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A Clinical Trial of Nitazoxanide and Albendazole in Biliary Ascariasis

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Abstract A clinical trial was conducted in 2009 to evaluate the efficacy of albendazole and nitazoxanide in case of biliary ascariasis patients admitted in the medicine ward of Chittagong Medical College Hospital (CMCH), Bangladesh. The clinical trial was carried out between two study groups, individually group A and Group B, where group A patients were treated with Albendazole and group B patients with Nitazoxanide. Albendazole was administered (400mg) tablet single dose and Nitazoxanide (500mg) tablet were twelve hourly for 3 days. Relieve of pain time after taking antihelminthics were recorded and serial ultrasonograms (USG) were performed to observe the worm present or absent in biliary tree. Most of the respondents were within 18 to 35 years age group and it was about 68%. The patients were admitted with different clinical complications where most of them complaints of vomitting. Among the total respondents, about 87% were cured, while only 13% were not cured off their diseases. It was also noted that, the cure rate is more in nitazoxanide (89 Vs 85%), while the percentage of not cured individuals were more in albendazole (15 Vs 11%). The association between study groups and treatment outcome was not found to be statistically significant (P>0.05). There were no significant adverse effects or abnormalities in clinical chemistry values.

Keywords: *helminth infections, ascariasis, albendazole, nitazoxanide*

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1. Introduction

Ascariasis is a helminthic infection caused by ascaris lumbricoides. It is the commonest helminthic infection worldwide effecting about 1.4 billion people [8,11]. In Bangladesh 82% of the population are affected [4,12]. Most of the people of this country are poor and live in an inadequate hygienic condition and sanitation facilities which are in favors of helminthic infection. The number of cases of biliary ascariasis has been found to be increasing day by day.

Biliary ascariasis is a common and severe complication of ascariasis. It is one of the most common causes of acute abdominal pain among the hospitalized patients in our country. The most common symptoms are acute upper abdominal pain, nausea, vomiting, occasional fever and jaundice simulating acute cholecystitis. Common complications of biliary ascariasis are acute cholecystitis, acute cholangitis, acute pancreatitis, liver abscess and hepatobiliary lithiasis is a remote complication.

Ascarial invasion of the biliary tree is a well known entity. It accounts for 10%-19% of ascaris related hospital admissions. [1] Prevalence of biliary ascarisis in Bangladesh is 0.45% in male patients & 0.55% in female patients. [9] Female of third decade are more likely to be affected. Progesterone is a known inhibitor of smooth muscle contraction and significantly increase gallbladder volume and decrease its emptying time [11]. Ultrasonography has been shown an extremely useful tool in the diagnosis of biliary ascariasis. It is safe, quick and non invasive and should be the first imaging method employed when the disease is suspected.

CT scan is another highly sensitive non invasive method of identification of biliary ascariasis, but it is only indicated when USG report is negative or confusing. The role of Endoscopic Retrograde Cholangio Pancreatography (ERCP) is not only diagnostic but also therapeutic in case of biliary ascariasis. It is technically demanding procedure and costly. Not easily available in our hospital setting. [11] Other investigations are routine blood test, liver function test like SGPT, AlPO4, prothombin time, serum bilirubin, serum amylase, urinary amylase. Different modalities of treatment are available for biliary ascariasis such as conservative, endoscopic and surgical. In our study we deal with conservative treatment. Conservative treatment in the form of nothing by mouth, nasogastric suction, intravenous fluid, analgesic, antispasmodics, and antihelminthics applied to all patients. Reported success rate varies from 14.24%-97% [11]. Conservative management along with oral antihelminthic medication was found to be effective in treating biliary ascariasis in the majority of patients and can avoid surgical intervention or invasive endoscopic extraction [3]. Commonly used antihelminthics are Albendazole, Mebendazole, Pyrantel Pamoate. Commonly used drug with highest efficacy in ascariasis is Albendazole (95%) [2,10] which is widely used in our country for the treatment of biliary ascariasis. But efficacy of this drug in

biliary ascariasis is not known in our country. It works by decreasing ATP production in worm causing energy depletion, immobilization and finally death. Adult dose-400mg as a single dose. Contraindication- documented hyper sensitivity, pregnancy. Adverse effects – GI discomfort, headache.

Nitazoxanite is a newly recommended antihelminthic agent elicits its activity by interfering with pyruvate: ferredoxin oxidoreductase (PFOR) enzyme dependent electron transfer reaction, which is essential for anaerobic energy metabolism. Adult dose 500mg PO bid for 3 days. Contraindication - documented hypersensitivity. Side effects – Abdominal discomfort, diarrhoea, vomiting, headache. Nitazonanide is a drug used primarily for protozoal infection was shown to have 89% clinical efficacy in the treatment of ascariasis in rural mexico and may offer a future alternative to other medications in ascaris lumbricoids infection [5,6,7]. We want to open a new door for conservative treatment of biliary ascariasis with nitazoxanide & also compare its efficacy with albendazole and also try to find out the efficacy of albendazole in biliary ascariasis. It was a clinical trial conducted in medicine ward of Chittagong Medical College Hospital to evaluate the efficacy of albendazole and nitazoxanide in case of biliary ascariasis.

2. Materials and Methods

It is a randomized clinical trial conducted in the in-patient department of medicine, Chittagong Medical College Hospital (CMCH), Chittagong, Bangladesh from February 2009 to September 2009. Study population was selected after fulfilling the inclusion and exclusion criteria.

To observe outcome (survival rate) sample size was determined by using following formula:

$$N = \left\{ \frac{Z\alpha\sqrt{\pi^{\circ}(1-\pi^{\circ})} - Z\beta\sqrt{\pi^{1}(1-\pi^{1})}}{\pi^{\circ} - \pi^{1}} \right\}^{2}$$

Where,

$Z\alpha$ = 2 tailed Z value related to α = 0.05 is ±1.96

$Z\beta$ = 1 tailed Z value related to β = 0.84

π° = 80% (Assumptive Cure rate in Group A with single dose Albendazole)

π^{1} = 90% (assumptive cure rate in group B with 3 days Nitazoxanide).

$$\mathbf{N} = \left\{ \frac{1.96\sqrt{80(1\text{-}80)} - 0.84\sqrt{90(1\text{-}90)}}{80\text{-}90} \right\}^{2}$$

$$\mathbf{N} = \left\{ \frac{1.96\sqrt{80\times 79} - 0.84 - \sqrt{90\times \text{-}89}}{80-90} \right\}^{2}$$

$$= \left\{ \frac{1.96\times 79.5 - 0.84\times 89.5}{-10} \right\}^{2}$$

$$= \left\{ \frac{155.82\text{-}75.18}{\text{-}10} \right\}^{2}$$

$$= \left\{ \frac{80.64}{\text{-}10} \right\}^{2}$$

$$= \{8.06\}^{2}$$

$$= \mathbf{64.96}$$

$$\approx \mathbf{65}$$

So, estimated sample size is 65 in each group.

Group "A": A total of 65 (Sixty Five) Biliary ascariasis patient.

Group "B": A total of 65 (Sixty Five) Biliary ascariasis patient. According to card number patients will grouped.

Group A

A total of 65 biliary ascariasis patients given Albendazole 400mg tablet single dose.

Group B

A total of 65 biliary ascariasis patients given Nitazoxanide 500mg tablet twelve hourly for 3 days.

Relieve of pain after taking antihelminthic was recorded and serial USG was done to see the worm present or absent in biliary tree. Patient those USG shows no worm in biliary tree counted as cured by conservative treatment and discharged with advice to maintain personal hygiene and sanitation and taking regular antihelminthic to prevent recurrence of infection. Patient those pain relieved but follow up USG shows worm in biliary tree was also discharged and advised to come with another follow up USG after 10 days. Patients those shows no worm in biliary tree after 10 days follow up USG were counted as cured by conservative treatment and those USG shows worm in biliary tree were counted as not cured by conservative treatment and advised for endoscopic (ERCP) or surgical treatment. During treatment all patients were observed for adverse effects of drugs. Some complaints nausea, anorexia, headache but none of the patient complaints of any major adverse effects. After giving antihelminthic maximum time were taken to see relieve of pain were five days. After that if pain not relieved, patients were advised to endoscopic treatment, ERCP or surgery.

2.1. Institutional Approval

Proper permission was taken for this study from the department of medicine and ethical clearance from ethical review committee (ERC) of Chittagong Medical College Hospital.

2.2. Data Collection Procedure

Study population was selected after fulfilling the selection criteria on the basis of history and physical examination and USG findings of worm in the biliary tree. Me, self in collaboration with trained, briefed and oriented research associates from IMo's/HMO's /Interns of all three Medicine units recruited for monitoring of the patients. All patients & attendants were informed about the treatment options and written witnessed consent was taken from them. The patient/attendant was requested to draw one piece of paper from the box which contained

both A slip and B slip. The patients were treated according to allotted group. Then treatment outcome was observed by regular monitoring and serial USG of HBS of the patient.

2.3. Variable of the Study

2.3.1. Markers used to assess clinically improved

1. Pain -relieve
2. Vomiting-stop
3. Body temperature - <98.4°F (If previously febrile)
4. Non ecteric

2.3.2. Outcome markers

Complete recovery –
Clinically – Pain relieved
Symptom improved
Serial USG – No worm in biliary tree
Not recovered –
Clinically - pain not relieved within five days of taking antihelminthic
Symptom not improved
Serial USG – worm in biliary tree

2.4. Statistical Analysis

Collected data was compiled, checked and edited. Data processing and analysis was done with the help of computer using statistical software SPSS version 12.0 for Windows. All data was evaluated using statistical methods. Chi-square test and pair "t" test. In the interpretation of result <0.05 level of probability (P) was accepted as significant level.

2.5. Rationale

It is expected that the result of this study will help the physician to make early diagnosis and prompt treatment of biliary ascariasis with result of decrease morbidity and mortality, shortening hospital stay and also can prevent recurrences of this disease. We can create awareness to the patient and attendant about the serious side effects of ascariasis and teach them how to prevent ascariasis.

3. Results and Discussion

3.1. Results

The objective of this study was to compare the use of Albendazole and Nitazoxanide in the Management of Biliary ascariasis in terms of efficacy and safety and to see the effectiveness of Nitazoxanide and Albendazole in Biliary ascariasis. Distribution of treated cases with Albendazole and Nitazoxanide group is shown in tabulated form. Statistical analysis was done to show the significance of difference in between two groups. The results obtained after treatment were compared and analyzed to observe statistical significance.

Table 1. Distribution of the study groups

Study Groups	Frequency	Percentage (%)
Group A (Albendazole)	65	50.0
Group B (Nitazoxanite)	65	50.0
Total	130	100.0

Table 2. Distribution of *age* among study groups (with X^2 test significance)

Age Groups	Study Groups				Total	
	Group A		Group B			
	n	%	n	%	n	%
< 18 Years	01	1.5	08	12.3	09	6.9
18 to 35 Years	45	69.3	43	66.2	88	67.7
> 35 Years	19	29.2	14	21.5	33	25.4
Total	65	100.0	65	100.0	130	100.0
X^2 value = 6.247. df = 2. P = 0.044. Significant.						

Table 2 shows most of the respondents were within 18 to 35 years age group (about 68% among the total). Pearson's Chi-Square test was done to find out the association between study groups and age groups was found to be significant statistically (P < 0.05).

Table 3. Distribution of *sex* among study groups (with X^2 test significance)

Sex	Study Groups				Total	
	Group A		Group B			
	n	%	n	%	n	%
Male	09	13.8	05	7.7	14	10.8
Female	56	86.2	60	92.3	116	89.2
Total	65	100.0	65	100.0	130	100.0
Male : Female Ratio	1 : 6.2		1 : 12		1 : 8.3	
X^2 value = 1.281. df = 1. P = 0.258. Not Significant.						

Table 4. Distribution of presenting symptoms among the study groups (with X^2 test significance)

Presenting Symptoms		Study Groups				Total		Sign.
		Group A		Group B				
		N	%	n	%	n	%	
Vomiting	Present	50	76.9	50	76.9	100	76.9	X^2 = 0.000
	Absent	15	23.1	15	23.1	30	23.1	P = 1.000
	Total	65	100	65	100	130	100	NS
Fever	Present	09	13.8	16	24.6	25	19.2	X^2 = 2.427
	Absent	56	86.2	49	75.4	105	80.8	P = 0.119
	Total	65	100.0	65	100.0	130	100.0	NS
Emesis of Worm	Present	11	16.9	15	23.1	26	20.0	X^2 = 0.769
	Absent	54	83.1	50	76.9	104	80.0	P = 0.381
	Total	65	100.0	65	100.0	130	100.0	NS
Diarrhea	Present	04	6.2	08	12.3	12	9.2	X^2 = 1.469
	Absent	61	93.8	57	87.7	118	90.8	P = 0.226
	Total	65	100	65	100	130	100	NS

Table 3 depicts the sex distribution among the study groups. In both the groups, females were predominant (about 89 % among the total), while in Group B, females were more (about 92 % in Group B versus 86 % in Group A). However, the association between study groups and sex was not found statistically significant (P > 0.05). The Male: Female Ratio was 1: 8.3 among the total.

Table 4 describes the presenting symptoms among the study groups. It was seen that, vomiting was present in about 77 % of the respondents, while emesis of worm and fever were present among 20 % and 19 % of the total respectively. Only 9.2 % of the total has got diarrhoea as a symptom. However, the associations between study groups and occurrence of symptoms were not significant statistically.

Table 5 illustrates the presenting signs among the study groups. It was noted that, epigastric tenderness was present in cent percent respondents, while right rectus abdominis muscle tenderness was found among about 85 % of the total. Jaundice was detected more among Group B (45 Vs 40 %). However, the associations between study groups and occurrence of signs were not found to be significant statistically.

Table 6 expresses the distinct clinical presentations among the study groups. It was observed that, biliary colic was the most common presentation among the total respondents (51.5 %), while acute cholangitis, cholecystitis and pancreatitis were found in about 22 %, 13 % and 10 % patients, respectively. Proportionately, biliary colic was found more among Group A (54 Vs 49 %), while acute cholangitis and cholecystitis were seen more among Group B (26 Vs 18 % and 17 Vs 9 %). However, the association between study groups and clinical presentations was not found to be statistically significant.

Table 7 details the statistics of haematological investigations among the study groups. The mean total WBC, neutrophil and eosinophil counts were 8946.2 ± 2521.9 per cu mm SD, 63.4 ± 10.4 % SD and 5.5 ± 2.4 % SD, respectively, among the total respondents. The mean ESR was 42.65 ± 28.7 mm SD among the total. However, the mean differences between the study groups were not significant statistically.

Table 5. Distribution of presenting signs among study groups (with X^2 test significance)

Presenting Signs		Study Groups				Total		Sign.
		Group A		Group B				
		n	%	n	%	n	%	
Epigastric Tenderness	Present	65	100	65	100	130	100	-
	Absent	00	0.0	00	0.0	00	0.0	
	Total	65	100	65	100	130	100	
Tenderness of Right Rectus Abdominis Muscle	Present	54	83.1	56	86.2	110	84.6	$X^2 = 0.236$ P = 0.627 NS
	Absent	11	16.9	09	13.8	20	15.4	
	Total	65	100	65	100	130	100	
Murphy's Sign	Positive	09	13.8	15	23.1	24	18.5	$X^2 = 1.840$ P = 0.175 NS
	Negative	56	86.2	50	76.9	106	81.5	
	Total	65	100	65	100	130	100	
Jaundice	Present	26	40.0	29	44.6	55	42.3	$X^2 = 0.284$ P = 0.594 NS
	Absent	39	60.0	36	55.4	75	57.7	
	Total	65	100	65	100	130	100	

Table 6. Distribution of distinct clinical presentations among study groups (with X^2 test significance)

Clinical Presentations	Study Groups				Total	
	Group A		Group B			
	N	%	N	%	n	%
Biliary Colic	35	53.8	32	49.2	67	51.5
Acute Cholangitis	12	18.5	17	26.2	29	22.3
Acute Cholecystitis	06	9.2	11	16.9	17	13.1
Acute Pancreatitis	08	12.4	05	7.7	13	10.0
Cholelithiasis	03	4.6	00	0.0	03	2.3
Hepatic Abscess	01	1.5	00	0.0	01	0.8
Total	65	100.0	65	100.0	130	100.0
X^2 value = 7.159. df = 5. P = 0.209. Not Significant.						

Table 7. Statistics of hematological investigations among study groups

Hematological Investigations		N	Mean	± Sd	Median	Range
Total Count of WBC (per cu mm)	Group A	65	8735.38	2397.62	8000	5000 – 18500
	Group B	65	9156.92	2642.08	8500	5000 – 18000
	Total	130	8946.15	2521.91	8000	5000 – 18500
Neutrophil Count (%)	Group A	65	62.97	9.24	62	47 – 88
	Group B	65	63.88	11.54	62	35 – 89
	Total	130	63.42	10.42	62	35 – 89
Eosinophil Count (%)	Group A	65	5.85	2.41	6	1 – 15
	Group B	65	5.06	2.29	5	1 – 12
	Total	130	5.45	2.37	5	1 – 15
ESR (mm in 1st Hour)	Group A	65	40.68	27.86	30	20 – 115
	Group B	65	44.63	29.64	32	18 – 124
	Total	130	42.65	28.72	32	18 – 124

Table 8. Statistics of biochemical investigations among study groups

Biochemical Investigations		N	Mean	± Sd	Median	Range
Serum Alkaline Phosphates (U/L)	Group A	65	85.66	83.55	70.00	48 – 665
	Group B	65	69.82	30.72	64.00	38 – 225
	Total	130	77.74	63.21	67.50	38 – 665
SGPT (U/L)	Group A	65	39.89	12.37	36.00	28 – 86
	Group B	65	45.08	26.59	38.00	28 – 210
	Total	130	42.48	20.82	38.00	28 – 210
Serum Bilirubin (mg/dl)	Group A	65	1.92	1.48	1.20	0.4 – 7.3
	Group B	65	1.94	1.44	1.20	0.4 – 5.0
	Total	130	1.93	1.45	1.20	0.4 – 7.3
Prothrombin Time (Minutes)	Group A	65	10.66	1.91	10.00	7 – 16
	Group B	65	11.08	2.06	11.00	8 – 17
	Total	130	10.87	1.99	11.00	7 – 17
Serum Amylase (U/L)	Group A	65	233.40	571.12	77.00	38 – 3491
	Group B	65	190.20	225.60	95.00	52 – 1026
	Total	130	211.80	433.07	78.00	38 – 3491

Table 8 expresses the statistics of biochemical investigations among the study groups. The mean serum alkaline phosphatase and SGPT were 77.7 ± 63.2 U/L SD and 42.5 ± 20.8 U/L SD, respectively, while the mean serum bilirubin and prothrombin time were 1.9 ± 1.5 mg/dl SD and 10.9 ± 2.0 minutes SD, respectively, among the total respondents. It was noted that, mean serum alkaline phosphatase was more in Group A (86 Vs 70 U/L), while mean SGPT was more in Group B (45 Vs 40 U/L), proportionately.

Table 9. Distribution of pain relief among study groups (n = 130) (with X^2 test significance)

Pain Relief	Study Groups				Total	
	Group A		Group B			
	n	%	N	%	n	%
Relieved	60	92.3	63	96.9	123	94.6
Not Relieved	05	7.7	02	3.1	07	5.4
Total	65	100.0	65	100.0	130	100.0
X^2 value = 1.359. df = 1. P = 0.244. Not Significant.						

Table 9 shows the distribution of pain relief among the study groups. It was seen that, among the total respondents, about 95% patients were relieved from their pain, while in only 5.4% cases, pain were not relieved. It was also noted that, the percentage of patients who were not relieved off their pain was more among Group A (7.7 Vs 3.1%). The association between study groups and pain relief was not found to be statistically significant (P > 0.05).

Table 10. Distribution of first follow-up USG findings among study groups (n = 123) (with X^2 test significance)

First Follow-Up USG Findings	Study Groups				Total	
	Group A		Group B			
	n	%	N	%	n	%
Worm in Biliary Tract	23	38.3	18	28.6	41	33.3
No Worm in Biliary Tract	37	61.7	45	71.4	82	66.7
Total	60	100.0	63	100.0	123	100.0
X^2 value = 1.318. df = 1. P = 0.251. Not Significant.						

Table 10 depicts the distribution of first follow-up ultrasonography findings among the study groups. It was seen that, among the respondents who has been relieved off their pain (n = 123), about 67 % has got no worm in their biliary tract, while in 33%, worm was found within the biliary tract. It was also noted that, the presence of worm within biliary tract was proportionately more in Group A (38 Vs 29%). The association between the study groups and first follow-up ultrasonography findings was not to be significant statistically (P > 0.05).

Table 11. Distribution of first follow-up USG comments among study groups (n = 41) (with X^2 test significance)

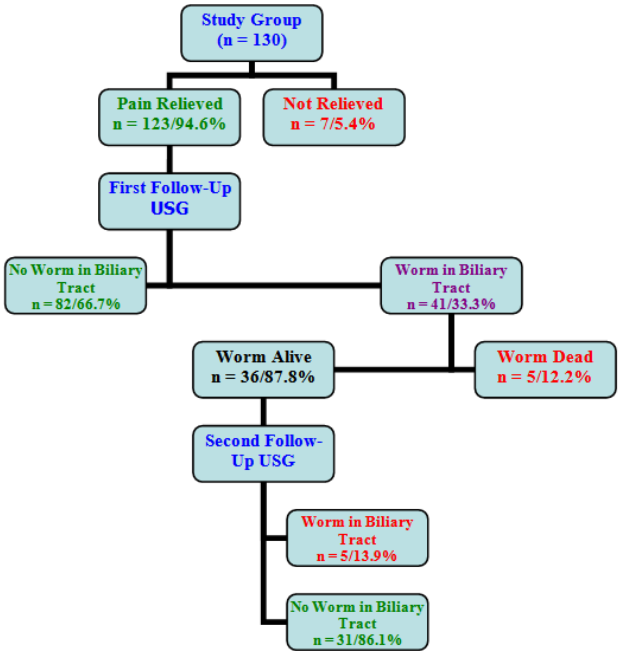
First Follow-Up USG Comments	Study Groups				Total	
	Group A		Group B			
	n	%	N	%	n	%
Worm Alive	21	91.3	15	90.0	36	87.8
Worm Dead	02	8.7	03	10.0	05	12.2
Total	23	100.0	18	100.0	41	100.0
X^2 value = 0.599. df = 1. P = 0.439. Not Significant.						

Table 11 shows the distribution of first follow-up ultrasonography comments among the study groups. It was seen that, among the respondents who has been found with worm in biliary tract in first follow-up ultrasonography (n = 41), about 88 % has got alive worm within. The association between the study groups and first follow-up ultrasonography comments was not to be significant statistically (P > 0.05).

Table 12. Distribution of second follow-up USG findings among study groups (n = 36) (with X^2 test significance)

Second Follow-Up USG Findings	Study Groups				Total	
	Group A		Group B			
	n	%	N	%	n	%
Worm in Biliary Tract	03	14.3	02	13.3	05	13.9
No Worm in Biliary Tract	18	85.7	13	86.7	31	86.1
Total	21	100.0	15	100.0	36	100.0
X^2 value = 0.007. df = 1. P = 0.933. Not Significant.						

Table 12 shows the distribution of second follow-up ultrasonography findings among the study groups. It was seen that, among the respondents who has been found with alive worm in biliary tract in first follow-up ultrasonography (n = 36), only about 14 % has got worm remaining within. The association between the study groups and first follow-up ultrasonography comments was not to be significant statistically (P > 0.05).



Flowchart 1. Illustrates the organization of overall treatment protocol and outcomes of treatment

Table 13. Distribution of treatment outcome among study groups (n = 130) (with X^2 test significance)

Treatment Outcome	Study Groups				Total	
	Group A		Group B			
	n	%	n	%	n	%
Cured	55	84.6	58	89.2	113	86.9
Not Cured	10	15.4	07	10.8	17	13.1
Total	65	100.0	65	100.0	130	100.0
X^2 value = 0.609. df = 1. P = 0.435. Not Significant.						

Table 13 depicts the distribution of treatment outcome among the study groups. It was seen that, among the total respondents, about 86.9% were cured, while only 13.1% were not cured off their diseases. It was also noted that, the cure rate is more in Group B (89 Vs 85 %), while the percentage of not cured / treatment failure was more in Group A (15 Vs 11 %). The association between study groups and treatment outcome was not found to be significant statistically (P > 0.05).

3.2. Discussion

Albendazole is a commonly used antihelminthic in patient of biliary ascariasis coming with acute abdominal pain. The present study was done to compare the efficacy of Albendazole and Nitazoxanide in the treatment of biliary ascariasis and to compare the effectiveness of Nitazoxanide and Albendazole in the treatment of biliary ascariasis. Among patients enrolled in the study majority were aged between 18-35 years (67.7%), majority were female (89.2%). Female were 6 times more likely to be affected than males. Nasima Akhter 2005 [9] shows overall prevalence of biliary ascariasis was 0.45% in male patients and 0.55% in female patients. Which translates into susceptibility of young female to biliary ascariasis. Our study shows that biliary ascariasis is more prone to develop in young female patients, but it is also a commonest cause of acute abdominal pain in young male in our country which is (10.8%) in our study. Age and sex across the groups were homgenous (P>0.5) and does not seem to put any confounder effect on the outcome.

Distinct clinical presentations among study group were biliary colic found in 67(51.5%) patients, acute cholangitis found in 29 (22.3%) patients, acute cholecystitis present in 17 patients (13.1%). acute pancreatitis present in 13 (10%) patients, cholelithiasis present in 3 patients (2.3%) and one (0.8%) patient came with hepatic abscess. Mobin Khan, department of Hepatology, BSMMU, Dhaka, 2007 [13] conducted a study which shows, 97.4% presented with biliary colic, 15.6% with acute cholangitis, 9.1% with obstructive Jaundice, 6.5% with acute pancreatitis, 6.5% with cholelithiasis,6.5% presented with acute cholecystitis and 2.6% presented with liver abscess. In our study data among clinical presentations were different from previous studies. Here acute pancreatitis prevalence is higher than previous study. So in our setting if any young patient comes with acute pancreatitis one important differential diagnosis will be biliary ascariasis. In a study done by Madhumita Mukhopadayay 2008 [14] the result was 28.56% come with obstructive jaundice, 16.7% came with cholangitis, 2.4% came with acute pancreatitis, 2.4% came with hepatic abscess.

In our study presenting symptoms were vomiting present in 76% patients, fever present in 19.2% patient, emesis of worm present in 20% of patients and diarrhoea present in 9.2% of patients. In Madhumita mukhopadhyay 2008 [14] data vomiting was present in 76.2% patients, fever present in 16.7% patients, emesis of worm in 38.1% patients and no patients present with diarrhoea. In a study conducted by Uzzal Kanti Das 2007 [3] shows 83.72% patient presented with vomiting, 13% with fever. In our study presenting symptoms among study groups were different from previous studies. Abdominal pain was present in 100% of patients signs among study groups were epigastric tenderness present in 100% of patients. Tenderness of right rectus abdominis muscle presents in 84.6% of cases. Murphy's sign positive in 18.5% cases, jaundice present in 42.3% cases. Tenderness of right rectus Abdominis muscle is a common presenting sign in biliary ascariasis patients. In 110 (84.6%) cases out of 130, it was present. There was no previous data about this sign. So this will be a new diagnostic sign in biliary ascariasis. When we suspect any patient as biliary ascariasis we must examine for this sign.

Haemotological investigations among study groups show that total count of WBC were mean 8946.15, ±SD 2521.91, (range 5000-18500), Nutrophill count were mean 63.42, ±SD 10.42, (range 35-89), Eosinophill count mean 5.45, ±SD 2.37, (range 1-15), ESR mean 42.65, ±SD 28.72, range (18-124), Haematological investigations were variable and total count of WBC & Neutrophil count was raised in patients presents with fever, acute cholecystitis and other complications. Antibiotics were given to those patients and 34 patients (26.2%) of this study received antibiotics with other conservative treatment. Serum Alkaline phosphatase was mean 77.74, ±SD 63.21, median 67.50 (range 38-665), SGPT mean 42.48, ±SD 20.82, median 38.00 (range 28-210). Serum bilimbin mean 1.93, ± 1.45, median 1.2 (range 4-7.3). Prothrombin time mean 10.87, ±SD 1.99, median 11, (range 7-17).

Our first parameter to see conservative treatment outcome was pain, 123 patients (94.6%) pain relived by conservative management. Maximum time we wait for pain relieve were 5 days after that time we advised them for other interventional treatment like Endoscopy, ERCP or surgery. Pains of 7 patients were not relieved within 5 days and we advised them for endoscopy. Pain relieved time was recorded. Also examined the patients for other symptomatic improvement. Group A taking Albendazole showed pain relieve in 92.3% patients and group B taking Nitazoxanide showed pain relieve in 96.9% patients. After that we advised for another USG as follow up to observe the worm. Among them 82 (66.7%) patients USG showed no worm in biliary tree. We discharged them with proper advice to take regular antihelminthic and proper education about personal hygiene to prevent recurrence. In 41 (33.3%) patients USG showed worm present in biliary tree. Among this 41 patients worm was alive in 36 patients and 5 patients having dead worm in their biliary tree. We also discharged 36 patients and advised them to come with another follow up USG after 10 days to see the worm as spontaneous migration of worm is also occurs. Those 5 patients presented with dead worm in their biliary tree were advised for Endoscopy or ERCP. In second follow up USG in 31 patients USG showed no worm in biliary tree and in 5 patients USG showed worm in biliary tree and they were advised for endoscopic treatment.

Among 130 patients 113 patients (86.9%) were cured by conservative treatment. 17 patients (13.1%) were not cured by conservative treatment and needs endoscopic management & ERCP or surgery. In group A 84.6% patients cured with conservative treatment and in group B it was 89.2%.

Our parameters observed treatment outcome with conservative treatment were pain relieved by conservative treatment along with antihelminthic drugs and worm removed after pain relieved in follow up USG. The results essentially translate into the superiority of group B over group A particularly in pain relieve and worm removal in follow up USG. In light of present study findings it can be assumed that Nitazoxanide will be a new option antihelmentihic in the treatment of biliary ascariasis and can be used where Albendazole is contraindicated.

4. Conclusion

Present study was conducted with a view to compare the efficacy of Albendazole & Nitazoxanide in biliary ascarasis and also see the effectiveness of Albendazole & Nitazoxanide in biliary ascariasis. Although Albendazole is an effective antihelminthic in treatment of biliary ascariasis but Nitazoxanide can be a newer option for treatment of biliary ascariasis. Nitazoxanide should be used in biliary ascariasis where Albendazole is contraindicated. Ultrasonography is a non-invasive and effective initial investigation for diagnosis of biliary ascariasis but follow up USG is also necessary to see the worm- whether it is present or removed from the biliary tree and can take decision about further management.

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