge, Attitude, Practices towards Anti-retroviral Therapy of the participants.

Materials and Methods : A cross Sectional study was conducted at Anti-retroviral Therapy Centre, Goa Medical College. Patients registered at ART centre of Goa Medical College who did not turn up during the month of appointment for 3 consecutive months.

Results : The final study included 66 participants from a list of 70 total MIS-3 patients. Travelling, stigma, timings of OPD were the main reasons for missing treatment. The knowledge about ART was egregious among the patients which reflected in the attitude & practices about ART.

Conclusion : Knowledge pertaining to various aspects of ART seemed to be an important component in increasing adherence to ART. Similarly a positive Attitude would result in better practices with regards to ART adherence, thus resulting in less MIS patients. Hence an effective communication to all aspects of ART is the way forward to achieve the goal of elimination that we have set.

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Key words **: HIV/AIDS, Adherence, Treatment Compliance, ART, Antiretroviral Treatment.**

The annual new HIV infections in India have decreased by 48% in contrast to the global average of 31% (the baseline year of 2010). The annual AIDS-related mortalities have declined by 82% against the global average of 47% (the baseline year of 2010)[1]. Adherence is defined as a patient's ability to follow a treatment plan, take medications at prescribed times and frequencies and follow restrictions regarding food and other medications[2,21].

Editor's Comment :

- Adherence to ART is mandatory for the treatment and improved Quality of Life of the patient.
- Poor adherence to ART is associated with less effective suppression of the viral load, which risks the health of the patient, but also risks creating permanent drug resistance.
- Robust efforts have to be made by the health services and the community to ensure adherence among the PLHAs to provide optimum Quality of Life.

Poor Adherence to Anti-retroviral Therapy (ART) is associated with less effective suppression of the viral load, which risks the health of the patient but also risks creating permanent drug resistance to that particular agent or group of agents within a given combination therapy regimen[2,3].

The causes of poor adherence to ART are diverse, and include a variety of therapeutic regimens (eg, pill burden and dosing frequency), adverse effects, health illiteracy, an ill patient-physician relationship and limited access to ART. It is vital that the members of the healthcare team address the barriers to adherence in

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order to achieve viral load suppression and optimize outcomes in patients with HIV/AIDS. To achieve the optimal result from Anti-retroviral Therapy a level of adherence to ART (at least 95%) is needed[2,3,10,15,20].

Goa has a good testing rate for detection of HIV but has a high loss to follow up and MIS-3 patients hence, we conducted this study to understand the reasons behind it.

Materials and Methods

Study design : Cross Sectional study

Study setting : Anti-retroviral Therapy Centre, Goa Medical College

Study period : 6 months from the date of receiving final approval from NACO (National AIDS Control Organisation).

Study population : Patients registered at ART centre of Goa Medical College.

Sample Size : All patients which fit the inclusion criteria were considered.

Operational definition : MIS-3 is a on ART patient who does not turn up during the month of appointment for 3 consecutive months

Inclusion criteria : People living with HIV/AIDS who have registered at ART Centre, Goa Medical College on or before 31st December, 2021 a) were started on ART on or before 31st December, 2021 b) missed ART for a period of 3 months.

Exclusion Criteria : The patients registered at ART Centre in Goa Medical College who were

(a) lost to follow up at the ART centre in Goa Medical College.

(b) Transferred to a different facility outside Goa.

Data Collection : Upon approval of the Institutional Ethics Committee of Goa Medical College, Goa State AIDS Control Society, National AIDS Control Organization, the study was initiated. Data was collected by personal interview of the patients after obtaining written informed consent. Patients were contacted via phone and were asked to come to Goa Medical College, ART centre for personal interview. If the patient could not come to the ART centre due to inconvenience or personal choice, the patient was visited at the nearby health centre. Treatment related data was collected from existing records. The details were entered in a pre-designed data collection questionnaire which included Socio-demographic data, disease history, past history, treatment history (ART and other regular treatment details), admission history, laboratory details, etc[4,6,14-19].

Data analysis: Interim data analysis was done after a period of 2 months and report was sent to NACO after 3 months after start of the study. Data was entered in Microsoft Excel and analysed in IBM SPSS version 22. Monitoring of data entry was carried out at regular intervals[11-16].

Results

This cross-sectional study was carried out from November, 2022 to February, 2023 at ARTC of Goa Medical College, Goa. The final study included 66 participants from a list of 70 total MIS-3 patients. Almost two third (70 %) of the study participants were males. Almost half (45%) of the study participants were aged between 40-59 years, one third belonged to 26 – 40-year age group, the mean age being 44.15 ± 3.08. Three fourth of the study participants were Hindu by religion followed by Christian (12%), Muslim (10%). More than half (60%) of the participants were working (Table 1)

The treatment details are described in Table 2. Various reasons were elicited from the MIS 3 for not following up to ARTC Centre. Around 11 (16 %) felt ARTC Centre was too far for regular follow up, 5 of them were aged above 60 years of age. Stigma associated with HIV/AIDS was also an important factor with 10 (15%) of the participants were reluctant to follow up due to it (Fig 1).

Many of the employed participants felt that the treatment timings have caused them to stop their regular follow up. Around 14 participants had adverse reactions following treatment with ART, among them 7 had stopped taking ART due to the adverse effect. One of the participants had retinal damage following ART Therapy. Some participants felt that ART was not

Table 1 — *Distribution of MIS 3 patients as per the Socio-demographic*

Variable		Frequency (nu.)	Percentage (%)
Sex	Male	46	70
	Female	20	30
Age group	18-25	7	11
	26-40	21	33
	40-59	31	45
	60 and above	7	11
Religion	Hindu	50	75.8
	Christian	8	12.2
	Muslim	7	10.5
	Others	1	1.5
Education	Illiterate	14	21.9
	Upto Primary	11	17.2
	Upto Secondary	24	37.5
	Higher Secondary and above	17	23.4
Occupation	Unemployed	16	24
	Retired	11	16
	Employed	39	60
Socio-economic Class	I & II	35	53
	III & IV	25	38
	V	6	9

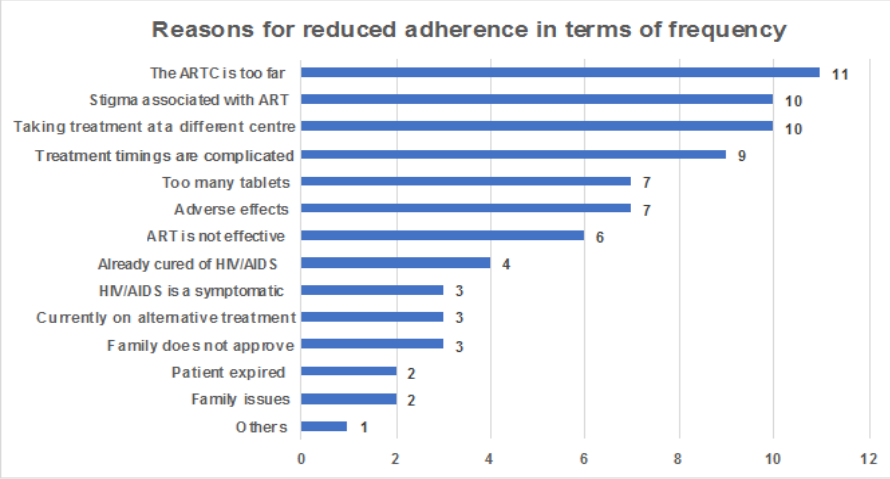

Fig 1 — Reasons for being MIS 3 on ART

Table 2 — *Treatment details of the participants*

Variable		Frequency (nu.)	Percentage (%)
Treatment initiated	ZLN	18	27
	TLE	28	42
	Others	20	30
Treatment changed to	33		
	ZLN	5	—
	TLD	20	—
	Others	8	—
Adverse effects	Yes	14	21
	No	52	79
INH Therapy given	Yes	16	24
CPT given	Yes	20	30

*Zidovudine + lamivudine + nevirapine (ZLN) , tenofovir + lamivudine + efavirenz (TLE) , tenofovir + lamivudine + dolutegravir (TLD) , isoniazid (INH) , cotrimaxazole preventive therapy (CPT)

effective in treatment of HIV hence they had decided to stop taking it. Around 4 (6%) participants felt they were cured of HIV hence there was no need to continue taking treatment.

The improvement in health (no symptoms of disease) lead to 3 (4.5%) of the participants to stop taking ART. A lacuna in knowledge was noted regarding knowledge of ART among the participants, with almost two third (67%) having no knowledge of ART Therapy helping in improving the immunity level (Table 3).

Almost two third participants (67%) knew that ART was available free of cost for treatment of HIV. Only half of the participants knew that there was a separate nodal centre for treatment of HIV. Almost one third (25%) of the participants did not know that ART was a lifelong treatment. Majority of participants agree that ART is important for their treatment and that it is effective for their treatment. A majority of them also believe that ART has scientific basis for treatment and it will prolong and improve their Quality of Life (Table 4).

A large group did not believe that ART will lead to worsening of their health. Most of the participants were of the attitude that they will recommend ART to other PLHAs. The majority of participants would often follow practices which included visiting ARTC as advised, storing medicines properly, taking the medicines on time and regularly, reporting to ARTC in case of any adverse effect and performing investigations on time as advised by the doctor. The participants however did not take the doctor's advice before seeking additional treatment which may be the possible cause of reduced adherence (Table 5).

Table 3 — *Distribution of MIS 3 patients as per knowledge of ART*

Statement	Yes (%)	No (%)	Don't know (%)
ART is used for treatment of HIV/AIDS	42 (65%)	21 (30%)	3 (5%)
ART is available free of cost.	44 (67%)	17 (25%)	5 (7.5%)
ART is provided by the Government of India	41 (63%)	15 (23%)	10 (15%)
ART is available at Nodal Centres in Goa.	35 (53%)	18 (28%)	13 (19%)
ART is a lifelong treatment	46 (70%)	17 (25%)	3 (4.5%)
ART helps to increase my immunity	17 (25%)	5 (8%)	44 (67%)
ART may result in some side effects	42 (65%)	14 (21%)	10 (14%)

Discussion

Our study found no significant change in adherence and age and were in congruence with a facility based cross-sectional study which was carried out among 116 People Living with HIV/AIDS (PLHAs) on ART by Madi, *et al*. AI which revealed that with increase in age there was reduced adherence to ART; however, it was not statistically significant (p=0.1).[2]

Age :

The results were similar to a study conducted in a tertiary health facility in cross-sectional study, conducted over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y, *et al* where increase in age was not significantly associated with adherence[4].

A facility based cross-sectional study was conducted by Banagi Yathiraj A, *et al* among PLHAs attending Infectious Disease Department of the tertiary care hospitals, at Mangalore, Karnataka where increase in age was not significantly associated with reduction in adherence and PLHAs who were

Table 4 — *Distribution of MIS 3 patients as per their Attitude to ART*

Statement	Mean ± SD	Categories
ART is important in treatment of HIV/AIDS	3.23 ± 0.934	Less than 3 = Disagree with statement
ART is effective for my treatment.	3.25 ± 0.939	More than 3 to 4 = Agree with statement
ART has scientific basis for treatment.	3.27 ± 0.981	More than 4 = Strongly agree with statement
ART will prolong my life.	3.30 ± 0.952	
ART will improve my quality of life.	3.07 ± 0.871	
ART will lead to worsening of my health.	2.96 ± 0.873	
I will recommend ART to other PLHAs	3.41 ± 1.041	

Table 5 — *Distribution of MIS 3 patients as per their Practices wrt ART*

Statement	Mean ± SD	Categories
I visit ARTC regularly as advised	3.23 ± 0.809	Less than 3 = Rarely follows the practice
I store the medicines properly	3.30 ± 0.829	
I make it a point to take my medicines on time	3.20 ± 0.883	More than 3 to 4 = Often follows practice
I take my medicines regularly.	3.14 ± 0.819	More than 4 = Frequently follows practices
I immediately report to ARTC in case of any adverse effect	3.04 ± 0.852	
I take additional treatment with consultation of my doctor.	2.95 ± 0.773	
I do my investigations on time as advised by my doctor.	3.18 ± 0.917	

more than 40 years of age were more adherent compared to those who were aged <40 years. This was explained by the authors that they considered the fact that PLHAs were aware of their HIV status in the later stage of their life because of opportunistic infections (OIs) and compromised immunity caused by HIV infection. This was given as be the reason for the concern about their health and better adherence[5].

In contrast to the above studies, a cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between November, 2007 and September, 2009 by Gokarn A, *et al* on univariate analysis, age was significantly associated with adherence. On multivariate analysis, age was significantly associated with adherence. Patients aged equal to or less than 40 years were less adherent than older patients[6].

Sex :

We found no association between gender and MIS-3 patients. The percentage of men was more compared to females in our study but it was not significant as more male were following up to ART Centre compared to females.

The results were similar to a study conducted in a tertiary health facility in cross-sectional study, conducted over a period of 12 months, from July, 2015 to June 2016 by Alvi Y, where gender was not significantly associated with change in adherence[4].

A cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between Nov 2007 and September, 2009 by Gokarn A, *et al* found that sex was not statistically significant with adherence to ART[6].

In contrast a facility based cross-sectional study was carried out Madi, *et al* which revealed that females had higher adherence as compared to males and it was a statistically significant finding (p=0.003)[2].

A facility based cross-sectional study was conducted by Banagi Yathiraj A, *et al* among PLHA attending Infectious Disease Department of the tertiary care hospitals, at Mangalore, Karnataka where sex was found to statistically significant (p=0.002) where it was observed that females were more adherent to ART than were males. This was explained by the authors that many of the female participants were widows and they were living with parents and/or other family members would remind them to take their treatment regularly without fail. The widows who got HIV infection through their husband after witnessing the distress they went through and with the diminishing health conditions of their spouse due to HIV infection[5].

Marital Status :

No association was found between marital status and MIS 3 patients.

A study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y. where Marital status found to be not significantly associated with change in adherence but our study found that people who were widowed had lesser encouragement to follow up to ART Centre after death of their spouse, also the challenges of transport were more among unmarried/widowed females[4].

Similar to the above study, a cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between November, 2007 and September, 2009 by Gokarn A, *et al* found that marital status was not statistically significant with adherence to ART[6].

In contrast to the above, a case series study was conducted at an ART centre attached to a medical

college from June, 1, 2012, to May, 31, 2013 by Hiregoudar V, *et al* where marital status was taken as married, not married, separated/widowed and it was found to be statistically significant where married patients had better adherence than unmarried and separated/widowed (p=0.009) and multivariate regression was carried out the p value was 0.014 which may be explained because of the better support they receive from their spouses[7].

A study was carried out in ART Centre at Government Medical College, Thrissur from the period of 20th March, 2009 and 1st July, 2009 by Ajithkumar K, *et al* where it showed that marital status was not statistically significant (p=0.06) by the method of multivariate regression[8].

Education :

No association was found between education level and MIS-3 status in our study.

A study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June 2016 by Alvi Y. where education was found to be not significantly associated with change in adherence[4].

Similar to the above study, a cross sectional observational study was conducted at the ART centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between November, 2007 and September, 2009 by Gokarn A, *et al* found that education was not statistically significant with adherence to ART[6].

Just like the above study, a case series study was conducted at an ART centre attached to a medical college from June, 1, 2012, to May, 31, 2013 by Hiregoudar V, *et al* where education was found to be statistically significant (p=0.016) where the higher the education meant improvement in adherence of the patient[7].

In contrast to the study conducted by Hiregoudar et al, a study was carried out in ART Centre at Government Medical College, Thrissur from the period of 20th March 2009 and 1st July 2009 by Ajithkumar K *et al* where it showed that education was not statistically significant (p=0.38) by the method of multivariate regression[8].

Socio-economic Status :

A study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y. where Socio-economic status was not found to be significantly associated with change in adherence where higher Socio-economic classes (IV, V) did not lead to higher level of adherence[4].

A cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between November, 2007 and Sept 2009 by Gokarn A, *et al* where employment status and total annual family income was studies and it was found that both the variables were not statistically significant with and being employed or having a higher income did not improve adherence to ART.[6]

Just like the above study, a case series study was conducted at an ART centre attached to a Medical College from June, 1, 2012, to May, 31, 2013 by Hiregoudar V, *et al* where Socio-economic status was not found to be statistically significant (p=0.098) where the higher the Socio-economic status did not mean improvement in adherence of the patient[7].

Similar to the study conducted by Hiregoudar, *et al*, a facility based cross-sectional study was conducted by Banagi Yathiraj A, *et al* among PLHA attending Infectious Disease Department of the tertiary care hospitals, at Mangalore, Karnataka where Socio-economic status was not statistically significant finding[5].

Occupation :

A case series study was conducted at an ART centre attached to a Medical College from June, 1, 2012, to May, 31, 2013 by Hiregoudar V, *et al* where occupation was not found to be statistically significant (p=0.607) where the difference in occupation did not mean a change in adherence[7].

A cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between November, 2007 and September, 2009 by Gokarn A, *et al* where occupation was taken as employed or unemployed and this was not statistically significant[6].

A study done by Molla, *et al* which was an institution based cross-sectional study conducted from May to June, 2015 at the University of Gondar Referral Hospital Chronic HIV Care and Treatment Clinic in Ethiopia where occupation was not statistically significant[9].

Residence :

A case series study was conducted at an ART centre attached to a Medical College from June 1, 2012, to May 31, 2013 by Hiregoudar V, *et al* where occupation was found to be statistically significant (p=0.009) where the rural population had a higher adherence than the urban population[7].

A cross sectional observational study was conducted at the ART Centre (ARTC) in the OPD of a tertiary-care hospital in Aurangabad between

November, 2007 and September, 2009 by Gokarn A, *et al* where residence was taken as rural or urban and this was not statistically significant[6].

A study done by Molla, *et al* which was an institution based cross-sectional study conducted from May, to June, 2015 at the University of Gondar Referral Hospital Chronic HIV Care and Treatment Clinic in Ethiopia where residence was statistically significant where urban population was found to have a higher level of adherence[9].

Pill burden :

Almost 11% participants described high number of pills as a reason for discontinuing ART which is in accordance with a study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y *et al* where pill burden was not found to be significantly associated with change in adherence (p=0.182)[4].

A facility based cross-sectional study was conducted by Banagi Yathiraj A, *et al* among PLHAs attending Infectious Disease Department of the tertiary care hospitals, at Mangalore, Karnataka where pill burden was not statistically significant finding where higher pill burden did not result in poor adherence[5].

Development of Adverse Effects :

A study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y, *et al* where development of adverse effects was found to be significantly associated[4].

Similar to the above study, a facility based cross-sectional study was carried out among 116 People Living with HIV/AIDS (PLHAs) on ART by Madi, *et al* which revealed that development of adverse effects was a statically significant finding (p=0,001)[2].

Similar to the above studies, a case series study was conducted at an ART centre attached to a medical college from June, 1, 2012, to May, 31, 2013 by Hiregoudar V, *et al* where development of adverse effects was found to be statistically significant where non development of adverse effects was found to have better adherence (p<0.005)[7].

In contrast to the above, a study was carried out in ART Centre at Government Medical College, Thrissur from the period of 20th March, 2009 and 1st July, 2009 by Ajithkumar K, *et al* where it showed that development of adverse effects was not statistically significant[8].

Knowledge about ART :

The knowledge of ART was poor among the MIS-3 Patients which could have been a factor for poor adherence although a study conducted in a tertiary health facility as a cross-sectional study, over a period of 12 months, from July, 2015 to June, 2016 by Alvi Y, *et al* where knowledge about ART was not significantly associated[4]. But a case series study was conducted at an ART centre attached to a medical college from June 1, 2012, to May 31, 2013 by Hiregoudar V. et al. where knowledge regarding ART was statistically significant (p<0.005) where better the knowledge, better was the adherence to ART and decreased MIS-3 rate[7].

Attitude :

The bulk of participants often adhered to certain behaviours, such as visiting ARTC as instructed, keeping medications appropriately, taking them on schedule, reporting side effects to ARTC, and scheduling investigations in accordance with doctor's orders.

The majority of participants concur that ART is crucial to their therapy and that it is successful. The majority of them also think that ART will lengthen their lives and enhance their Quality of Life and has a scientific foundation for therapy. But a paucity in knowledge that ART is a life-long treatment exists which has led to them being MIS-3 patients even after having a positive attitude towards ART.

Similar findings were noted by Mihaja, *et al* where only (30 %) were aware about the continuation of ART even after improvement of symptoms which were in accordance to our reasons to stop ART.

Reasons :

Feeling healthy, busy schedule and stigma were the main reasons for stopping of ART in our study which echoed the findings of the study conducted by Bukyenka, *et al* who concluded that feeling healthy, stigma being the main reasons for poor adherence to ART.

Another study by Brretzki J, *et al* found a poor adherence to ART following decrease viral loads which would suggest decreased adherence following decrease in symptoms in addition to complexity of dosing, dissatisfaction with regimen which was also noted in our study.

Conclusion

The launch of the National AIDS and STD Control Programme (NACP) was in 1992 was the beginning of the comprehensive response to the pandemic which after 35 years is still working towards elimination of this disease.

Adherence to ART is mandatory for the treatment and improved quality of life of the patient. Poor

adherence to ART is associated with less effective suppression of the viral load, which risks the health of the patient, but also risks creating permanent drug resistance to that particular agent or group of agents within a given combination therapy regimen.

Knowledge pertaining to various aspects of ART seemed to be an important component in increasing adherence to ART. Similarly a positive Attitude would result in better practices with regards to ART adherence, thus resulting in less MIS patients. Hence an effective communication to all aspects of ART is the way forward to achieve the goal of elimination that we have set.

Funding : Funding was provided by Goa State AIDS Control Society in collaboration with National AIDS Control Organization through proper channel to the extent of One lakh rupees.

Conflict of Interest : Nil

Recommendations :

- **Related to Patient factors:** Linking the patient to an NGO to allow for vocational rehabilitation
- **Related to Health-system related factors:** An effective strategy would be using the vehicle provided to the nearby Primary Health Centre (PHC) to transport ART patients from the PHC to ARTC, Goa Medical College or the nearby link ART centre.

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Case Report

Diagnostic Peritoneal Biopsy in Koch's Abdomen : A Case Report and Review of Literature

Ananth Rupesh Kattamreddy[1], Pravin Panditrao Kalyankar[2], Ravivir Singh Bhalla[3], Nikhil Gupta[4]

Abdominal tuberculosis presents diagnostic challenges due to its subacute and non-specific clinical features. Diagnostic peritoneal biopsy, specifically using laparoscopy, plays a pivotal role in confirming the diagnosis by providing magnified visualization of peritoneal surfaces. A few contraindications to peritoneal biopsy in Koch's abdomen include unstable hemodynamics, bleeding diathesis, uncontrolled ascites and severe abdominal distension. An elevated Adenosine Deaminase (ADA) level suggests a probable diagnosis of tuberculosis, but ascitic fluid culture has limited diagnostic yield. Diagnostic peritoneal biopsy remains the gold standard, providing histopathological confirmation. In cases where biopsy is inconclusive, empirical antitubercular therapy should be considered. Careful evaluation of alternative etiologies is crucial for optimal patient management.

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Key words **: Mycobacterium, Granuloma, Koch's Abdomen, Ascites, TB Peritonitis, Tuberculosis.**

Abdominal Tuberculosis (TB) is a condition that involves the gastrointestinal tract, peritoneum, lymph nodes and/or solid organs. It accounts for approximately 5 percent of all reported TB cases. The peritoneum is a common site for extrapulmonary TB and becomes overtly manifest when the latent tubercular foci get activated due to immense spread from the primary sites of infection in the lung.

Koch's abdomen is often difficult to diagnose due to its subacute nature and non-specific clinical presentation. The routine clinical manifestations of peritoneal TB include ascites, abdominal pain and fever. These symptoms often range over weeks to months before a patient seeks the attention of a physician.

Abdominal TB is diagnosed by various modalities including ascitic fluid analysis, calculating the Serum-ascites Albumin Gradient (SAAG), performing microbiological tests such as mycobacterial culture growth, conducting a peritoneal biopsy, laparoscopy, or mini-laparotomy. More than 90 percent of patients with tuberculous peritonitis have ascites at the time of presentation and a SAAG <1.1 g/dL (in the absence of cirrhosis) is typically observed. An elevated level of Adenosine Deaminase (ADA) activity in the ascitic fluid (≥30 U/L) is also suggestive of TB, especially in cirrhotic patients. However, additional investigations like ascites cytology and imaging studies are recommended given false positives[1,2].

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Editor's Comment :

- Koch's abdomen is challenging to diagnose due to its non-specific symptoms.
- Elevated adenosine deaminase levels in recurrent ascites suggest tuberculosis, with diagnostic peritoneal biopsy being the gold standard.
- Empirical antitubercular therapy should be initiated in TB endemic areas even when the biopsy is inconclusive, after excluding other causes of ascites.

The diagnostic procedures for abdominal Tuberculosis (TB) have limitations, such as low diagnostic yields from Acid-fast Bacilli (AFB) staining and fluid culture. Although radiological abnormalities on Computed Tomography (CT) imaging can differentiate between peritoneal carcinomatosis which typically has more nodules and generalized irregularity from abdominal TB findings, even that is quite nonspecific. As a result, acquiring tissue samples via diagnostic peritoneal biopsy is critical for a more reliable diagnosis, allowing direct evaluation of the afflicted tissue and identification of mycobacteria or other TB-related abnormalities. A diagnostic peritoneal biopsy is critical in verifying the diagnosis of abdominal Tuberculosis[3]. We present a case of Koch's abdomen confirmed with a diagnostic peritoneal biopsy and discuss the advantages of doing one, and contraindications of the procedure with emphasis on recent advances on Abdomen Koch's.

Case Report

A 36-year-old female presented to the Medicine Outpatient Department with a one-month history of progressive abdominal distension, weight loss (8 kg), fever, and generalized weakness. Physical examination revealed fever, non-jaundiced appearance, normal breath sounds and large amounts of non-tense ascites. Initial blood tests were normal, including complete blood count, prothrombin time, and liver enzymes. The Mantoux test for tuberculosis was negative and the chest X-ray appeared

normal. Diagnostic paracentesis showed increased cellularity with predominantly lymphocytes and the serum-to-ascites albumin gradient was less than 1.1, consistent with Tubercular Ascites. However, Acid-fast Bacilli (AFB) stain*, gene Xpert* and AFB cultures of the ascitic fluid were negative. Adenosine Deaminase (ADA) activity was elevated (84 IU/L), further supporting the possibility of tubercular ascites. The patient was started on Anti-tuberculosis Treatment (ATT), (HRZE) and discharged in stable condition with follow-up advice. However, after 23 days on ATT, the patient returned with complaints of recurrent abdominal distention, decreased appetite, nausea and vomiting. Liver enzymes were within normal limits, and further screening for viral hepatitis and HIV was negative. An abdominal and pelvic CT scan revealed omental nodularity and diffuse streakiness. A repeat paracentesis ruled out malignancy but showed high ADA activity. Diagnostic laparoscopy was then performed, revealing multiple small nodules consistent with peritoneal Tuberculosis. Peritoneal biopsies (Figs 1-3) confirmed the presence of granulomas suggestive of tuberculosis, patient was restarted on first-line ATT and responded considerably well.

Discussion

Abdominal Tuberculosis, including tuberculous peritonitis and gastrointestinal tuberculosis (GITB),

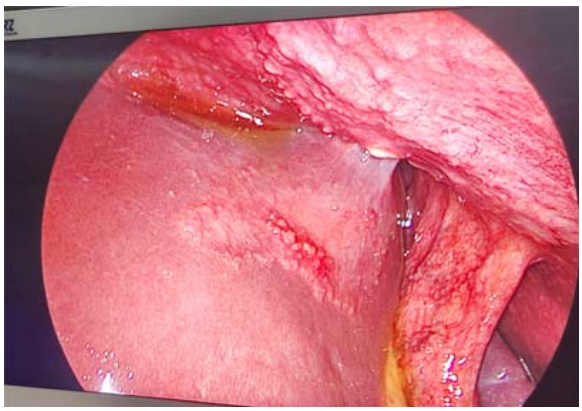

Fig 1 — Peritoneal Surface Showing Multiple Tiny Tubercles

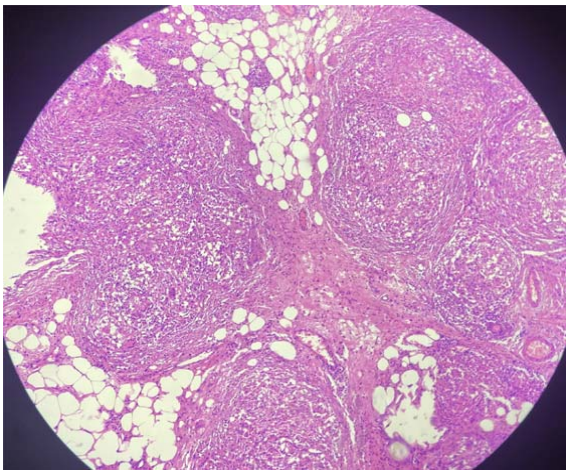

Fig 2 — H&E, Granulomas, Gaint Cells, Epitheloid Cells

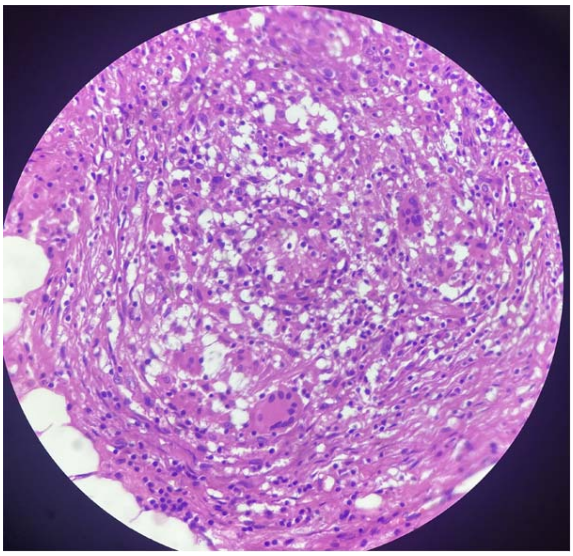

Fig 3 — H&E, Granulomas, Gaint Cells, Epitheloid Cells

presents a complex challenge in diagnosis and treatment despite its historical existence. Alongside the more prevalent forms, such as tuberculous peritonitis and GITB, there are also rarer manifestations affecting the esophagus, gastroduodenal region, pancreas, liver, gallbladder and biliary system. Accurate differentiation from conditions like peritoneal carcinomatosis and Crohn's disease is crucial in clinical practice.

Imaging techniques such as ultrasound, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and occasionally Positron Emission Tomography (PET) play vital roles in evaluating abdominal tuberculosis. Imaging alone is often insufficient for reaching a conclusive diagnosis of tubercular involvement of solid abdominopelvic organs due to the potential for overlapping imaging features with neoplastic and nonneoplastic conditions. Therefore, image-guided tissue sampling is crucial to obtain definitive histopathological confirmation and differentiate tuberculosis from other potential differential diagnoses.Advances in diagnostic research, particularly in imaging and endoscopy, have improved the ability to obtain tissue samples for histological and microbiological analysis[4].

While rapid diagnostic tests like the Xpert Mtb/Rif Polymerase Chain Reaction (PCR) offer quick results, their sensitivity may be limited.Nowadays, Interferon-Gamma Release Assays (IGRAs) are being considered as an important tool for the diagnosis of latent TB infection. In such cases, additional investigations like ascitic adenosine deaminase levels and histological features (eg, granulomas, caseating necrosis, histiocyte-lined ulcers) can enhance diagnostic specificity.

In challenging scenarios where the diagnosis remains uncertain, particularly in regions with high Tuberculosis prevalence, a diagnostic trial of Anti-tubercular Therapy (ATT) may be considered as a last resort after exhausting other diagnostic avenues. Early response assessment can be based on factors like mucosal healing (ulcer

closure within two months) and resolution of ascites. Biomarkers such as faecal calprotectin show promise in detecting intestinal Tuberculosis.

Most forms of abdominal Tuberculosis typically require a six-month course of ATT. However, complications associated with GITB may necessitate interventions such as endoscopic balloon dilatation for intestinal strictures or surgical procedures to manage recurrent intestinal obstruction, perforation, or severe bleeding[1].

In Tuberculosis peritonitis, the worsening of symptoms in some cases can be attributed to a paradoxical reaction, which is a known phenomenon associated with Antitubercular Therapy (ATT) as we noticed in this case (? Paradoxical Reaction? TB immune inflammatory reconstitution syndrome)[5]. The paradoxical reaction occurs when the immune system is boosted after initiating treatment, leading to a temporary exacerbation or recurrence of symptoms. This reaction is believed to be a result of the immune system recognizing residual mycobacterial antigens or inflammatory components in the peritoneal cavity. The approach followed by us in the present case is summarised in Fig 4.

Diagnostic peritoneal biopsy in Koch's abdomen (abdominal Tuberculosis) serves multiple purposes, including diagnostic confirmation in cases of high clinical suspicion but inconclusive other diagnostic tests; differentiation from other conditions such as peritoneal carcinomatosis or peritoneal lymphomatosis; assessment of disease severity to guide treatment and prognosis viz, (mesenteric lymphadenopathy extent, involvement of peritoneal surfaces, etc); identification of drug-resistant strains when there is a lack of response to standard Anti-tubercular Therapy (ATT); evaluation of complications like fibrosis, strictures, or perforation that may require specific interventions or surgical management[6]. Abdominal Tuberculosis should be considered in patients with non-specific abdominal symptoms, unexplained peritoneal thickening on CT scan, and elevated ADA levels. Laparoscopy is highly regarded as the optimal approach for early diagnosis due to its ability to provide magnified visualization of the peritoneal surfaces[7].

A few general contraindications to peritoneal biopsy in Koch's abdomen (abdominal tuberculosis) include unstable hemodynamic status, active bleeding diathesis, uncontrolled ascites, and severe abdominal distension.

Conclusion

In conclusion, while an elevated adenosine deaminase (ADA) level suggests a probable diagnosis of Tuberculosis (TB) in cases of recurrent ascites, it is essential to maintain a clinical suspicion for alternative causes like peritoneal carcinomatosis. The diagnostic yield of ascitic fluid analysis for culture is generally low, and no other less invasive procedure can definitively confirm TB. Diagnostic Peritoneal Biopsy (DPB) remains the gold standard, providing a reliable method for obtaining tissue samples to confirm TB. However, in cases where DPB fails to provide a conclusive diagnosis, a clinical diagnosis of TB should be considered, and empirical Anti-tubercular Therapy (ATT) should be initiated.

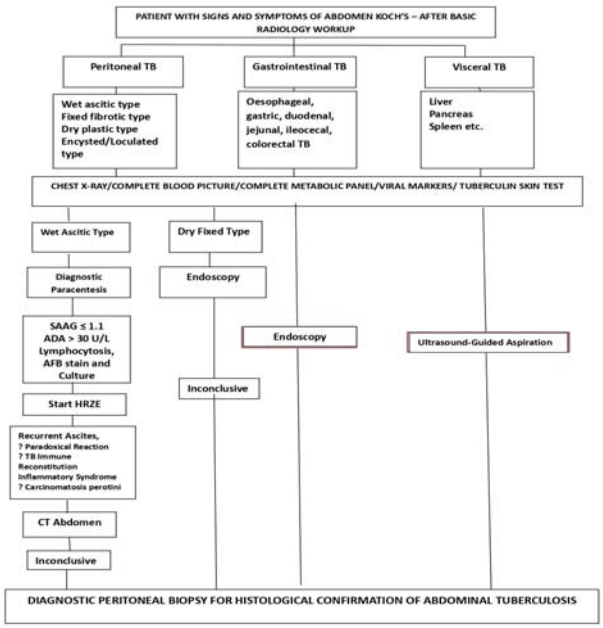

Fig 4 — Diagnostic Workflow in the Present Case

Conflicts of Interest : None to declare.

Ethics and Patient Privacy Issues : Addressed by the authors.

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Letters to the Editor

[The Editor is not responsible for the views expressed by the correspondents]

Urgent Need for Dedicated Clinical Pharmacology Departments and to Address Faculty Shortage in West Bengal

Sir, — We are writing to highlight an urgent issue regarding the current state of clinical pharmacology education in West Bengal. Despite the introduction of DM clinical pharmacology courses at School of Tropical Medicine in 2011 and at R G Kar Medical College in 2023, there is a critical shortage of qualified faculty (with DM clinical pharmacology degree) in the two institutions, as a recent survey reveals. This shortage threatens the quality of education and training of DM students on one hand, and missed the opportunity to optimise patient care in terms of rational medication management on the other, leave alone losing sight the huge potential of utilising this unique subdiscipline (of clinical pharmacology) in shaping drugs and clinical research ecosystem in the state.

The survey finds that currently both at School of Tropical Medicine and at R G Kar Medical College there is only one trained faculty each (with DM degree) which is grossly inadequate in handling the curricular training as per the prescribed norms of National Medical Commission[1]. This precarious state continues while trained faculty (with DM clinical pharmacology degree) with different designations (four professors, three associate professors, one assistant professor) are available in permanent positions in the medical education service (MES) at different medical colleges in the state. Their expert services remain unutilized. We even see illogical transfer of trained faculty from these DM clinical pharmacology training departments without suitable replacement[2]. Thus we witness a collosal waste of useful resources and a blatant demonstration of lack of planning and vision, on the part of the authority concerned.

Clinical pharmacologists in India are highly trained professionals who play a vital role in drug development, drugs and clinical research, medication management and patient safety, and rational use of medicines. They are crucial in optimizing patient care and minimizing medication errors. In optimizing patient care, the implementation of a clinical pharmacological reconciliation, review, and feedback intervention bundle (CPRRF) is proposed. This bundle includes strategies such as evaluating prescribed medicines for redundancy and (un)safety, deprescribing unnecessary and potentially harmful medicines, preventing and managing adverse drug reactions, and improving treatment adherence. These strategies are essential in continuously calibrating the risk-benefit balance for individual patients[3].

It is extremely unfortunate that despite the availability of expert professionals in the MES, dedicated clinical pharmacology departments are yet not established in West Bengal. This contrasts with institutions such as The Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER) Puducherry, Seth Gordhandas Sunderdas Medical College (GSMC) and the King Edward Memorial (KEM) Hospital Mumbai, and Nizam's Institute of Medical Sciences Hyderabad, where dedicated departments are in charge of imparting postdoctoral training, serving patients, and fostering research.

In fine, we draw the attention of the relevant authority in the health department of West Bengal to this matter and plead for urgent redressal to the issue highlighted, in the best interest of the society and science.

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Solve the Mystery of Biochemistry in Every Square

Sir, — Biochemistry, being a subject bridging the basic medical sciences and clinical practice, requires a strong foundation of knowledge.But many students see it as feats of memorization rather than understanding because it involves study of various biomolecules, memorization of their metabolic pathways and so students often consider Biochemistry as a difficult subject.

Didactic lectures are one of the most common method of teaching used in medical curriculum, making students passive listeners. Hence there is a need to develop and adopt some modern pedagogic methodologies in Medical Education to supplement conventional lecture teaching. The use of active learning strategies is recognized as good practice in undergraduate education and is now a widely accepted tool for information delivery and retention[1].

Keeping this in mind, on the occasion of birth anniversary of the father of modern biochemistry "Carl Alexander Newberg", we, the teachers of Biochemistry department had conducted Biochemistry Fun Day, "Let's Decode Biochemistry" for first professional MBBS students. Various activities were conducted on this day like Role play illustrating the importance of biochemical investigations in diagnosing the common clinical conditions like Jaundice and Acute myocardial infarction, Flameless cooking for understanding the importance of nutrition in biochemistry, treasure hunt where the treasures were various diseases and students hunted them using various clues etc.

Crossword Puzzle was one of the interesting activities

conducted on this day.In Biochemistry, games like crossword puzzles can be used as it brings interest and is a welcome variation in the repetitive routine lectures. Soan innovative crossword puzzle was constructed on various important topics like nutrition, biochemical tests for diagnosis of various disorders, diagnosis of various disorders from the given biochemical laboratory reports, identification of techniques used for performing biochemical investigations.The crossword was created with clues given across and down, using crossword maker website. Hints were provided for each question in the form of pictures that relate to the correct answer. The students participated in the activity with great zeal and enthusiasm. Majority of the students were able to solve the entire crossword puzzle within the stipulated time and first three students who were able to solve the puzzle in minimum time were given rewards.Most of the students agreed that the use of the crossword was fun and an innovative method of teaching and learning.

With regard to teaching biochemistry to medical students at the undergraduate level, many new terms and concepts are introduced in a short time frame. The crossword puzzles provide anopportunity to recall essentialconcepts and build critical thinking[2]. The crossword puzzles provide students a unique, innovative and fun filled opportunity to evaluate their own level of learning by identifying concepts that have not been mastered[3-5]. The student's inability to answer a question help them to identify areas of concern or weakness that can be corrected by targeted studying.

Active learning tools like crossword puzzle can used as a complementary aid to traditional teaching for undergraduate medical students to learn biochemistry.

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ALL INDIA MEDICAL CONFERENCE

IMA NATCON

27th & 28th December 2024 | Venue : Hall 4, HITEX Exhibition Centre, Hyderabad

Hosted by IMA HYDERABAD CITY BRANCH under aegis of IMA TELANGANA STATE

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DISCOUNT 1st Jun to 31st Aug 2024	**REGULAR** 1st Sept to 30th Nov. 2024	**LATE** 1st Dec to 15th Dec 2024	**SPOT** 16th Dec 2024 onwards
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5) Medical Exhibition

TSMC CME Credit Hours will be applicable

For any assistance kindly contact : Dr. Dilip Bhanushali - 98480 41402 | Dr. Sanjeev Singh Yadav - 98480 50363 | Dr. Srirang Abkari - 98485 40595

Abstracts for Platform & Poster Presentations to be submitted before 15th Nov. 2024 to drsrirangabkari@gmail.com

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