

Treatment Outcome in Patients of Abdominal Tuberculosis receiving Antitubercular Chemotherapy according to National Tuberculosis Guideline of Bangladesh

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Summary:

Back ground: Abdominal tuberculosis is common in Bangladesh and there is a national guide line for its management, which includes six months course of anti tubercular therapy (ATT). This study was done to evaluate the treatment outcome of abdominal tuberculosis following national guide line. **Materials and Methods:** This prospective study of descriptive nature was done between November 2009 to October 2010 at the department of Medicine, Sir Salimullah Medical College, Mitford hospital, Dhaka, Bangladesh. Total 6 months ATT was given to the selective 50 patients of abdominal tuberculosis following national guide line and out come measurement was done after completion of treatment. **Result:** Five patients died out of 50 patients during the course of treatment. The range of age was 13-70 years and mean \pm SD = 33.2 \pm 14.77 and male female ratio was 0.72:1.

Out of 50 patients 17(34%) patients had Intestinal TB, 24(48%) had Peritoneal TB, 2(4%) had abdominal lymph node TB, and 7(14%) had other types. Three patients of peritoneal TB patient died while rest 2 patients died were diagnosed as intestinal TB. Out of 45 patients who survived, 43(95.6%) improved and 2(4.4%) did not improve. Out of 15(33.3%) intestinal TB patients, 14(31.1%) improved and 1(2.2%) did not improve. Out of total 21(46.7%) peritoneal TB, 20(44.4%) improved and 1(2.2%) did not improve. Remaining 2(4.4%) abdominal lymph node TB, all were improved. In other variety cases (15.6%), all improved. **Conclusion:** Total 6 months regimen of ATT recommended by national guide line is proved as a complete and effective treatment course of abdominal tuberculosis.

Key words: Abdominal tuberculosis, Treatment out come, National guide line.

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Introduction:

Tuberculosis can involve any organ system in the body. While pulmonary tuberculosis is the most common presentation, extra-pulmonary tuberculosis (EPTB) is

also an important clinical problem^{1,2,3}. Abdominal TB is common in Bangladesh and other tropical countries and poses a significant health hazards⁴. There is no extensive study done in our country regarding abdominal tuberculosis. One retrospective study done by Rouf HMA in general Hospital. Sirajgonj.⁵ He showed that 16 cases presented with acute surgical emergencies out of 43 cases, 12 of them presented with intestinal obstruction (25%), and rest 27% had chronic symptoms. Faiz MA did another retrospective study in 1989 in IPGM&R on extra- pulmonary tuberculosis⁶. He found intestinal tuberculosis in five cases out of 47 patients having extra-pulmonary tuberculosis⁶. The diagnosis of gastrointestinal tuberculosis is often delayed, increasing the morbidity associated with this treatable condition⁷. Abdominal TB has a good prognosis if promptly diagnosed and treated⁸. A high clinical index of suspicion and judicious use of diagnostic procedure can certainly help in timely diagnosis and treatment and thus reduce the mortality of this curable but potentially lethal disease⁹. Marshal et al and Anond et al also

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recommend clinical trial in endemic countries^{9,10}. Management of all patients with abdominal tuberculosis should be given standard full course of antitubercular therapy (ATT). Duration of treatment is different in different canters. Treatment with three drug regimen for nine month was also used as anti tuberculosis treatment.

Successful treatment of abdominal tuberculosis for one to one and a half year¹¹ is also the recommendation by Kilmach et al, Quorian et al and Schfield et al.^{12,13,14}. Previously 18-24 months regime was popular, then 1 year regime and now six months of total duration is considered sufficient for chemotherapy^{15,16,17}.

In Bangladesh, there is a national guide line for treatment of all kinds of TB patients. It is recommended total six months ATT for the treatment of abdominal tuberculosis patients¹⁸. All patients of abdominal tuberculosis should receive conventional anti-tubercular therapy for at least six months including initial two months of rifampicin, isoniazide, pyrazinamide, ethambutol and next four months of rifampicin and isoniazide¹⁸.

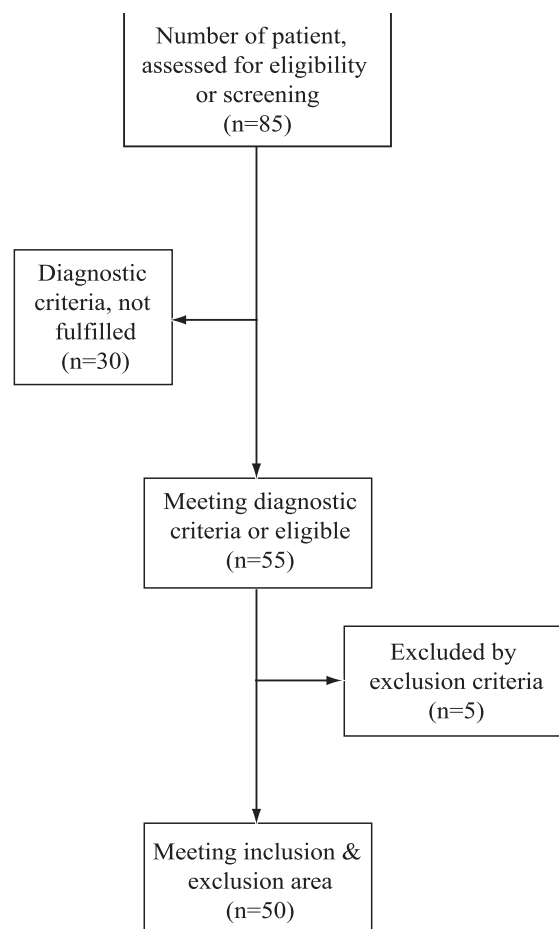
There is still contradiction in the treatment of abdominal tuberculosis about its duration of treatment. Most of the clinician and specialist are still continuing the previous duration of treatment. There has been no attempt before to see the outcome of national guideline based treatment before.

So, this study was done in the department of Medicine, SSMC & Mitford Hospital to evaluate the treatment outcome of abdominal tuberculosis following national guide line.

Materials and Methods:

This prospective study of descriptive nature was done between November 2009 to October 2010 in the department of Medicine, Sir Salimullah Medical College, Mitford hospital, Dhaka, Bangladesh. Total 50 patients were purposively selected, after screening and considering inclusion and exclusion criteria. All patients aged more than 13 to 70 years, both male and female. and diagnosed as abdominal tuberculosis and getting anti-TB drugs following National guide line were included in the study. The patients, getting anti-TB-drugs on the basis of clinical suspicion (not confirmed cases), patients getting anti-TB drugs not following national guide line, patients getting other drugs which reduce the effectiveness of anti-TB drugs and patient,

taking anti-TB drugs irregularly and not giving consent were excluded from the study.



The detailed clinical history was obtained from patient admitted with suspected abdominal tuberculosis attending in the department of medicine, gastroenterology and surgery of SSMC & Mitford Hospital or other teaching hospitals in Dhaka city. The suspected case was sought and screened from focused history and examination. In taking history certain points were undertaken as screening part. These are: 1) History of contact with TB. Patient, 2) History of smoking or non smoking tobacco, 3) History of alcohol intake 4) History of hypertension 5) History of diabetes mellitus 6) Past history of tubercular infection and 7) History of relevant symptoms-

Abdominal pain, fever, weight loss, anorexia, diarrhea, constipation, nausea/vomiting, night sweating, melaena, haematochezia. Thorough physical examination was

done in all cases, which includes especially for abdominal examination –abdominal tenderness, ascites, hepatomegaly, splenomegaly, abdominal mass, intestinal obstruction, intestinal perforation, abdominal lymphadenopathy. After screening procedure, 5 ml blood was taken from every patients and sent to SSMC pathological laboratory for total count (TC), differential count(DC) of white blood cell (WBC), ESR, Hb & peripheral blood film (ESR > 50 mmHg was considered as high ESR) , urine-routine microscopic examination, fasting Blood sugar, CXR PA view (evidence of active pulmonary tuberculosis was observed). Hundred and fifty ml ascitic fluid was drawn whenever patient presented with this sign and sent for cytology(Lymphocyte predominance in a total cell count excessive of 150 was searched), biochemistry (protein raised was searched) and bacteriology for AFB was searched in every case. The standard laboratory procedure for ascetic fluid study was performed. An ultrasonography of whole abdomen by an expert single handed radiologist was done in every case. Those fulfilling criteria for other diagnosis from ultrasonography were excluded from the study.

Mantoux test (> 10 mm indurations was considered as positive) was done in every case. In selected cases few invasive Investigation was done like Peritoneal fluid analysis, Adenosine deaminase (ADA) for ascitic fluid (> 37 IU/L is diagnostic of abdominal TB), colonoscopy and biopsy (presence of granulation tissue with caseation necrosis), CT-scan (if needed, laparoscopic biopsy (Presence of granulation tissue with caseation necrosis).

The diagnosis of tuberculosis was confirmed by fulfilling one or more of the following four criteria along with high clinical index of suspicion —

- Histological evidence of tubercle with caseation necrosis.
- Histological demonstration of acid fast bacilli in a lesion.
- Culture of suspected tissue resulting in growth of *M. tuberculosis*.
- Increased ADA (Adenosine deaminase) in ascitic fluid (> 37IU/L)

Treatment:

All diagnosed patient with abdominal TB were under treatment of anti tubercular therapy (ATT) cat-1 for six months as per national guide line in which rifampicin, INH, ethambutol and pyrazinamide were given in first

two months and after that rifampicin and INH for next four months according to index dose. But no one was under treatment by ATT cat-2.

The isoniazid dose was 300 mg/day for those under 50 kg in body weight and 400 mg/day for those 50 kg and over. The rifampin dose was 450 mg/day for patients under 50 kg and 600 mg/day for those 50 kg and above. The ethambutol (15 to 20 mg/kg of body weight) and pyrazinamide doses (20 to 30 mg/kg) were 1,000 mg/day and 1,250 mg/day, respectively, for those under 50 kg and 1,200 mg/day and 1,500 mg/day for those 50 kg and over. All patients were advised to take medicine from directly observed treatment (DOT) corner, nearby their residence.

Follow-up: All enrolled patients were followed up fulfilling the criteria below:

- (1) Follow up was given two months after ATT and six months completion of ATT.
- (2) Treatment outcome was assessed by comparing the symptoms and signs, before starting ATT and after six months of ATT.
- (3) TC, DC, ESR & Hb% of blood was done after completion of ATT to compare with the same as done before ATT for treatment outcome measurement
- (4) Body weight before and after ATT was measured in all cases.

Treatment outcome measurement:

Treatment completed: After completing of full treatment course, a patient is declared “treatment completed”

Cured: Completed six months treatment of ATT and disappearance of all symptoms and signs and absence of acid fast bacilli and caseation in lesion and normal ADA in ascitic fluid.

Improved: Completed six months treatment of ATT and disappearance of all symptoms and signs.

Not improved: Persistent of symptoms and signs after six months ATT and presence of caseation necrosis after six months ATT and presence of acid fast bacilli in lesion after six months ATT and Increased ADA in ascitic fluid after six months ATT

Death: Patient who died for any reason during the course of treatment

Data collection and statistical analysis: Statistical analysis related with this study was performed by use of SPSS 16.0 package program (SPSS -16 package Chicago

Illinois). The data gathered was expressed by descriptive statistical methods (frequency distribution, percentage, mean & standard deviation) as applicable. Comparison between groups was done by standard statistical test, example: Student's paired 't' test. Result of this study was shown by different tables, chart and diagram etc.

Ethical issue: The study protocol was approved by the Institutional review board of SSMC, Dhaka. Informed consent was obtained from each subject. In every steps of methodology ethical consideration was followed strictly (e.g- blood collection, biopsy, peritoneal fluids aspiration, consent proceedings etc). Data was collected in an approved data collection form.

Results:

During the period of November 2009 to October 2010 total 50 patients were selected as per inclusion and exclusion criteria for treatment outcome measurement. Out of 50 patients 45 patients completed total treatment course of anti tubercular therapy (six months) and 5 patients died on the course of treatment and were not able to complete the treatment course

Table-1

<i>Socio demographic status (n=50)</i>			
Parameters		Patient number	Percentage (%)
Age (years)	Mean \pm SD	33.2 \pm 14.77	
	Range	13-70	
Sex	Male	21	42
	Female	29	58
	M:F(Ratio)		0.72:1
Occupation	House wife	22	44
	Student	6	12
	Service holder	7	14
	Business man	8	16
	cultivator	7	14
Marital status	Married	38	76
	Unmarried	12	24

Total number of patient is 50 with a range of 13-70 years and mean \pm SD =33.2 \pm 14.77. 21 (42%) patients were male, 29 (58%) patients were female and male & female ratio is 0.72 : 1.

Out of total 50 patients 2(4%) patients had past history of TB infection, 7(14%) had history of TB contact, 8(16%) had history of smoking, 6(12%) had history of tobacco chewing and 1(2%) had history of alcohol intake.

Table-II

Type of clinically diagnosed abdominal TB (n=50)

Type	Patient number	Percentage (%)
Intestinal TB	17	34
Peritoneal TB	24	48
Abdominal lymph node TB	2	4
Others (Other abdominal organ TB or combination of other types)	7	14

Table-III

Frequency of symptoms of patients at presentation (n=50).

Symptoms	Patient number	Percentage (%)
Abdominal pain	47	94
Fever	48	96
Anorexia	47	94
Diarrhoea	7	14
Constipation	4	8
Vomiting	41	82
Night sweating	41	82
Melaena	0	0
Haematochezia	1	2

Among the total 50 patients 47(94%) patients presented with abdominal pain ,48(96%) with fever and 47 (94%) with anorexia.

Table-IV

Distribution of signs of patients at presentation (n=50)

Signs	Patient number	Percentage (%)
Abdominal tenderness	45	90
Ascites	29	58
Hepatomegaly	4	8
Splenomegaly	0	0
Abdominal mass	20	40
Intestinal obstruction	6	12
Intestinal perforation	1	2
Abdominal lymphadenopathy	1	2

Among the total 50 patients, abdominal tenderness was recorded on 45(90%), ascites on 29(58%) and Abdominal mass on 20(40%).

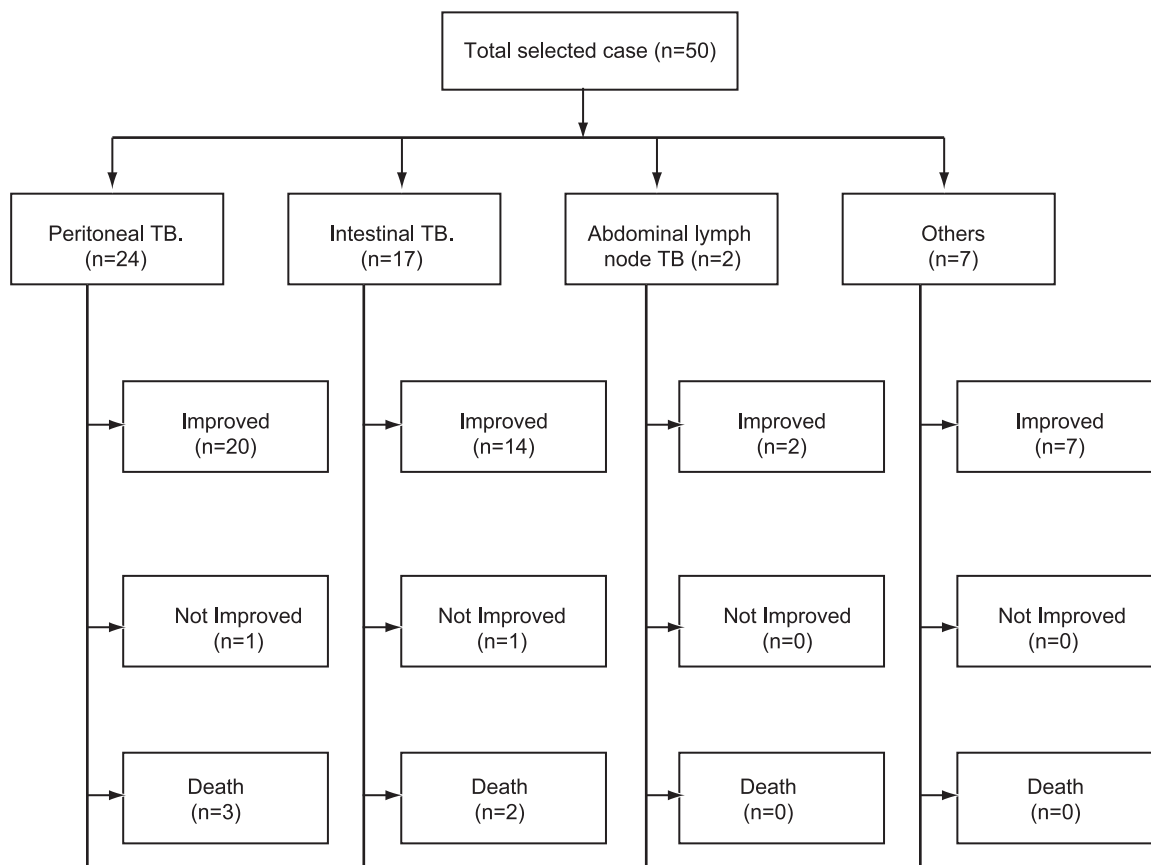
Table-V*Treatment out come of abdominal TB. (n=45)*

Treatment Out come	Intestinal TB	Peritoneal TB	Abdominal Lymph node TB	Others	Total
Improved	14(31.1%)	20(44.4%)	2(4.4%)	7(15.6%)	43(95.6%)
Not improved	1(2.2%)	1(2.2%)	0(0%)	0(0%)	2(4.4%)
Total	15(33.3%)	21(46.7%)	2(4.4%)	7(15.6%)	45(100%)

Total 45 patients were evaluated for treatment outcome measurement. Amongst them 43(95.6%) improved. In case of total 15 (33.3%) intestinal TB, 14 (31.1%) improved. In case of total 21 (46.7%) peritoneal TB, 20(44.4%) improve. Remaining total 2(4.4%) abdominal Lymph node TB and 7(15.6%) other variety TB all improved.

In investigation mean value of haemoglobin of total 45 patients which were under treatment outcome measurement was 9.7 ± 1.6 before treatment and 11.7 ± 1.5

after treatment. Student pair t-test was done with recorded t-value was -10.94. P-value was <0.001 . Mean value of ESR (In mm/1st hour), before treatment was 56 ± 27 and after treatment was 28 ± 15 . Student pair t-test was done with recorded t-value was 8.09. P-value was <0.001 . Mean value of absolute lymphocyte count (per cu mm of blood) before treatment was 2425 ± 926 and after treatment was 1709 ± 260 . Student pair t-test was done with recorded t-value was 4.74. P-value was <0.001 . Mantoux test was done over total 42 patients out of 50



patients. MT-positive 37(88%) and MT-Negative 5 (11.9%). Out of 50 patients 24 (48%) were diagnosed on the basis of increased ADA level (In ascitic fluid) and 26 (52%) on the basis of Tissue biopsy (histopathology) along with high index of clinical suspicion.

Discussion:

Abdominal tuberculosis can be presented in different form and outcome can be also vary according to variable site involvement. Although there may be many variables which can alter the outcome of disease (age, nutrition, demography etc) the ATT usually overcome all the variables to have a better outlook of the disease if the treatment taken through DOTS strategy¹⁸.

In this study out of total 50 patients 34% patients had intestinal TB, 48% had Peritoneal TB, 14% had other abdominal organ TB or combination of other types. This finding is consistent with other studies where peritoneum was the common site of involvement in abdominal tuberculosis.¹⁹.

Among the patients with intestinal involvement, ileocecal region were the common site in our series. It is consistent with studies done by Palmar et al. and Jakubosky et al.²⁰ In contrast jejunum and ileum were the predominant site of involvement according to other studies.^{12,21}

Five patients died during the course of treatment of this series. One of the patient died within three days of ATT and interestingly he had AFB positive in his ascitic fluid. The other two patients who had raised ADA also died at one month in one case and other one at 2nd months of treatment. The iliocaecal TB cases who died were also were within treatment schedule. One of the patient died as a complication of intestinal obstruction and died after operation done in SSMCH for his obstruction. The other case that died was having advanced disease with severe malnutrition.

The survived 45 patients were evaluated for treatment outcome measurement. Amongst them 95.6% improved and 4.4% had no improvement. In case of intestinal TB, 93.3% had improved. In case of peritoneal TB, 95.6% shown improvement. Remaining total two (4.4%) abdominal lymph node TB and 7 (15.6%) other variety TB all improved. This study is consistent with another study where all tuberculosis patients improved with the same regimen of 6-months duration^{22,23}.

This study was undertaken to test whether a six month regimen is effective in eliminating abdominal TB or not. To date, increasing evidence suggests that 6- to nine month regimens that include isoniazid and rifampin are indeed effective in this regard^{24,25} However, few properly randomized trials of extrapulmonary disease treatment, featuring appropriate clinical end points, have been conducted, except for reports on tuberculous lymphadenitis (6–8) and spinal TB patients^{26,27,28}

Two patients out of 45 did not improve. They had persistent previous symptoms and signs even treatment completed. The cause of which may be non-compliance with ATT, MDR-TB or HIV infection. It deserves further study whether extension of ATT duration required or not. So they were referred to respective higher centre to exclude MDR-TB or concomitant HIV infection and for further management. These two patients were lost to follow up and so the ultimate outcome could not be measured.

There are few studies in Bangladesh on clinical aspects of abdominal tuberculosis. It was seen in this study that highest number of cases were recorded in younger age group. Abdominal tuberculosis can occur at any age, but most commonly in young age. The mean age of 33.2 years in the present study reflects the observations of various studies.^{29,30} Age distribution of this study does not coincide with other studies.^{31,32} The mean age of presentation in their study was 6-11 yrs. Because their study was among the children. Male-female ratio was 0.72:1. In another study, the disease was observed with female predominance, which co-incides with this study³³. Moreover, in this study, age of the patients was not in the same age group but it was also observed in the later part of second decade with a female preponderance and the numbers of female patients were more than other series. Sheldon et al also observed similar age distribution in Bangladeshi migrants in East London.³⁴

Non-specific abdominal pain, low grade fever, anorexia and night sweating are common symptom in this study which coincides with the studies of Tanrikulu AC et al.³⁵, Demir k et al³⁶, Talwar BS et al³⁷. Though abdominal distension, ascites and anorexia have also been reported as the common presenting symptoms in some studies.^{32,38} Present study revealed abdominal tenderness, ascites, abdominal mass as common sign

while organomegaly and intestinal obstruction or perforation and abdominal lymphadenopathy were not very common. This data is consistent with other studies.^{13,21,39} These signs were not co-insides with the findings of Bernhard JS et al⁷. Peripheral lymphadenopathy was uncommon findings in patients with intestinal or peritoneal tuberculosis. It was not reported in the earlier studies as well.³⁹.

Routine laboratory investigations although non-specific but were helpful in this study to suspect the possibilities of abdominal tuberculosis. ESR was raised in all cases and mean value of ESR (In mm/1st hour), before treatment was 56 and after treatment was 28. Raised ESR has been reported in 50-100% of patients in earlier studies.^{13,19,33} Total and differential count of WBC were non-specific in our series, other studies had similar findings. But mean value of absolute lymphocyte count (per cu mm of blood) before treatment was 2425 and after treatment was 1709, which is consistent with earlier studies.^{13,19,33} In this study Mantoux test was done over total 42 patients out of 50 patients. MT-positive was in 88% case. These findings are similar with the report of a 10-year review by Gilinsky NH et al.¹⁹ In other studies, tuberculin test was positive in 70-80% patients.^{13,21,39} Patients with abdominal tuberculosis may have a negative tuberculin test and a normal ESR.^{13,19,33,39} One study has reported high ESR in 60% and positive Mantoux test in 24% of cases.⁴¹ In areas where TB is highly endemic, positive Mantoux test neither confirms nor excludes the diagnosis.^{35,42,43} In this study, 48% were diagnosed on the basis of increased ADA level (in ascitic fluid) and 52% were on the basis of tissue biopsy (histopathology) along with high index of clinical suspicion. In other studies ascitic fluid ADA has been considered to be a useful screening test with ATB, which are consistent with this study.^{44,45} Bacteriological diagnosis by culture of AFB was not possible due to lack of facilities. Other studies have also faced similar difficulties in the microbiological confirmation of the disease; most of them relied on histopathological diagnosis.^{13,46,47}

Previously there was longer duration of treatment schedule of ATT in the treatment of abdominal tuberculosis. Now six months treatment of four drugs ATT is recommended . But there is still contradiction among the physicians. The evidence in this study not only evaluate the national guideline but also shows its

effectiveness as 96% cases showed improvement in this series. A short course of ATT is justified for any form of abdominal tuberculosis in Bangladesh. The strength of this study was 52 % had tissue diagnosis and 48% had ADA raised status which indicates its importance in diagnosing tuberculosis in extrapulmonary sites.

There was many limitations in this study. ADA was done during the time of diagnosis but ADA was not possible to measure after completion of treatment during last follow up. It was due to non availability of ascetic fluid to perform ADA test. Some patients were diagnosed after laparotomy and some were after colonoscopy followed by biopsy. But all of them did not agree to do the same procedure after clinical improvement. So, 'cure' was not possible to declare to that group of patients. Sampling was random and in an urban medical college hospital. So that it may not be a representative of community or country. So, large scale study is required which should include private hospital and private chambers of specialist doctors, which may give real reflection of the country. HIV screening and MDR-TB screening were not done due to financial constrains. Culture of AFB was not done due to limited finance & availability.

Conclusion:

Short course six months regimen was found to be sufficient for treatment of abdominal TB, which were introduced by national guideline of tuberculosis control. Though there is much evidence of improvement of abdominal TB by nine months treatment or twelve months treatment or more time consuming treatment, but improvement by minimum time duration is cost effective and beneficial to increased compliance.

Though there is negligible failure of the regimen it can be concluded that six months regimen of ATT can be recommended for routine use of treatment of abdominal TB. Further large scale double blind trial to evaluate validation of this study is recommendation.

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