"A PROSPECTIVE STUDY ON THE EFFICACY OF CECT ABDOMEN, HISTOPATHOLOGICAL EXAMINATION AND CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST IN PREDICTING ABDOMINAL TUBERCULOSIS" IN GMKMCH, SALEM

DISSERTATION SUBMITTED TO

THE TAMIL NADU DR.MGR MEDICAL UNIVERSITY, TAMILNADU IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SURGERY

IN

GENERAL SURGERY



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DR. N.KAVIYA

ABBREVIATIONS

TB	-	Tuberculosis.
CBNAAT	-	Cartridge based nucleic acid amplification test.
СТ	-	Computed Tomography
CECT	-	Contrast Enhanced Computed Tomography.
MTB/RIF	-	Mycobacterium Tuberculosis/ Rifampicin.
HPE	-	Histopathological examination.
WHO	-	World Health Organisation.
ELISPOT	-	Enzyme linked immune absorbent spot
PCR	-	Polymerase chain reaction
ESR	-	Erythrocyte sedimentation rate
ADA	-	Adenosine de aminase
rt-PCR	-	Reverse transcriptase Polymerase chain reaction
H & E	-	Hematoxylin & eosin
AIDS	-	Acquired immuno deficiency syndrome

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ABSTRACT

Background

Despite continuous and varied efforts, "Tuberculosis has come back with a vengeance in various parts of the world". Multiple investigation techniques were available for the diagnosis of abdominal tuberculosis including ultrasonography, CT abdomen, Capsule endoscopy and enteroscopy, Ultrasound guided Fine needle aspiration, Histopathology, Nucleic acid amplification, Gene Xpert assay etc.

Objective

To compare the efficacy of CECT abdomen, catridge based nucleic acid amplification test and histopathological examination in predicting abdominal tuberculosis.

Methodology

The present study was a prospective observational study carried out in the department of general surgery, Government Mohan Kumaramangalam medical college and hospital located in Salem, Tamilnadu. The study was conducted between 2017 to 2019. All the persons who were admitted into the surgery ward during the study period with clinical diagnosis of abdominal tuberculosis were enrolled into the study. To all the study participants with appropriate indications either CECT abdomen or CBNAAT or both were administered. Histopathological examination were also performed in indicated persons. Diagnosis from all the three modalities were recorded. Sensitivity, specificity, diagnostic accuracy were calculated among those in whom all three modalities were administrated.

Results

The sensitivity of CECT abdomen was found to be 83.3% and the specificity was 66.6%. The diagnostic accuracy was found to be 80.6%. The sensitivity of CBNAAT was found to be 63.3% while the specificity was found to be 83.3%. The diagnostic accuracy of CBNNAT was found to be 66.7%.

Conclusion

CECT abdomen is more a screening tool for abdominal tuberculosis and CBNAAT though can be looked upon as diagnostic tool, the low sensitivity should be scrutinized. Other advantages of CBNAAT like rapidity of testing, decentralization and finding resistance would come to its aid.

Key words

CECT abdomen, CBNAAT, Histopathology, Sensitivity, specificity, Diagnostic accuracy.

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Signature Di Member Secretary Govt. Mohan Kumaramangalam Medical College, SALEM-636 030.

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ABBREVIATIONS

TB	-	Tuberculosis.
CBNAAT	-	Cartridge based nucleic acid amplification test.
СТ	-	Computed Tomography
CECT	-	Contrast Enhanced Computed Tomography.
MTB/RIF	-	Mycobacterium Tuberculosis/ Rifampicin.
HPE	-	Histopathological examination.
WHO	-	World Health Organisation.
ELISPOT	-	Enzyme linked immune absorbent spot
PCR	-	Polymerase chain reaction
ESR	-	Erythrocyte sedimentation rate
ADA	-	Adenosine de aminase
rt-PCR	-	Reverse transcriptase Polymerase chain reaction
H & E	-	Hematoxylin & eosin
AIDS	-	Acquired immuno deficiency syndrome

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ABSTRACT

Background

Despite continuous and varied efforts, "Tuberculosis has come back with a vengeance in various parts of the world". Multiple investigation techniques were available for the diagnosis of abdominal tuberculosis including ultrasonography, CT abdomen, Capsule endoscopy and enteroscopy, Ultrasound guided Fine needle aspiration, Histopathology, Nucleic acid amplification, Gene Xpert assay etc.

Objective

To compare the efficacy of CECT abdomen, catridge based nucleic acid amplification test and histopathological examination in predicting abdominal tuberculosis.

Methodology

The present study was a prospective observational study carried out in the department of general surgery, Government Mohan Kumaramangalam medical college and hospital located in Salem, Tamilnadu. The study was conducted between 2017 to 2019. All the persons who were admitted into the surgery ward during the study period with clinical diagnosis of abdominal tuberculosis were enrolled into the study. To all the study participants with appropriate indications either CECT abdomen or CBNAAT or both were administered. Histopathological examination were also performed in indicated persons. Diagnosis from all the three modalities were recorded. Sensitivity, specificity, diagnostic accuracy were calculated among those in whom all three modalities were administrated.

Results

The sensitivity of CECT abdomen was found to be 83.3% and the specificity was 66.6%. The diagnostic accuracy was found to be 80.6%. The sensitivity of CBNAAT was found to be 63.3% while the specificity was found to be 83.3%. The diagnostic accuracy of CBNNAT was found to be 66.7%.

Conclusion

CECT abdomen is more a screening tool for abdominal tuberculosis and CBNAAT though can be looked upon as diagnostic tool, the low sensitivity should be scrutinized. Other advantages of CBNAAT like rapidity of testing, decentralization and finding resistance would come to its aid.

Key words

CECT abdomen, CBNAAT, Histopathology, Sensitivity, specificity, Diagnostic accuracy.

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Introduction

Tuberculosis is specific infectious disease caused by bacteria from the species Mycobacteria(1). A life threatening disease with an ability to infect any organs or system of the body(2). It is an age-old disease that is known to mankind for many centuries. Autopsy of Louis XIII in the year 1643 has showed not only a large pulmonary cavity but also associated intestinal lesions(3).

Lot of newer interventions for diagnosis and treatment of tuberculosis have been developed in the past 50 years, with an aim to eliminate Tuberculosis. Despite continuous and varied efforts, "Tuberculosis has come back with a vengeance in various parts of the world"(4). It is still a 'global epidemic'(5). World Health Organisation has reported that "nearly one third of the world population is infected by tuberculosis with the highest incidence observed in South-East Asia followed by Western Pacific regions, India, China, Indonesia and Pakistan(6)."

India has the largest tuberculosis burden in the world. World Health Organisation has estimated 2.79 million cases in India alone in the year 2016(7). Though tuberculosis is most commonly an infection of lung parenchyma, they can spread to extra-pulmonary sites during the latent phase of infection(8). Abdominal tuberculosis is the sixth common form of Extra-pulmonary tuberculosis(9).

Patients with abdominal tuberculosis presents with wide variety of symptoms ranging from fever, abdominal pain, weight loss, loss of appetite, diarrhoea, constipation, bleeding per rectum(3). The above constellation of symptoms overlaps with lot of other diseases which makes the diagnosis of abdominal tuberculosis very difficult(10).

Multiple investigation techniques were available for the diagnosis of abdominal tuberculosis including ultrasonography, CT abdomen, Capsule endoscopy and enteroscopy, Ultrasound guided Fine needle aspiration, Histopathology, Ascitic fluid Adenosine Deaminase, Quantiferon-TB (Gold), ASCA (Anti-saccharomyces Cerevisiae antibody), Elispot (T-cell based testing for mycobacterium tuberculosis), Nucleic acid amplification, Gene Xpert assay(3).

Computed tomography is the primary investigation of choice in most places in the scenario of suspected tuberculosis cases. The points in favour of CT are its rapidity, availability and wide coverage with good spatial and temporal resolution(7). Most of the abdominal tuberculosis cases are either missed or diagnosed late, both this late and missed diagnosis contributes to high mortality and morbidity(11)(10). The clinician must have a higher suspicion for the proper diagnosis of abdominal tuberculosis(11). The one another way of diagnosing abdominal tuberculosis is through histopathological examination of the tissues following laparoscopy or laparotomy(3).

World Health Organisation has recommended Xpert MTB/ RIF as the newer replacement for the initial diagnostic modality to be used in case of tuberculosis(12). The above is a cartridge based fully automated PCR test. The intervention was implemented with an objective of decreasing the time of diagnosis and decentralising the diagnosis of resistant mycobacterium. It is looked as one of the novel interventions placed in the path of eradicating mycobacterium tuberculosis. Though many studies have documented the efficacy of Gene Xpert for pulmonary tuberculosis, very few studies have been done with an objective of finding out the efficacy of CBNAAT in extrapulmonary samples.

The present study was done in order to compare the efficacy of CBNAAT and CECT abdomen in diagnosing extrapulmonary tuberculosis taking HPE as a standard test. Similar kind of study have never been undertaken in the study area.

Objectives

To compare the efficacy of CECT abdomen, catridge based nucleic acid amplification test and histopathological examination in predicting abdominal tuberculosis.

Review of literature

Tuberculosis is one of the most important communicable disease worldwide(4). As an ageold disease, the earlier documentation of tuberculosis dates back to the year 1643 in an autopsy done on Louis XIII. The autopsy showed an ulcerative intestinal lesion associated with large pulmonary cavity(3).

The chronic infectious disease is caused by Mycobacterium tuberculosis. World Health organisation has declared Tuberculosis as a "global emergency". Though the organism most commonly affects lungs, Tuberculosis of other organs like intestine, meninges, bones and joints, lymph glands, skin etc., have also been reported in considerable proportions(1).

Estimation states that around 30% of the population is infected with tuberculosis(13). At present tuberculosis is estimated to cause 3 million deaths every year and is increasing in incidence in developed and developing countries(10).

Abdominal Tuberculosis

Abdominal tuberculosis denotes "involvement of the gastrointestinal tract, peritoneum, lymph nodes, and solid viscera, eg, liver,

spleen, pancreas, etc"(14). It constitutes up to 1-3% of the total tuberculosis cases and 12% of the extrapulmonary Tuberculosis cases(10). Bacilli isolated in patients with abdominal tuberculosis were most commonly, Mycobacterium tuberculosis and not Mycobacterium bovis(4).

Pathogenesis

Abdominal tuberculosis is usually followed by invasion of pathogenic mycobacteria. This invasion triggers a damaging granulomatous inflammation. The damage caused includes ulceration, bleeding and perforation(5). John Hunter, a pioneer in surgery described microscopic tubercles in "liver, spleen, uterus, coats of intestine, the peritoneum". He also proposed that the above said tubercles could have initially arisen in the lungs and spread here. The above observation lead to the proper description of ulcers in the intestine and to the word "intestinal phthisis"(3).

The mechanisms by which the tuberculosis organism reaches the gastrointestinal tract include

- "Hematogenous spread from the primary lung focus in childhood along with later reactivation.
- 2. Ingestion of bacilli in sputum from active pulmonary focus.
- 3. Direct spread from adjacent organs.
- 4. Through lymph channels from infected nodes"(14).

The primary focus in the gastrointestinal tract will be established by the haematogenous spread of bacilli from a pulmonary focus. The other way would be a swallowed bacillus leading to infection. These bacilli cross the Peyer's patches of the intestinal mucosa and the macrophages transport them through the lymphatics to the mesenteric lymph nodes. They remain dormant there till the suppression of host defences by conditions such as malnutrition, weight loss, alcoholism, diabetes, chronic renal failure, immunosuppression, AIDS, etc,.(4)

The most common site of involvement was ileocecal region. The frequency of bowel involvement decreases as one proceeds both proximally and distally from the ileocecal region(14). Kapoor V K stated that the most common region will be ileum and ileocecal region followed by colon and the jejunum(4). Malikowski T et al stated that "Areas within the gastrointestinal tract containing high concentrations of lymphoid tissue and M-cells, such as the terminal ileum, are particularly susceptible to invasion(5)."

The above could be attributed to

- a. "increased physiological stasis,
- b. increased rate of fluid and electrolyte absorption,
- c. minimal digestive activity and an abundance of lymphoid tissue at this site"(14).

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Pathology

The gastrointestinal tract is found to be involved in 65% to 78% of Abdominal tuberculosis sufferers. Associated peritoneal and lymph node involvement was also common in these patients(14). Intestinal involvement is reflected by various forms like hypertrophic or mass forming lesions, intestinal ulceration, intestinal strictures(13).

a. Tuberculous granulomas.

They are initially formed in the mucosa or the Peyer's patches. Granulomas are variable in size and tend to confluent. The above is in contrast to Crohn's disease. Granulomas are most commonly seen in the submucosal layer just beneath the ulcer bed. They are usually superficial. They do not penetrate beyond the muscularis. Submucosal oedema or widening is inconspicuous.

Fig 1: H&E stain of TB granuloma with visible TB organism

(arrow)(5)



a. Tubercular ulcer

Tubercular ulcers are relatively superficial and usually do not penetrate beyond the muscularis. They are present either single or multiple, and the intervening mucosa is most probably uninvolved. These ulcers are usually transversely oriented in contrast to Crohn's disease where the ulcers are longitudinal or serpiginous(14).

Three types of intestinal lesions are commonly seen – "ulcerative, stricturous, and hypertrophic". cicatricial healing of the ulcerative lesions results in the formation of strictures. Occlusive arterial changes leads to ischaemia and ultimately lead to the formation of strictures(4).

Fibrosis of the bowel wall could be present in case of long-standing lesions. These fibrosis extends from submucosa into the muscularis. Most commonly histology shows only non-specific chronic inflammation and granulomas will be absent.

Characteristic granulomas will be present in the mesenteric lymph nodes. Mesenteric lymph nodes were reported to be enlarged, matted and sometimes caseated. The changes were most common in patients who have taken antitubercular therapy for some time. The reverse, i.e., the presence of granulomas in the intestine and no granulomas in the draining lymph nodes is rare.

The gross morphological appearance of the involved bowel could be classified into "ulcerative, ulcero-hyperplastic and hyperplastic" varieties. Ulcerative form has been predominant in malnourished adults, while hypertrophic form in relatively well-nourished adults. The bowel wall will be thickened. The serosal surface is studded with nodules of variable size. Lesions of the small intestine will either ulcerative or stricturous. Colonic ileocaecal lesions and are found to be ulcerohypertrophic.

The patient most commonly presents with a right iliac fossa lump comprising of the ileocaecal region, mesenteric fat and lymph nodes. The ileocaecal angle is distorted and often obtuse. Both sides of the ileocaecal

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valve are usually involved leading to incompetence of the valve, another point of distinction from Crohn's disease.

In tuberculous peritonitis, the peritoneum is characterised by multiple yellow-white tubercles. Peritoneum becomes thick and hyperaemic without its shiny lustre(14). Tubercular peritonitis as a result of rupture of mesenteric lymph nodes that initially got the infection through hematogenous spread from primary pulmonary lesion(15). Peritoneal involvement may be of either an ascitic or adhesive (plastic) type(4).

Peritoneal tuberculosis occurs in 3 forms:

- (i) "Wet type with ascites;
- (ii) Encysted (loculated) type with a localized abdominal swelling; and
- (iii) Fibrotic type with abdominal masses composed of mesenteric and omental thickening, with matted bowel loops felt as lump(s) in the abdomen. A combination of these types are also common"(14).

Table 1: Pattern of involvement in gastrointestinal tuberculosis(13).

Peritoneal ✓ Wet-ascitic type ✓ Dry and fibrotic type ✓ Mixed (ascitic and fibrotic) ✓ Tubercular abdominal cocoon (sclerosing) encapsulating peritonitis) Luminal Intestinal Ulcerative Hypertrophic Stricturing **Oesophageal** Gastro-duodenal Lymph-nodal tuberculosis Visceral Hepatic tuberculosis Splenic tuberculosis Pancreatic tuberculosis Gall bladder and biliary tuberculosis

Clinical manifestation of abdominal tuberculosis(13)

Clinical presentation of abdominal tuberculosis were documented to be of three types namely, acute, chronic, acute on chronic(14). Depending on the site of involvement, Abdominal tuberculosis presents with wide variety of symptoms. The constitutional symptoms common to any morphological involvement would be fever, night sweats, loss of weight and loss of appetite(13). Abdominal pain due to tuberculosis could be either colicky or a dull, continuous pain. Colicky pain can be due to luminal compromise while dull, continuous pain can be attributed to the involvement of mesenteric lymph nodes(14).

✓ Intestinal tuberculosis:

Both the ulcerative form and hypertrophic forms of intestinal tuberculosis produces varied symptoms. The ulcerative form presents with chronic diarrhoea and malabsorption, while the hypertrophic and stricturing form presents with abdominal pain and episodes of intestinal obstruction.

In the case of haematochezia, rectal involvement should be looked into. Sometimes intestinal tuberculosis also presents with gastrointestinal perforation and gastrointestinal bleeding.

✓ Oesophageal tuberculosis:

Oesophageal tuberculosis will be involved in only 0.2% of all the abdominal tuberculosis cases making it a rare disease(14).

Most common pathway of spread of tuberculosis will be direct spread from adjacent mediastinal lymph nodes.

Symptomatology of Oesophageal tuberculosis involves dysphagia, odynophagia and hematemesis.

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The most commonly affected site is the middle third of the oesophagus due to proximity to mediastinal lymph nodes(3).

Fig 2 :Reported complications of tuberculous involving the gastrointestinal tract and associated viscera(5).



✓ Gastroduodenal tuberculosis:

This is one of the uncommon sites for tuberculosis to occur. The gastric acid was proposed to have protective effect, thus decreasing the probability of tuberculosis infection in that particular region. The characteristic symptoms of gastroduodenal tuberculosis includes abdominal pain, dyspeptic symptoms, gastric outlet obstruction, failure to thrive (Paediatric age groups), hematemesis.

✓ Peritoneal tuberculosis

Peritoneal tuberculosis has three forms, namely wet, dry and mixed. Wet ascitic pattern presents with abdominal distension, loss of weight, loss of appetite with ascites. The dry form and the mixed forms usually present with abdominal pain, intestinal obstruction.

✓ Hepatic tuberculosis

It occurs in two forms a. military tuberculosis, b. localised involvement.

The clinical features consist of hepatomegaly, deranged liver function test along with constitutional symptoms of tuberculosis.

✓ Pancreatic tuberculosis

Pancreatic tuberculosis characterised by abdominal pain, fever, loss of weight, loss of appetite, jaundice, biliary obstruction, abdominal lump etc.,

Site	Туре	Clinical Features
Small Intestine	Ulcerative	Diarrhoea Malabsorption
	Strictures	obstruction
Large intestine	Ulcerative	Rectal bleeding
	Hypertrophic	Lump Obstruction
Peritoneal	Ascitic	Pain Distension
	Adhesive	Obstruction
Lymph nodes		Lump Obstruction

Table 2 : Site of infection and corresponding clinical features.

Clinical profile from various studies

Aghrahari S et al in their study described the clinical profile of patients with abdominal tuberculosis in rural North India. They reported that the disease was common in both the sexes. The commonest symptom was abdominal pain (93%), followed by weight loss (83%), anorexia (68%). Ascites was reported to be the most common sign. The other signs included were lymphadenopathy, abdominal distension and abdominal tenderness(6).

Uzunkoy A et al reported that fever was the most common symptom. While dealing with differential diagnosis, positive family history of tuberculosis should increase the probability of diagnosis in favour to abdominal tuberculosis.

Muneef et al reported that women were more affected than male. Fever, abdominal pain and weight loss were the most common symptoms. He also reported that "symptoms in tuberculosis patients persisted for several weeks before diagnosis". Abdominal swelling due to ascites was the most common presentation. Anaemia, Raised ESR and hypoalbuminemia were present biochemically(11).

Symptoms	Mukewar et al	Makharia et al	Khan et al
Abdominal Pain	80.6%	90.5%	93%
Weight Loss	74.6%	83%	47%
Loss of appetite	62.7%	69.8%	52%
Fever	40.3%	41.5%	64%
Diarrhoea	16.4%	37.7%	12%
Constipation	25%	49%	31%
Bleeding per	11.9%	16.9%	14%
rectum			

Table 3: Distribution of symptoms of intestinal tuberculosis in various studies(16)(17)(18).

Diagnosis of abdominal tuberculosis

In the past decade, the amount of strides in tuberculosis control was momentous. Still a problem remained and that is the misdiagnosis of tuberculosis cases. The misdiagnosis contributed to both magnitude of severity of cases and new incident cases(19). Laparoscopy followed by direct biopsy is the most common diagnostic method for abdominal tuberculosis(11)(10).

Table 4: Findings that should increase suspicion of abdominal tuberculosi
infection(5).

Peritoneal	Ascitic fluid analysis showing protein ≥ 2.5 g/dL, SAAG < 1.1 g/dL, elevated ADA > 30 U/L, and lymphocytic predominance CT findings of ascites, thickened hypervascular peritoneal membrane, with scattered nodular lesions
Small bowel	Endoscopic finding of transversly oriented circumferential ulcerations CT finding of mesenteric lymphadenopathy with hypodense centers
Hepatobiliary	Liver function test abnormalities with unexplained hepatomegaly
Esophageal	Endoscopic finding of ulcerations in the mid esophagus with medistinal lymphadenopathy
Gastroduodenal	Unexplained gastric outlet obstruction Non-healing gastric ulceration
Colorectal	Unexplained spontaneous colonic perforation
Pancreas	CT finding of an inflammatory pancreatic mass lesion

A wide variety of diagnostic modality are available for the diagnosis of abdominal tuberculosis. The tools are listed as follows(3)

a. Ultrasonography.

- b. CT abdomen.
- c. CECT abdomen.
- d. Capsule endoscopy and enteroscopy.
- e. USG guided Fine Needle Aspiration.
- f. Histopathology.
- g. Ascitic fluid ADA.
- h. Quantiferon TB (Gold).
- i. ASCA (Anti-saccharomyces cerevisiae antibody)
- j. ELISPOT.
- k. Nucleic acid amplification (CBNAAT).
- 1. Gene Xpert assay.

We will look into some selected modalities below

Ultrasonography

Most useful tool in case of peritoneal tuberculosis.

The features include

- Intra-abdominal fluid will be either free or loculated, clear or complex. The collection of the fluid in the pelvic region sometimes mimic ovarian cyst. The above said collection may sometimes present with thick septa.
- 2. Club sandwich or sliced bread appearance sometimes present due to exudates from the affected segment of the bowel.

- Lymphadenopathy will be present. They can be either discrete or matted.
- A uniform and concentric bowel wall thickening could be present in the ileocecal region.
- 5. Pseudo-kidney sign may be positive.

Computed Tomography (CT) abdomen:

CT abdomen is helpful in assessing intraluminal, extraluminal lesion and extent of the disease in case of abdominal tuberculosis(3).

Epstein BM and Mann JH indicated in their case series a series of findings highly suggestive of abdominal tuberculosis. These included

"1. High density ascites

- 2. Irregular soft tissue densities in the omental area
- 3. Low-density masses surrounded by thick solid rims

4. A disorganised appearance of soft-tissue densities, fluid and bowel loops forming a poorly defined mass.

5. A low density lymph node with a multilocular appearance after intravenous contrast administration"(15).

Hulnick DH et al reported that no CT finding alone or in combination are pathognomic of tuberculosis. The most common manifestation of abdominal tuberculosis in CT scan was abdominal lymphadenopathy. The notable feature in lymphatic adenopathy is the involvement of mesenteric and peripancreatic nodes which either accompany or overshadow the involvement of retroperitoneal nodes.

Sometimes as a rare complication, lymphnode enlargement cause obstructive jaundice due to adenopathy in the porta hepatis, hepatoduodenal ligament and peripancreatic areas. Illiac, lumbar and lower abdominal lymphnodes are always sparsely involved. Caseation necrosis within the lymphnodes will be seen as low-density area, a notable characteristic feature of tuberculous adenopathy.

A high-density ascites shall increase the probability of tuberculous peritonitis, similarly a low density ascites shall not entirely rule out tuberculous peritonitis. Some added features can be tubo-ovarian abscess, adenopathy, peritoneal enhancement, dirty appearance of mesentry. Hepatic involvement will be diffuse, macronodular form or pseudotumor form. Splenomegaly and hepatomegaly can be present(20).

The other findings includes concentric mural thickening of the ileocecal region with or without proximal intestinal dilatation. The differential diagnosis for Abdominal tuberculosis includes crohn's disease, lymphoma and carcinoma.

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Fig 3: Computed tomography of abdomen shows peritoneal and bowel wall thickening in tuberculous enteritis (21).



Fig: 4 Tuberculous Peritonitis(22).



CT scan shows a large amount of ascites with even peritoneal thickening (arrowhead) and diffuse omental infiltration (arrow) without associated lymphadenopathy.

Capsule endoscopy and enteroscopy

Capsule endoscopy contains a capsule of size 26*11 mm. Within the capsule is located a battery powered complementary metal oxide silicon imager (CMOS), a transmitter, antenna and four light emitting diodes. When the capsule is removed from its magnetic holder the imager gets activated. The imager is capable of taking two images per second. Once

swallowed, peristalsis aids in the movement of the capsule through the intestine(23).

The data available regarding the utility of capsule endoscopy in the diagnosis of intestinal tuberculosis is very limited. Under a capsule endoscopy and enteroscopy the intestinal ulcers were document to be multiple, scattered, shallow, short, oblique or transverse mucosal ulcers with necrotic base in jejunum or ileum(3).

Colonoscopy

Colonoscopy is seen as important diagnostic tool when it comes to differentiate between tuberculosis abdomen and crohn's disease. The most common site of occurrence for both the diseases was ileo-caecal junction. There are certain characteristic features which differentiate between the two. Firstly, the ulcers will be circumferential surrounded by inflamed mucosa in case of TB abdomen. Secondly, features like patulous valve with heaped up folds around it or destroyed valve mimicking fish mouth opening are more a characteristic of tuberculosis than that of crohn's disease(3).

Serological tests

"Serological tests refer to blood tests that detect the humoral immune responses to Mycobacterium tuberculosis antigens" Advantages(19)

- 1. "The results would be available within few hours.
- A serological test, if developed into point of care technique and extended to lower level of health service. The test will have the potential to replace microscopy.
- 3. Blood test becomes more practical in those conditions where sputum is difficult to obtain".

Genotypic Method – CBNAAT and GeneXpert MTB/RIF

CBNAAT is a semi quantitative nested real time PCR in-vitro diagnostic tests. World Health Organisation has introduced the above test and has published blue prints for decentralizing the above test, globally. In addition to the diagnosis of Mycobacterium tuberculosis present in sputum or other specimens, the test also aids in the identification of Rifampicin resistance associated mutations of the rpo B gene. The test has the potential to become one rapid, feasible, affordable and when decentralized the "near point of care" diagnostic tool. The tool that is the answer for some of the barriers in tuberculosis diagnosis(24). GeneXpert is constructed based on the principles of Polymerase Chain Reaction and will act as a rapid and simple to use Nucleic acid amplification test (NAAT)(1).

Standard Assay Procedure of NAA assays:

Single use plastic cartridges with multiple chambers are utilized by the assay. These chambers are loaded in advance with liquid buffers and lyophilized reagent beads. These are essential for sample processing, DNA extraction and heminested rt-PCR. Sodium hydroxide and isopropanol containing sample reagent will be used to treat clinical samples. The above will be incubated at room temperature for a period of 15 mins. Manually the above sample is then transferred to the cartridge loaded into the CBNAAT instrument.

From here on the process will be fully automated. Mycobacterium bacilli will be liberated from the clinical sample. These liberated bacilli pass through the syringe drive. Followed by the syringe drive, it crosses the rotary drive and ultimately gets deposited to the filter. At the cartridge base is located a sonic horn. He sonic horn is responsible for "ultrasonic lysis" of the bacilli and due to the ultrasonic lysis genetic material will be released. These released genetic material is then amplified by the heminested rt-PCR. The portion of gene which gets amplified is the 192bp segment of the rpo B gene. MTB will finally be detected by 5 overlapping molecular probes. These probes are complimentary to the entire 81bp rpo B core region. MTB is said to be positive when two out of the five probes give a positive signal(24).

Fig:5 CBNAAT machine.





Comparison of diagnostic accuracy between various diagnostic modalities in case of extrapulmonary tuberculosis.

Pai M et al. Pai M et al did a meta-analysis with an objective of finding out overall accuracy of nucleic acid amplification tests in diagnosing tubercular meningitis. The study reported the sensitivity of NAA to be 56% and specificity to be 98%. The study concluded NAA to have a significant role to play in the diagnosis of tubercular meningitis as reflected by the specificity, But the lack of sensitivity means a negative test must be scrutinised further with more care(25). Scott LE et al reported that the sensitivity using ascitic fluid in NAA assay was 51% which was similar to the present study(26).

Another Meta-analysis by Denkinger CM et al also reported a very high specificity for NAA assays for both pulmonary and extrapulmonary samples. The study also has documented a variable sensitivity for variable samples ranging from 21.4% to 81.3%. The lowest being for pleural fluid and highest for lymph node tissue(27).

Penz et al in his meta-analysis with an objective of finding out the diagnostic accuracy of NAA assays for extrapulmonary tuberculosis reported the pooled sensitivity to be 77% and pooled specificity to be 97%.

Causse M in her study also reported a similar pattern of higher specificity in their study(28). In contrast to the present study Bahr NC et al

reported a higher sensitivity among NAA assays(12). Lawn S D also reported a pooled sensitivity of 80% and pooled specificity of 90%(29).

METHODOLOGY

The present study was a prospective observational study carried out in the department of general surgery, Government Mohan Kumaramangalam medical college and hospital located in Salem Tamilnadu. The objective of the study was to compare between three diagnostic modalities of abdominal tuberculosis CECT abdomen, CBNAAT and Histopathological examination. All the persons who are admitted into the surgery ward during the study period with clinical diagnosis of abdominal tuberculosis was taken as study participants. The study was conducted between 2017 to 2019.

The inclusion criteria for the study consisted of patients with low grade fever, malaise, night sweats, anaemia and weight loss. Patient with chronic abdominal pain, lower gastrointestinal bleed, fistula in ano, intestinal obstruction, intestinal perforation and mass abdomen were also included into the study. Patients with Crohn's disease, appendicular mass, psoas abscess, retroperitoneal tumour, comorbid systemic conditions like diabetes mellitus, malignancies, long term steroid therapy etc., were excluded from being study participants.

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Informed consent was obtained from all the 50 participants who were all selected for the study. The data for the study was collected using a pre-tested semi-structured questionnaire. The questionnaire collected data on all characteristics including the sociodemographic characteristics like name, age, sex, education, occupation, symptoms and signs with which the patient has been admitted in to the hospital, vital signs at the time of admission to the hospital. Selected biochemical parameters measured like haemoglobin levels and ESR were also been collected.

The outcome of selected diagnostic procedures like CT, CECT and CBNAAT were recorded only when these techniques were employed for the diagnostic process. The appropriate specimen for CBNAAT will be collected and was duly sent to the laboratory and the results were recorded into the questionnaire. Tissue for histopathological examination was sought for in those case where laparotomy, laparoscopy, colonoscopy were planned for. The specimens were sent to the department of pathology for histopathological examination and the final results of the HPE was also recorded.

Statistical analysis:

All the data collected was entered into excel spread sheet. The data was then imported into SPSS software version 23. Descriptive statistics like proportions and percentages were employed for describing the
qualitative data and whenever quantitative data was encountered, they were expressed using mean and standard deviation.

For comparing the diagnostic accuracy of the tests, the results were obtained after obtaining the distribution into medcalc's diagnostic test evaluation calculator. The results consisted of sensitivity, specificity, predictive values and diagnostic accuracy.

In order to find out the agreement in diagnosis between two modalities kappa statistics were employed. A p value of less than 0.05 was taken as statistically significant result. Fig: 6a, 6b, 6c CECT scan showing multiple enlarged conglomerate lymph nodal masses with areas of central necrosis largest measuring 7.6x4.2 cms.



Fig: 6a







Fig: 6c



Fig:7a Low power view showing cluster of epitheliod cells & lymphocytes



Fig:7b Scanner view showing caseous necrosis

Fig 8a, 8b, 8c Intraoperative pictures showing multiple





Fig:8a



Fig:8b



Fig:8c

Results

	T٤	ıb	le	5:	Dist	rib	ution	l of	stu	dy	partici	pants	accordin	g to) age
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Age	Frequency	Percentage
21-30	11	22
31-40	12	24
41-50	8	16
51-60	15	30
>60	4	8
Total	50	100

Chart 1: Bar chart showing age distribution between the study participants.



30% of the study participants were in the age group of 51-60 years.

Sex	Frequency	Percentage
Male	30	60
Female	20	40
Total	50	100

Table 6: Distribution of study participants according to sex.

Chart 2: Distribution of study participants according to sex.



60% of the study participants were males.

Education	Frequency	Percentage
Illiterate	9	18
Primary	7	14
Middle	5	10
Secondary	3	6
Higher secondary	11	22
Technical education	5	10
Undergraduate	8	16
Postgraduate	2	4
Total	50	100

Table 7: Distribution of study participants according to education.





22% had finished up to higher secondary education and 18% were illiterates.

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Education	Frequency	Percentage
Skilled	6	12
Semi-skilled	16	32
Unskilled	28	56
Total	50	100

Table 8: Distribution of study participants according to occupation.

Chart 4: Distribution of study participants according to occupation.



56% were doing unskilled occupation.

Abdominal Pain	Frequency	Percentage
Present	43	86
Absent	7	14
Total	50	100

Table 9: Distribution according to the symptoms abdominal pain.

Chart 5: Distribution according to abdominal pain.



86% reported that they suffered from abdominal pain.

Weight loss	Frequency	Percentage
Present	35	70
Absent	15	30
Total	50	100

Table 10: Distribution According to complaint of weight loss.

Chart 6: Distribution according to weight loss.



70% of the study participants reported weight loss.

Fever	Frequency	Percentage
Present	13	26
Absent	37	74
Total	50	100

Table 11: Distribution according to complaint of fever.

Chart 7: Distribution according to the complaints of fever.



26% reported that they had fever.

Table 12: Distribution according to complaint of diarrhoea.

Diarrhoea	Frequency	Percentage
Present	5	10
Absent	45	90
Total	50	100

10% Present Absent

Chart 8: Distribution according to complaint of diarrhoea.

10% of the study participants reported that they suffered from diarrhoea.

Constipation	Frequency	Percentage
Present	16	32
Absent	34	68
Total	50	100

Table 13: Distribution according to complaint of constipation.

Chart 9: Distribution according to complaint of constipation.



32% of the study participants reported that they had constipation.

Bleeding per rectum	Frequency	Percentage
Present	11	22
Absent	39	78
Total	50	100

Table 14: Distribution according to complaint of bleeding per rectum.

Chart 10: Distribution according to bleeding per rectum.



22% reported that they had bleeding per rectum.

Vomiting	Frequency	Percentage
Present	7	14
Absent	43	86
Total	50	100

Table 15: Distribution according to complaint of vomiting.

Chart 11: Distribution according to complaint of vomiting.



14% of the study participants complained vomiting.

Table 16: Distribution according to pallor.

Pallor	Frequency	Percentage
Present	24	48
Absent	26	52
Total	50	100

Chart 12: Distribution according to pallor.



48% of the study participants had pallor.

Table 17: Distribution according to lymphadenopathy.

Lymphadenopathy	Frequency	Percentage
Present	19	38
Absent	31	62
Total	50	100

Chart 13: Distribution according to lymphadenopathy.



38% of the study participants had lymphadenopathy.

Abdominal distension	Frequency	Percentage
Present	17	34
Absent	33	66
Total	50	100

Table 18: Distribution according to abdominal distension.

Chart 14: Distribution according to abdominal distension.



34% had abdominal distension.

Table 19: Distribution according to presence of fluid thrill.

Fluid thrill	Frequency	Percentage
Present	8	16
Absent	42	84
Total	50	100

Chart 15: Distribution according to presence of fluid thrill.



Fluid thrill was elicited in 16% of study participants.

Table 20: Distribution according to presence of shifting dullness.

Shifting dullness	Frequency	Percentage
Present	8	16
Absent	42	84
Total	50	100

Chart 16: Distribution according to presence of shifting dullness



Shifting dullness was present in 15% of the study participants.

Table 21: Distribution according to the presence of abdominal lump.

Abdominal lump	Frequency	Percentage
Present	12	24
Absent	38	76
Total	50	100

Chart 17: Distribution according to the presence of abdominal lump.



24% had abdominal lump.

Table 22: Mean blood pressure and pulse rate of the study

participants.

Variable	Mean	Standard deviation
Systolic blood pressure	123.88 mmHg	11.70 mmHg
Diastolic blood pressure	77.32 mmHg	8.20 mmHg
Pulse rate	78.4 bpm	4.8 bpm

Chart 18: Whisker box plot showing Mean blood pressure and pulse rate of the study participants



The mean systolic blood pressure was 123.88 (112 - 134) mmHgThe mean diastolic blood pressure was 77.32 (69 - 85) mmHg. The mean pulse rate was 78.4 (74-82) bpm.

Table 23: Mean haemoglobin levels of the study participants.

Variable	Mean	Standard deviation
Haemoglobin (mg/dl)	8.73	1.11

Chart 19: Whisker box plot for haemoglobin.



The mean haemoglobin level was 8.73 (7-9) mg/dl.

 Table 24: Mean ESR levels of the study participants.

Variable	Mean	Standard deviation
ESR mm/hr	48.73	12.17

Chart 20: Whisker box plot for ESR.



The mean ESR was 48.7 (36.6-60.0) mm/hr.

Table 25: Mean SGOT, SGPT levels of the study participants.

Variable	Mean	Standard deviation
SGOT u/l	49.25	9.33
SGPT u/l	44.18	7.65

Chart 21: whisker box plot for SGOT, SGPT.



The mean SGOT levels were 49.25 (39.7-58.5) u/l. The mean SGPT levels were 44.18 (36.8-51.7) u/l

Table 26: Distribution according to findings of CT abdomen.

CT findings	Frequency	Percentage
Ileocecal thickening with enlarged lymph nodes	15	30
Conglomerate bowel loops	5	10
Matted bowel loops	7	14
Multiple enlarged lymphadenopathy	7	14
Omental thickening with enlarged lymph nodes	7	14

Chart 22: Distribution according to findings of CT abdomen.



30% had ileocecal thickening with enlarged lymphnodes.

Table 27: Distribution of study participants according to diagnosis with CT abdomen.

Abdominal tuberculosis	Frequency	Percentage
Present	32	64
Absent	18	36
Total	50	100

Chart 23: Distribution of study participants according to diagnosis with CT abdomen.



According to CT abdomen, 64% of the study participants were diagnosed to have abdominal tuberculosis.

Table 28: Distribution of study participants according to diagnosiswith CECT abdomen.

Abdominal tuberculosis	Frequency	Percentage
Present	27	54
Absent	16	32
Not done	7	14

Chart 24: Distribution of study participants according to diagnosis with CECT abdomen.



According to CECT abdomen, 54% of the study participants suffered from abdominal tuberculosis.

Table 29: Distribution of study participants according to diagnosiswith CBNAAT abdomen.

Abdominal tuberculosis	Frequency	Percentage
Present	27	54
Absent	23	46
Total	50	100

Chart 25: Distribution of study participants according to diagnosis with CBNAAT abdomen.



According to CBNAAT, 54% of the study participants suffered from abdominal tuberculosis.

Table 30: Distribution of study participants according to diagnosiswith Histopathological examination.

Abdominal tuberculosis	Frequency	Percentage
Present	30	60
Absent	13	26
Not done	7	14
Total	50	100

Chart 26: Distribution of study participants according to diagnosis with Histopathological examination.



60% of the study participants were diagnosed to have abdominal tuberculosis via histopathological examination.

Table 31: Cross tabulation between CECT and histopathological examination findings.

CECT	HPE-positive		HPE-negative	
	Ν	%	Ν	%
Positive	25	92.6	2	7.4
Negative	5	55.6	4	44.4
Total	30	83.3	6	16.7

Chart 27: Cross tabulation between CECT and histopathological examination findings.



25 study participants were diagnosed by both HPE and CECT to have abdominal tuberculosis.

Table 32: Cross tabulation between CBNAAT and histopathological examination findings.

CBNAAT	HPE-p	HPE-positive		HPE-negative	
	Ν	%	Ν	%	
Positive	19	95	1	5	
Negative	11	68.8	5	31.3	
Total	30	83.3	6	16.7	

Chart 28: Cross tabulation between CBNAAT and histopathological examination findings.



19 study participants were diagnosed by both CBNAAT and HPE to have abdominal tuberculosis.

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		Value	Asymptotic Standardized Error ^a	Approximat e T ^b	Approximate Significance
Measure of Agreement	Kappa	.417	.179	2.582	.010
No of valid cases	n	36			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Both CECT and HPE were found to have statistically significant agreement in diagnosing abdominal tuberculosis.

Table 34: Measure of agreement between CBNAAT and HPE.

		Value	Asymptotic Standardized Error ^a	Approxim ate T ^b	Approximate Significance
Measure of Agreement	Kappa	.280	.134	2.100	.036
No of valid cases	n	36			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Both CBNAAT and HPE were found to have statistically significant agreement in diagnosing abdominal tuberculosis.

Table 35: Diagnostic accuracy of CECT.

Statistic	Formula	Value	95% CI
Sensitivity	$rac{a}{a+b}$	83.33%	65.28% to 94.36%
Specificity	$rac{d}{c+d}$	66.67 %	22.28% to 95.67%
Positive Predictive Value	$\frac{a}{a+c}$	92.59% (*)	79.95% to 97.51%
Negative Predictive Value	$rac{d}{b+d}$	44.44 % (*)	23.09% to 68.07%
Accuracy	$\frac{a+d}{a+b+c+d}$	80.56% (*)	63.98% to 91.81%

The sensitivity of CECT abdomen was found to be 83.3% and the specificity was 66.6%. The diagnostic accuracy was found to be 80.6%.
Statistic	Formula	Value	95% CI
Sensitivity	$\frac{a}{a+b}$	63.33%	43.86% to 80.07%
Specificity	$rac{d}{c+d}$	83.33 %	35.88% to 99.58%
Positive Predictive Value	$\frac{a}{a+c}$	95.00% (*)	75.67% to 99.15%
Negative Predictive Value	$rac{d}{b+d}$	31.25 % (*)	20.11% to 45.08%
Accuracy	$\frac{a+d}{a+b+c+d}$	66.67% (*)	49.03% to 81.44%

Table 36: Diagnostic accuracy of CBNAAT.

The sensitivity of CBNAAT was found to be 63.3% while the specificity was found to be 83.3%. The diagnostic accuracy of CBNNAT was found to be 66.7%

Discussion

The present study was a prospective follow up study were three diagnostic modalities for abdominal tuberculosis, namely CECT abdomen, CBNAAT and histopathological examination were compared to find out their diagnostic efficacy. The study was carried out in the department of General Mohan general surgery of surgery, Government Kumaramangalam Medical College, Salem, a tertiary care institute. The study was conducted 2017 to 2019. During the study period 50 cases that had clinical features suggestive of abdominal tuberculosis and also fulfilled the inclusion criteria were enrolled into the study. A pretested semistructured proforma was used as study tool in order to collect data from the study participants.

Socio-demographic characteristics of the study participants.

30% of the study participants were in the age group of 51-60 years. 60% of the study participants were males and 40% of the study participants were females. 22% had finished up to higher secondary education and 18% were illiterates. 56% were doing unskilled occupation.

Clinical profile among the study participants

a. Pattern of symptoms among the study participants

Out of the enrolled study participants, 86% reported that they suffered from abdominal pain followed by 70% of the study participants reported that they had weight loss. 32% complained of constipation, 26% complained to have been suffered from fever. 22% reported that they suffered from bleeding per rectum. 14% and 10% reported to have vomiting and diarrhoea respectively.

The most common symptom according to the present study was found to be abdominal pain followed by weight loss and constipation. Similar pattern was also obtained by Aghrahari S et al, where they reported 93% to have abdominal pain and 83% to have nausea(6). Saha S et al in their study regarding the clinicoepidemiological profile of abdominal tuberculosis reported 69.6% to have incurred weight loss and 60% to have abdominal pain(30). Similar results were also obtained by Makahria et al, khan R et al and Mukewar et al (16)(17)(18).

Signs of abdominal tuberculosis:

Out of the 50 enrolled study participants 48% of the study participants were found to have pallor,38% had lymphadenopathy, 34% had abdominal distension, 16% had fluid thrill and shifting dullness, 24% had abdominal lump. Similar results were obtained by Aghrahari et al were he reported 56% to have pallor and 43.3% to have abdominal distension(6).

Pattern of diagnosis of abdominal tuberculosis among study participants

According to CT abdomen, 64% of the study participants were diagnosed to have abdominal tuberculosis. CECT abdomen diagnosed 54% of the study participants to have from abdominal tuberculosis.

According to CBNAAT, 54% of the study participants suffered from abdominal tuberculosis. 60% of the study participants were diagnosed to have abdominal tuberculosis via histopathological examination.

Comparing the diagnosis between the three modalities:

All the three diagnostic procedures have been performed in 36 out of the 50 enrolled study participants. Hence for comparing between the three diagnostic modalities CECT abdomen, CBNAAT and histopathological examination, 36 study participants were taken into consideration.

25 study participants were diagnosed by both CECT and HPE to have Abdominal tuberculosis, while 19 study participants were diagnosed as having abdominal tuberculosis by both CBNAAT and HPE. True positive rates in case of CECT and CBNAAT was 69.4% and 52.7%, respectively. Both CECT and HPE have reported negative in 4 study participants against 5 study participants in case of CBNAAT and HPE. The true negative percentages for CECT and CBNAAT was 11.1% and 13.8%, respectively.

Both CECT and CBNAAT were found to have statistically significant agreement with HPE in diagnosing abdominal tuberculosis. CECT was found to have a moderate agreement and CBNAAT was found to have weak agreement with HPE.

Diagnostic accuracy of CECT, CBNAAT and HPE:

The sensitivity of CECT abdomen was found to be 83.3% and the specificity was 66.6%. The diagnostic accuracy was found to be 80.6%. If HPE diagnose 100 persons to have abdominal tuberculosis in about 83 times the result was found to be true in CECT. Similarly, if HPE reports negative in 100 persons, it was found to be correct in 67 times using CECT.

The sensitivity of CBNAAT was found to be 63.3% while the specificity was found to be 83.3%. The diagnostic accuracy of CBNNAT was found to be 66.7%. If HPE diagnoses 100 persons to have abdominal tuberculosis in about 63 instances CBNAAT also diagnosed that the persons had abdominal tuberculosis. Similarly, if HPE reports 100 persons as negative, it was found to be negative in 83 times using CBNAAT.

Similar results were obtained by Pai M et al. Pai M et al did a metaanalysis with an objective of finding out overall accuracy of nucleic acid amplification tests in diagnosing tubercular meningitis. The study reported the sensitivity of NAA to be 56% and specificity to be 98%. The study concluded NAA to have a significant role to play in the diagnosis of tubercular meningitis as reflected by the specificity, But the lack of sensitivity means a negative test must be scrutinised further with more care(25). Scott LE et al reported that the sensitivity using ascitic fluid in NAA assay was 51% which was similar to the present study(26).

Another Meta-analysis by Denkinger CM et al also reported a very high specificity for NAA assays for both pulmonary and extrapulmonary samples. The study also has documented a variable sensitivity for variable samples ranging from 21.4% to 81.3%. The lowest being for pleural fluid and highest for lymph node tissue(27).

Penz et al in his meta-analysis with an objective of finding out the diagnostic accuracy of NAA assays for extrapulmonary tuberculosis reported the pooled sensitivity to be 77% and pooled specificity to be 97%.

Causse M in her study also reported a similar pattern of higher specificity in their study(28). In contrast to the present study Bahr NC et al reported a higher sensitivity among NAA assays(12). Lawn S D also reported a pooled sensitivity of 80% and pooled specificity of 90%(29). Scott LE also reported that the difference in sensitivity was found in specimens being classified as thick and clear. The study also reported that utilisation of NAA assays is better as they are less affected by any bacterial contamination, reduces laboratory labour and diagnostic delay(26).

Conclusion

With regard to abdominal tuberculosis, the specificity of CBNAAT was found to be higher making it an inevitable tool in the diagnosis of the disease. Since the sensitivity of the tool is low all the negative results from CBNAAT assay have to be scrutinized properly before declaring the patient is negative for abdominal tuberculosis. In contrast to CBNAAT, CECT had high sensitivity and low specificity, making it more a screening tool than a diagnostic tool. CECT have to be combined with other modalities like HPE, CBNAAT or Culture to make it better diagnostic tool. The diagnostic accuracy of the above-mentioned combinations has to be evaluated through further studies.

Limitations of the study

- The sample population for the study was from a single tertiary care hospital so generalisation of the results of the study was not possible.
- 2. Certain unaddressed bias can still be present in the study.

Recommendations

- CECT abdomen can play a vital role as a tool for screening in case of abdominal tuberculosis.
- CBNAAT is a remarkable diagnostic tool for abdominal tuberculosis due to its high specificity but the uncertainty in sensitivity shall be overcome by combining it with newer diagnostic methods or newer procedures.
- Further studies shall be done to find out the diagnostic accuracy of various combination of diagnostic tools.
- The same study have to be repeated in various setting for generalization of results.

Summary

- \checkmark 30% of the study participants were in the age group of 51-60 years.
- $\checkmark~60\%$ of the study participants were males.
- ✓ 22% had finished up to higher secondary education and 18% were illiterates.
- ✓ 56% were doing unskilled occupation.
- $\checkmark~86\%$ reported that they suffered from abdominal pain.
- \checkmark 70% of the study participants reported weight loss.
- $\checkmark~26\%$ reported that they had fever.
- ✓ 10% of the study participants reported that they suffered from diarrhoea.
- \checkmark 32% of the study participants reported that they had constipation.
- $\checkmark~22\%$ reported that they had bleeding per rectum.
- \checkmark 14% of the study participants complained vomiting.
- $\checkmark~48\%$ of the study participants had pallor.
- ✓ 38% of the study participants had lymphadenopathy.
- ✓ 34% had abdominal distension.
- ✓ Fluid thrill was elicited in 16% of study participants.
- ✓ Shifting dullness was present in 15% of the study participants.
- ✓ 24% had abdominal lump.
- ✓ The mean systolic blood pressure was 123.88 (112 134) mmHg

- ✓ The mean diastolic blood pressure was 77.32 (69 85) mmHg.
- ✓ The mean pulse rate was 78.4 (74-82) bpm.
- ✓ The mean haemoglobin level was 8.73 (7-9) mg/dl.
- ✓ The mean ESR was 48.7 (36.6-60.0) mm/hr.
- ✓ The mean SGOT levels were 49.25 (39.7-58.5) u/l.
- ✓ The mean SGPT levels were 44.18 (36.8-51.7) u/l
- ✓ 15% had ileocecal thickening with enlarged lymphnodes.
- According to CT abdomen, 64% of the study participants were diagnosed to have abdominal tuberculosis.
- According to CECT abdomen, 54% of the study participants suffered from abdominal tuberculosis.
- According to CBNAAT, 54% of the study participants suffered from abdominal tuberculosis.
- ✓ 60% of the study participants were diagnosed to have abdominal tuberculosis via histopathological examination.
- ✓ 25 study participants were diagnosed by both HPE and CECT to have abdominal tuberculosis.
- ✓ 19 study participants were diagnosed by both CBNAAT and HPE to have abdominal tuberculosis.
- ✓ The sensitivity of CECT abdomen was found to be 83.3% and the specificity was 66.6%. The diagnostic accuracy was found to be 80.6%.

✓ The sensitivity of CBNAAT was found to be 63.3% while the specificity was found to be 83.3%. The diagnostic accuracy of CBNNAT was found to be 66.7%.

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ANNEXURES

PATIENT CONSENT FORM

STUDY TITLE:

"A PROSPECTIVE STUDY ON THE EFFICACY OF CECT ABDOMEN, HISTOPATHOLOGICAL EXAMINATION AND CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST IN PREDICTING ABDOMINAL TUBERCULOSIS" IN GMKMCH, SALEM

Department of General surgery, GMKMCH

PARTICIPANT NAME : AGE : SEX:

I.P. NO :

I confirm that I have understood the purpose of surgical/invasive procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the possible complications that may occur during and after medical procedure. I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I hereby consent to participate in this study. Time :

Date : Signature / Thumb Impression Of Patient

Place :

Patient's name:

Signature of the investigator: _____

Name of the investigator : _____

PATIENT PROFORMA

A PROSPECTIVE STUDY ON THE EFFICACY OF CECT ABDOMEN, HISTOPATHOLOGICAL EXAMINATION AND CARTRIDGE BASED NUCLEIC ACID AMPLIFICATION TEST IN PREDICTING ABDOMINAL TUBERCULOSIS IN GMKMCH, SALEM

А.										
Name:		Age/Sex:	:							
Address:		Occupa	tion:							
Religion:	O.P No:		I.P No:							
Date & time of admission:										
Date of discharge:										
B. CHIEF COMPLAI	B. CHIEF COMPLAINTS:									
Duration of symptoms:										
C.PAST HISTORY:	C.PAST HISTORY:									
1. DM										
2.TB										
3.EPILEPSY										
4.CARDIAC DISEASE	S									
5.PREVIOUS SURGER	RY									
6. HYPERTENSION										
7.JAUNDICE/HEPATI	7.JAUNDICE/HEPATITIS									
8.CIRRHOSIS										

D.PERSONAL HISTORY:

SMOKER

ALCOHOLIC

E.INITIAL ASSESSMENT OF PATIENT

1.VITALS:

PR:

BP:

RR :

SPO2 :

TEMPERATURE :

2.GENERAL SIGNS:

PALLOR

PEDAL EDEMA

CYANOSIS

ICTERUS

LYMPHADENOPATHY

K.SYSTEMIC EXAMINATION:

CVS

RS

CNS

ABDOMEN:-

EXTERNAL GENITALIA:

INGUINOSCROTAL REGION:

PER RECTAL EXAMINATION:

CLINICAL DIAGNOSIS :

INVESTIGATIONS

A. CBC WITH ESR, RBS, RFT, SERUM ELECTROLYTES

B. GROUPING & TYPING, BT/CT

C. LFT

D. MANTOUX TEST

E. HBSAG HIV

F. ECG

G. URINE:

Albumin

Sugar

H. CHEST X RAY PA VIEW

I. X-RAY ABDOMEN ERECT

J. USG ABDOMEN & PELVIS:

K.CECT ABDOMEN AND PELVIS

L.CBNAAT

M.HISTOPATHOLOGICAL EXAMINATION

N.COLONOSCOPY

IF OPERATED

OPERATIVE PROCEDURE

ANAESTHESIA

INCISION

POST OPERATIVE PERIOD / COMPLICATIONS

TREATMENT GIVEN

Sno	Name	Age	Sex	Edu	Occ	Abdominalpain	Weightloss	fever	diarrhoea	constipation	nausea	Vomiting	Pallor	lymphadenopathy	abdominal distension	fluidthrill	shiftingdullness	abdominallump	dqs/s	diasbp	pulserate	유	ESR	SGOT	SGPT	ileocaecal_thickening_with_enlarged_lymphnodes	conglomerate_bowel_loops	matted_bowel_loops	multiple_enIrged_lymphadenopathy	Omental_thickening_with_enIrged_lymphnodes	CTabdomen	CECT	CBNAAT	HPE
1	KUPPUSAMY	65	М	1	2	1	1	99	99	1	1	1	1	1	99	99	99	99	106	60	79	7.2	30.4	48.8	34.2	1	99	99	1	1	1	99	99	1
2	MADHESWARI	40	F	7	2	1	1	1	99	99	99	99	99	99	1	99	1	99	118	74	83	8.5	55.3	44.8	38.2	99	99	99	99	99	99	99	1	1
3	RAMYA	23	F	3	3	1	1	99	99	99	1	99	1	1	1	1	99	1	118	84	77	9.2	75.9	62.7	33.9	99	99	99	99	99	99	99	99	1
4	SETHU	65	М	2	3	99	1	99	1	99	99	99	99	99	1	99	99	99	120	72	88	7.5	30.0	34.2	42.7	99	99	99	99	1	1	1	99	99
5	PONGARANAM	25	М	7	1	1	1	1	99	99	99	99	99	99	1	1	99	1	110	74	74	8.3	74.7	38.2	30.5	1	99	99	1	99	1	99	99	99
6	RAMU	50	М	4	2	1	1	99	99	1	1	1	1	1	99	99	99	99	120	78	84	9.8	44.8	33.9	38.9	99	99	99	99	99	99	1	1	1
7	SHANTI	34	F	2	3	1	1	1	99	99	99	99	99	99	99	1	1	1	132	80	75	10.4	62.7	42.7	40.5	99	99	99	99	1	1	1	99	1
8	RAMAN	60	М	5	3	1	1	99	99	1	99	99	99	99	99	99	99	99	126	90	80	9.4	34.2	30.5	55.3	1	99	99	99	99	1	1	99	99
9	PONRAJ	60	М	3	2	99	1	1	99	99	99	99	1	1	99	1	99	1	114	70	78	10.2	38.2	38.9	47.8	99	99	99	99	99	99	99	99	99
10	MADHAVI	30	F	7	1	1	1	99	99	99	1	1	99	99	99	99	99	99	124	82	74	7.3	33.9	40.5	40.2	99	99	99	99	99	99	1	1	1
11	MADHAIYAN	35	М	7	1	1	1	99	99	1	99	99	1	1	1	99	1	99	130	76	70	8.3	42.7	55.3	37.6	1	99	99	99	1	1	1	1	1
12	GOVINDHARAJ	54	м	1	3	1	1	1	99	99	99	99	99	99	99	99	99	99	118	70	78	8.9	30.5	47.8	47.9	99	99	1	99	99	1	99 9	99	99
13	PONNARASI	47	F	4	2	1	1	99	99	1	1	99	1	1	1	99	99	1	108	72	90	10.2	38.9	40.2	49.9	99	1	99	99	99	1	1	1	1
14	DAMAKDICUNAN	F 1		~	2	1	1	00	1	00	00	1	00	00	00	00	00	00	104	70	70	7 5	40.5	20.7	F7 3	00	00	00	00	00	00	99	00	00
14	RAMAKRISHNAN	51	IVI F	5	3	1	1	99	1	99	99	1	99	99	99	99	99	99	104	78	79	7.5	40.5	39.7	57.3	99	99	99	99	99	99	9	99	99
15		20	г м	2	2	1	1	1	99	99	1	99	1	1	1	99	99	1	140	90	04 76	8.9 10.2	33.3	35.4	20.0	1	99	99	1	99	1	99	1	999
10		40	IVI F	5	3	1	1	99	99	99	1	99	99	99	99	99	99	99	140	90	70	10.2	47.8	46.2	38.2	99	99	1	99	1	1	1	1	1
1/	NAIVIATEE	41	г	/	T	T	99	33	33	T	33	33	T	T	33	33	T	33	140	80	02	7.4	40.2	43.8	33.9	33	33	33	33	33	33	99	T	1
18	MURUGESAN	48	М	5	3	1	1	1	99	99	99	1	99	99	99	99	99	1	120	80	79	7.0	39.7	62.9	42.7	99	99	99	99	99	99	9	99	99
10	CELVADAL	60	6.4	1	2	1	1	00	00	00	00	00	1	00	00	00	00	00	110	70	00	0.4	A1 C	22.0	12 7	1	00	00	00	00	1	1	1	1

MASTER CHART

																				10														
20	NATARAJAN	55	М	1	2	99	99	99	99	1	1	99	99	99	1	99	99	1	160	0	77	10.2	52.8	45.9	30.5	99	99	1	99	1	1	99	1	999
21	TAMILMANI	50	F	5	3	1	99	1	99	1	99	99	1	99	1	99	99	99	140	70	78	7.3	54.6	50.3	38.9	99	99	99	99	99	99	99	99	1
22	SUBRAMANI	40	М	1	2	1	1	99	99	99	99	99	99	1	99	99	99	99	122	78	85	8.3	49.6	34.2	40.5	99	99	99	1	99	1	1	99	1
23	MAHALAKSHMI	36	F	2	3	1	99	1	99	1	1	1	1	1	1	99	99	1	130	90	84	8.9	32.1	63.3	55.3	1	99	99	99	99	1	99	1	999
24	RENGARAJ	53	м	5	2	99	1	99	99	99	99	99	1	99	99	99	99	99	130	90	76	8.2	41.2	68.5	47.8	99	99	99	99	99	99	99 9	99	99
25	CHINAPPAN	70	м	7	2	1	99	1	99	1	99	99	1	99	99	99	99	1	116	68	76	8.9	49.8	42.7	40.2	99	1	99	99	99	1	1	99	1
26	DHANALAKSHMI	34	F	5	3	1	1	99	99	99	1	1	1	1	1	99	99	99	120	78	79	7.2	43.7	50.7	37.6	99	99	99	99	99	99	99	1	99
27	MOORTHI	42	М	6	3	1	99	1	99	99	99	99	1	1	1	1	1	1	120	80	71	8.5	43.8	38.9	47.9	1	99	99	1	1	1	1	99	1
28	SANGEETHA	28	F	5	3	1	1	99	99	99	99	99	99	99	99	99	99	1	120	80	86	9.2	52.7	40.5	40.5	99	99	99	99	99	99	99	1	999
29	MOHAN	55	М	5	2		1	1	99	99	99	99	99	1	99	99	99	99	130	90	73	7.5	43.3	55.3	55.3	1	99	99	99	99	1	1	1	1
30	PRADEEP	29	М	7	1	1	99	99	99	99	1	99	1	99	1	99	99	99	130	70	75	8.3	73.8	44.9	37.6	99	99	99	99	99	99	99	99	1
31	CHINAPPAN	55	М	5	3	1	1	1	99	99	99	99	99	99	99	99	99	99	140	90	74	9.8	72.6	52.5	47.9	1	99	1	99	99	1	1	1	1
32	AANDIVEL	25	м	2	2	1	1	99	99	1	99	99	1	99	99	99	99	99	120	74	84	10.4	53.9	63.4	49.9	99	99	99	1	99	1	99 9	99	99
33	SELVAM	52	м	5	2	99	1	99	99	1	1	99	1	1	99	1	1	99	110	66	75	9.4	45.4	60.4	57.3	99	99	1	99	99	1	1	1	1
34	SARAVANAN	22	м	8	3	1	1	99	1	99	99	99	1	99	99	99	99	99	114	80	80	10.2	62.6	62.9	55.8	1	99	99	99	99	1	1	1	1
35	RIYASH	32	М	6	3	1	99	99	99	99	99	99	1	1	1	99	99	99	110	70	78	7.3	54.8	53.9	38.2	99	99	99	1	99	1	1	1	1
36	MANIKANDAN	44	М	7	1	1	1	99	99	1	99	99	99	99	99	1	99	99	140	78	74	8.3	55.9	45.4	33.9	1	99	99	99	99	1	1	1	1
37	VASANTHI	60	F	1	3	1	1	99	99	99	99	99	99	99	99	99	1	99	130	74	70	8.9	45.4	62.6	42.7	99	99	99	99	99	99	99	1	999
38	BAKIYAMMAL	31	F	4	3	1	99	99	99	1	99	99	1	1	1	99	99	99	124	74	78	10.2	55.9	54.8	42.8	99	99	1	99	99	1	99 9	99	99
39	GANESAN	35	м	2	3	1	99	99	99	99	99	99	1	99	1	99	99	99	116	66	90	7.5	42.9	55.9	38.9	1	99	99	99	99	1	1	99	1
40	CHITRA	34	F	8	2	1	1	99	99	1	99	99	1	99	1	1	1	99	120	80	73	8.9	44.9	46.8	40.5	99	99	99	99	99	99	99	1	999
41	PADMA	21	F	6	2	1	99	99	99	99	99	99	1	99	99	99	99	99	150	70	75	10.2	55.4	54.8	55.3	99	1	99	99	99	1	1	99	1
42	RAJAGOPAL	52	М	1	3	1	1	99	1	99	99	99	99	99	99	99	99	99	120	78	74	8.2	46.2	55.9	47.8	1	99	99	99	99	1	1	1	1
43	SELVARAJ	62	м	1	2	1	99	99	99	1	99	99	99	1	1	99	99	99	110	60	84	7.4	43.8	49.8	52.3	99	99	99	99	99	99	99 9	99	99
44	THIRUPATHI	55	м	3	3	1	1	99	99	99	99	99	99	99	1	99	99	99	120	74	75	8.4	62.9	46.3	51.7	99	99	99	99	99	1	1	1	1
45	MALLIKA	46	F	5	3	1	99	99	99	99	99	99	99	99	1	99	99	99	132	84	80	7.5	33.8	52.8	52.8	1	99	99	99	99	1	1	1	1
46	KEERTHANA	25	F	3	3	1	99	99	99	99	99	99	99	1	1	99	99	99	126	72	78	8.3	45.9	54.8	38.6	99	1	99	99	99	1	1	1	1
47	POONKODI	32	F	5	3	1	1	99	1	99	99	99	99	99	99	99	99	99	140	74	75	9.8	50.3	55.9	38.9	99	99	99	99	99	99	99	1	999
48	KARUNANIDHI	58	м	1	3	1	1	99	99	99	99	99	99	99	99	99	99	99	124	78	74	10.4	34.2	45.4	40.5	99	99	99	99	99	99	99	99	99
49	AMUDHAVALLI	28	F	3	3	1	99	99	99	99	99	99	99	1	99	99	99	99	110	80	84	10.4	63.3	55.9	55.3	99	99	1	99	99	1	1	99	1
50	RAJAMMAL	55	F	2	3	1	1	99	99	99	99	99	99	99	99	99	99	99	130	80	75	7.3	72.0	56.8	47.8	99	1	99	99	99	1	1	1	1

Key to Master Chart

М	-	male,
F	-	female,
Edu	-	Education,
occ	-	occupation,
sysbp	-	systolic blood pressure,
diasbp	-	diastolic blood pressure,
Hb	-	haemoglobin,
ESR	-	erythrocyte sedimentation rate,
SGOT	-	serum glutamic oxaloacetic transaminase,
SGPT	-	serum glutamate pyruvate transaminase,
CECT	-	Contrast Enhanced Computed Tomography
HPE	-	Histopathological examination
CBNA	AT -	Cartridge based nucleic acid amplification test
1	-	present
99	-	absent
999	-	not done