MEDICAL

NEWSLETTER

BEYOND βETA

APR-JUN 2023

www.pathkindlabs.com

ABOUT PATHKIND

Pathkind was started by the promoters of Mankind Pharma and Mr. Sanjeev Vashishta to provide superior quality diagnostics services accessible to the masses at affordable prices through innovative means. Our National Reference Lab (NRL) is in Gurugram, spread across 40,000 square feet and has state-of-the-art equipment. We started our operations on 11th August 2017 and in a short span of a little over 5 years, Pathkind has set up an impressive network of 88 labs (including 12 NABL (National Accreditation Board for Testing and Calibration Laboratories) Accredited / Certified Labs), 2500+ collection centres, about 5000 pickup points across 26 states, 375 districts and about 1000 cities / towns across India. It has six centres of excellence namely:

- Histopathology and IHC (Immunohistochemistry)
- Molecular Biology and NGS (Next Generation Sequencing)
- Genomics, Cytogenetics and FISH (Fluorescence in Situ Hybridization)
- HLA (Human Leukocyte Antigen) and Transplant Immunology
- Flow Cytometry
- Specialized Chemistry (LCMS / ICPMS)

The company's endeavor is to reach out with its superior quality diagnostics offerings to the masses including tier III/IV cities/ towns. Some of the tests which are being promoted by the company include:

- Newborn Screening Tests (NBS)
- Non Invasive Prenatal Screening (NIPS)
- Phadiatop for Allergy Screening
- Therapeutic drug monitoring with LCMS (Tacrolimus, Sirolimus, Everolimus, Cyclosporine) etc.

We have a very passionate and dedicated team of professionals including the doctors, scientists, technicians and other professionals who are highly skilled and experienced in their respective areas of expertise.

In our newsletter – Beyond Beta, we are going to showcase some of those rare cases which are seen first hand by our specialists and share the best practices of the diagnostic industry with our readers. We hope and wish this will pave the way for a robust academic connect between our pathologists and our esteemed prescribers/clinicians and would help in creating a meaningful engagement platform.

From the Desk of our MD & CEO

Healthcare including diagnostics is a dynamic arena. As we are evolving as a race, so is science. Over the last few years, we have witnessed enormous changes the way diagnostics services are dispensed. These changes are not just limited to the "Analytical" stage where we have seen considerable improvements and enhancements in analysers (Integrated Platforms / Track / Bi-directional Interface / least human intervention), the changes are glaring in "pre and post analytical" stages as well. Technology is being put to use ubiquitously to reach out to the customers, facilitating the sample collection from the comfort of patients' home, monitoring the movement of samples using GPS, ensuring the integrity of the sample is maintained throughout samples journey to the lab by using temperature loggers etc. What we have witnessed so far in terms of technological changes are a mere proverbial "tip of the iceberg". Thanks to Artificial Intelligence, Machine Learning and Deep Learning capabilities, the face of diagnostics industry is poised to be transformed considerably. At one level, many jobs, which are of repetitive nature, are going to become redundant, at another level, technology will augment diagnostics work significantly. The new age diagnostics is going to be far more accurate, faster, affordable, replicable and consistent than the one we are accustomed to.

Clearly if we have to split the modern period into two, it will be best defined as "Pre-Covid" and "Post-Covid"era. The havoc caused by the monstrous virus has been etched deeply in our minds and psyche. People became conscious of their vulnerabilities and have become far more discerning about their health. It was heartening to see how everyone came together irrespective of their religion, colour, creed, nationalities to fight the demon. Our resolve to remain a step ahead of notorious micro-organisms which have the proclivity to threaten the sheer existence of human beings is going to keep us in good stead. Given the need, demand and it's utility, healthcare (and diagnostics) work is going to increase multi-fold and technology is going to play a pivotal role in this.

In consonance with the evolving needs, we at Pathkind are also gearing up to meet and beat the challenges that we expect to come our way. Right from strengthening our I.T. capabilities, all the way up to reinforcing our analytical strengths, we are not leaving any stone unturned. During the past few months we have introduced a few technologies in our National Reference Lab (NRL) including:

- Liquid Chromatography – Mass Spectrometry (LCMS)
- Inductively Coupled Plasma Mass Spectroscopy (ICP-MS)
- Reinforced our capability to detect allergic disorders using Phadiatop by thermofisher.
- Using newer advanced methodologies in the histopathology deptt to provide timely and clinically relevant reports for all specimens.
- HLA typing by reverse sequence specific oligonucleotide probes (r-SSO) on Luminex platform and high resolution typing by NGS.
- Cell based methods of antibody detection such as Complement Dependent Cytotoxicity (CDC) and flowcytometry crossmatch (FCXM) for detection of donor specific antibodies
- Luminex X-map technology for antibody detection
- Panel reactive antibody qualification (PRA-ID) by Phenotype Bead assay and single Antigen Bead assay.

In our pursuit to give the best to our customers, we are working in all earnest towards adopting and absorbing new technologies, processes and intensify the use of AI enabled algorithms and digitization for making more precise, accurate and timely diagnosis.

As we are progressing towards making meaningful diagnostics eco-system, our esteemed customers, who have always reposed tremendous faith and confidence in us would always be our top priority. We shall continue to proactively reach out to all our worthy prescribers, doctors, hospitals, customers and channel / partners with the most novel tests, technologies and methodologies to enable you to advise the best treatment, prognosis and services to your patient and customers. We shall also strive to continue convening topical and meaningful CMEs to share our views & pick your brains / ideas to do better and better.

I take this opportunity to thank you all from the bottom of my heart to support us at all times and for appreciating each and every initiative of Pathkind which is extremely humbling and gratifying for us. I look forward to your continuing guidance, trust and support and wish you and your family a very happy and healthy life.

With kind regards,

Sanjeev Vashishta

Deceased Organ Donation – Time for a Revolution

HLA & Transplant Immunology

Dr Prof. (Col) Mahendra N Mishra

Department of MD (Pathology) FRCP Part 1 (H&I) from Royal College of Pathologists, UK

Organ transplant is the final treatment for any recipient with end stage solid organ disease. According to the Global Observatory on Organ Donation and Transplantation (GODT) data of 2021, in India only 830 deceased renal transplants were performed out of a total of 9105 kidney transplants, thus accounting for only 9.1 % of the total transplants. Tragically only a minuscule of the needy are able to receive the treatment. Many die while waiting, which leads to commerce in organ transplantation. Although India ranks third globally in the number of kidney transplants performed, the number of pancreas, heart and lung transplants is abysmally low - Table 1.

The MOHAN Foundation which is a not-for-profit, non-governmental organization started to promote organ donation in 1997 in Chennai, has made significant inroads in promoting deceased donation and making organ transplants affordable. Unfortunately, much of the deceased donation takes place without doing HLA typing of the deceased donor and without adequate antibody work up of the potential recipients. There is a burning need to have multiple regional centres similar to NHSBT-ODT (UK), Eurotransplant and UNOS (USA) to monitor the sensitization status of all potential recipients and facilitate Virtual Crossmatch. This will provide an impetus to deceased donation and curb unethical practice of illegal donation. The BSHI /BTS guidelines can serve as a reference and may be modified as deemed necessary for our country (2).

In India it is recommended to perform HLA DNA typing for HLA-ABDRB1DQB1 at low / intermediate resolution of all organ recipients and the potential donors along with monitoring of antibody profile of recipients (3). It is legally binding to carry out HLA typing for all related donations to confirm relationship, but many centres do not do HLA typing for unrelated donations.

In this scenario, HLA typing will help in selection of best matched donor where there are multiple donors, and also help to identify donor specific antibodies in future and hence must be carried out at least for young recipients who are likely to require a second transplant in their lifetime.

The Consensus Guidelines on the testing and clinical management issues mandate use of both cell based and solid phase assays for detection and specification of donor specific antibodies (4). Antibody profiling of a recipient can be done by a 2 – step procedure using pooled beads assay followed by phenotype / single antigen bead assay depending on the level of sensitization which has been revolutionised with the availability of Luminex which uses X- Map Technology (Figure 1). If the former is negative, antibody screening is required at quarterly intervals and also following any sensitizing events like transfusions, pregnancies, retransplant and also if there is non-adherence to immunosuppression. Sensitized patients will require more frequent monitoring. Infections are also considered as sensitizing event and positive crossmatch may be observed due to epitope sharing between the microorganism and HLA molecules. This immunogenetic work up will result in optimal donor – recipient matching and promote organ longevity as well as provide a clue to high risk transplants, because all mismatched HLA alleles from previous transplants and high titre donor–specific anti HLA IgG antibodies constitute high risk.

Table 1 Data of major Solid Organ Transplants performed in India and globally in 2021 in absolute numbers and rate per million population

Type and organ donated	India	Global
Deceased Donors	875 (0.65)	39530 (6)
Deceased renal transplants	1164 (0.86)	61,993 (10.45)
Living donor renal transplants	6772 (5)	36028 (6.09)
Deceased liver transplants	631 (0.47)	27,442 (4.64)
Living donor liver transplants	1,313 (0.97)	6,532 (1.1)
Heart transplants	241 (0.18)	8,450 (1.43)
Lung transplants	191 (0.14)	6,481 (1.1)
Pancreas transplants	25 (0.02)	2,368 (0.4)
Small intestine transplants	2 (0)	163 (0.03)

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Fig-1: *Bead based assays performed on the* ***Luminex***^{200} *platform*

Gynecomastia with Coexistent Microfilariasis in FNAC: A rare finding

Dr Saloni Dwivedi

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ABSTRACT

Filariasis is a major endemic problem in India. Filariasis in male patient with gynaecomastia is very rare. Here we report a very unusual finding of gynaecomastia with coexistent microfilaria in 21 year old young male patient. Majority of infected individuals do not show any symptoms for a long period of time.

INTRODUCTION

Filariasis is a major endemic problem in India. The usual sites of filariasis are the lymphatics of the lower limbs, upper limbs, and male genitalia. Extranodal filariasis is very rare. Majority of individuals infected with microfilaria are asymptomatic for long period of time (1). Filariasis of male breast is extremely rare. On extensive search of the published literature, only two case report of filariasis in male breast was found (2,3).

CASE REPORT

21 year male patient presented with diffuse lump in right breast since 3 month. He complained of tenderness in the breast lump. Clinical diagnosis of Gynecomastia was made and Fine Needle Aspiration Cytology was requested. On examination, the swelling measured 2X1.5cm and was tender. The contralateral breast was normal. On FNAC blood mixed material was aspirated. Cytosmears stained with papanicolau and Giemsa were paucicellular with presence of few clusters of benign ductal epitheial cells in a hemorrhagic background. Interestingly, a microfiaria of Wuchereria bancrofti was also noted (Fig.3,4). Detection of microfilaria was an incidental finding. The larva was sheathed with cental column of nuclei. Cephalic and tail end were free of nuclei. Peripheral smear did not show presence of any microfilaria. On the basis of above findings final diagnosis of Gynecomastia with coexistent filariasis was made. Patient was treated with Diethylcarbamazine and on further follow up it was noticed that breast lump reduced in size.

DISCUSSION

Filariasis accounts for 40% of world's disease and is one of the major health problem faced in India. The disease is endemic in India especially in states like Uttar Pradesh, Bihar, Jharkhand, Andhra Pradesh, Orissa, Tamil Nadu, Kerala (1). Lymphatic filariasis is caused by Wucheria bancrofti, Brugia malayi, and Brugia timori. Wucheria bancrofti is more prominent and accounts for more than 90% cases. Gynecomastia with coexistent microfilaria is extremely rare. After extensive search only two case of microfilaria was reported in male breast. FNAC being a simple, cheap and very effective investigation, can be used as a tool for early diagnosis of microfilariae at unusual site. Thorough screening of cytological smears can help in targeted therapy and any undue delay in management (2,3).

CONCLUSION

Microfilaria of breast is very rare. A cytopathologist in endemic area should carefully screen all cytological smears for presence of parasite so that timely diagnosis can direct clinician for definitive treatment and avoid any complication.

Keywords : Gynaecomastia, Microfilaria, Fine Needle Aspiration Cytology.

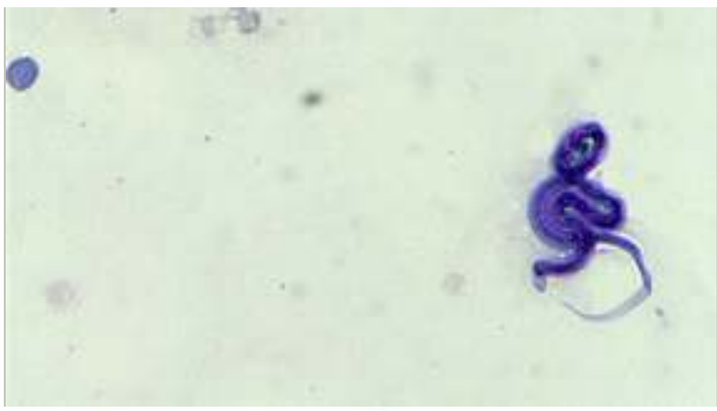

Fig.2

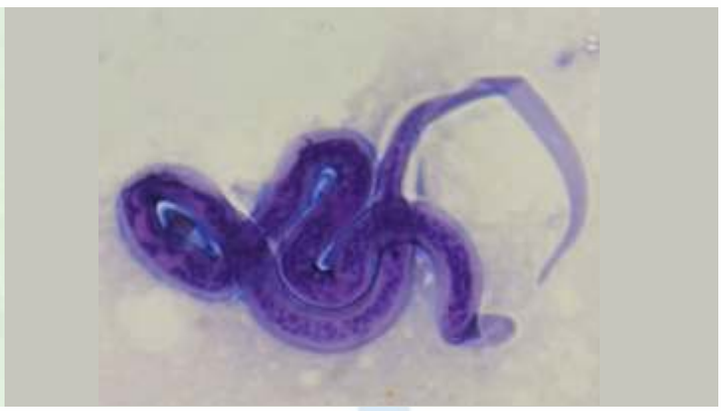

Fig.3

Fig 2 & 3: *FNAC of male breast showing sheathed microfilariae (Wuchereria bancrofti) showing nuclei extending throughout body except tail (10X & 40X respectively)*

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Rare And New Findings:

Inflammatory Bowel Disease By Cryptosporidium

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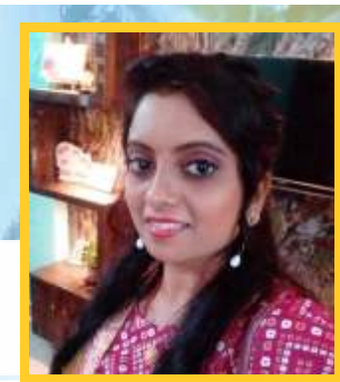

BACKGROUND

Cryptosporidium is a protozoa which can infect both humans and animals. Cryptosporidium parvum (formerly known as C. parvum genotype II) and C. Hominis (Formerly known as C. Parvum Genotype-I) are the leading causes of human cryptosporidiosis. C. Parvum has been implicated in human infections and are commonly associated with cattle. Incubation period can range from 2–10 days. Immunocompetent patients may present with diarrheal illness typically resolving within 2–3 weeks. Immunocompromised patients may have more severe complications, such as life-threatening malabsorption and wasting (1,2,3).

CASE REPORT

A patient had history of colicky abdominal pain since 10 days and increased stool frequency from last 2 months. No history of fever but on per abdominal examination diffuse tenderness and pallor was present. On investigation histopathology report showed active ulcerative colitis. Sigmoidoscopy and CECT Enterography report showed inflammatory bowel disease with ulcerative colitis. Patient was anaemic too with haemoglobin level of 5.7 gm/dl.

DIAGNOSIS

- **Stool microscopy :**

1. By Modified Ziehl – Neelsen Stain:

We saw bright pink stained oocyst of size around 4-5µm which were 5-6 in each oil immersion field and almost equal in size as shown in the figure 4.

2. Stool routine and microscopy: Also found Giardia cyst on microscopy along with Cryptosporidium.

- **Stool culture :** Non enteric pathogen grown

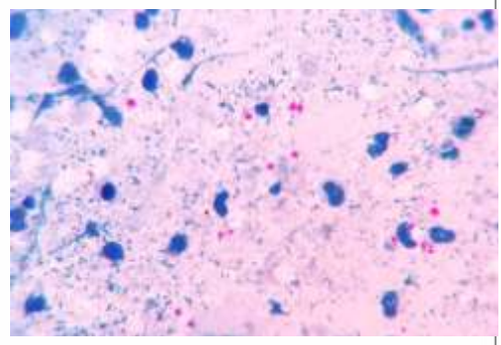

***Fig 4: Stool Microscopy**- By modified ZN stain*

CONCLUSION

As per patient there was history of colicky abdominal pain, increased stool frequency. Patient was anaemic, had pallor and by other investigations like Modified ZN stain and Sigmoidoscopy, it was concluded that it was a case of inflammatory bowel disease caused by Cryptosporidium. Hitherto, at our Varanasi lab, approximately 15 cases of Cryptosporidium have been reported.

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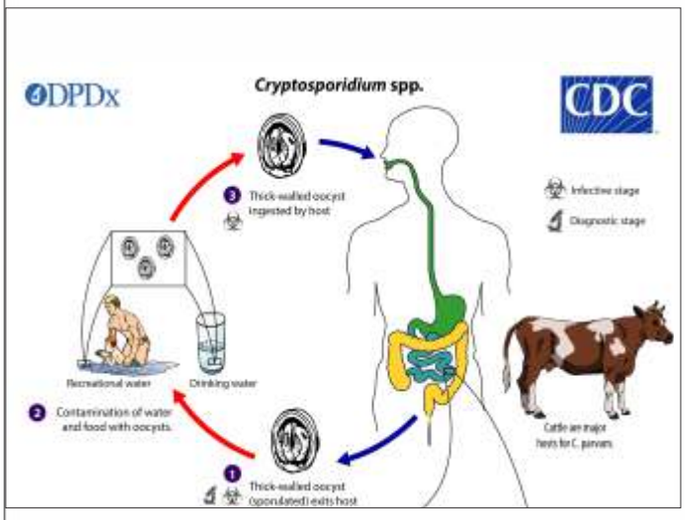


Fig 5: Life cycle of Cryptosporidium spp.

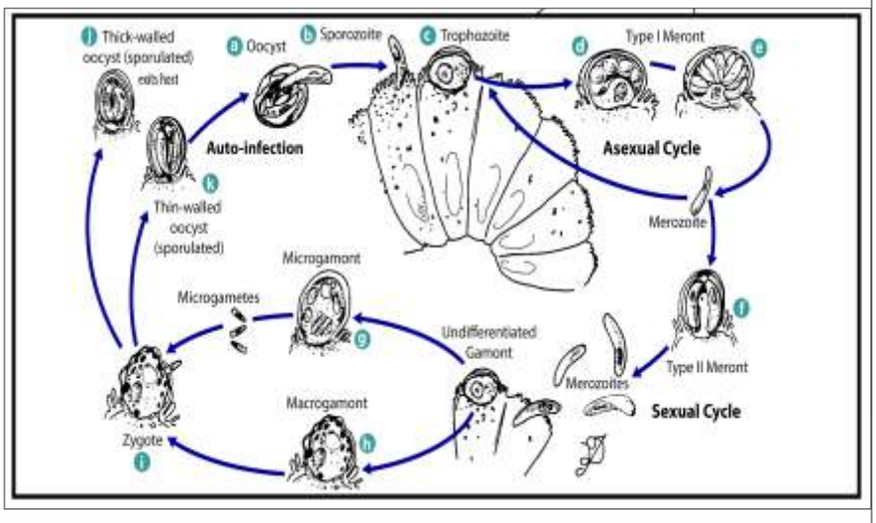
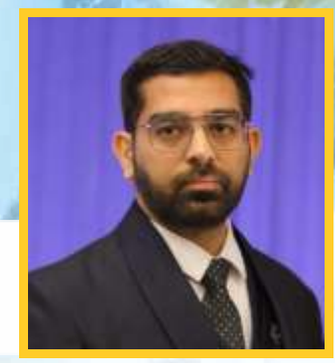


Fig 6: Asexual and sexual life cycle of Cryptosporidium spp.

Role of Quality Assurance in Laboratory diagnostics



Amit Pruthi

AGM- Qualtiy Assurance, Pathkind Labs, Gurugram

Clinical laboratories are the important component of health care system. Apart from supporting the diagnosis and treatment of individual patients, labs also provide health authorities with the statistical data needed to develop, implement and evaluate national health policies. We at Pathkind Diagnostics Pvt Ltd (PDPL) believe in providing accurate reports to our customers at affordable price. This could be achieved by maintaining healthy Quality management system. Universally, Quality department works on 7 principles of Quality Management system i.e

- **Customer focus**
- **Leadership**
- **Engagement with People**
- **Process Approach**
- **Improvement**
- **Evidence-based Decision Making**
- **Relationship Management**

PDPL Quality Assurance (QA) team encompasses a range of activities that enables our lab to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. This will be achieved by dual review of every test results, timely reporting of tests, effective communication with clinical staff and participation in various proficiency programs to assess the accuracy of test results.

The aim of Quality Management System (QMS) of the laboratory is continual improvement in Lab Operations. This could be achieved by continuous monitoring of our Internal Quality Control (IQC) data and by participation in proficiency testing surveys (EQAS).

Quality control must be practical, achievable and affordable. The primary aim of quality control is to do the test reliably. The broad aim of quality control is that the results from one lab should be comparable with that from any lab in the world provided the same method is followed.

QUALITY CONTROL CAN BE IMPLEMENTED IN TWO WAYS

Internal laboratory QC-performed by individual labs at their own levels. It forms the day to day basis working quality assurance. For monitoring of IQC data, we have created Lab wise spread sheets which are accessible to Central QA team, Lab Heads, Lab Team & Lab director. Central QA team is monitoring these sheets on fornightly basis and sharing feedback to lab head for the continuous improvement.

External or inter laboratory QC-performed by many labs at the same time and monitored by the third party. From day one of lab inception central QA team enroll labs in appropriate (National/international) proficiency testing surveys like Biorad, CAP, AIIMS, CMC Vellore etc.

Quality Assurance is now being gradually recognized as an important part of the lab operations and more focused towards producing good quality lab results for the better management of patient care. For the implementation & checking of QMS PDPL is using methods like;

- Conducting Virtual Audits to check implementation of policies & Procedures
- Conducting training through various digital platforms
- Conducting competency assessment of staff through online quizzes

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