

ETHICAL REVIEW COMMITTEE, ICDDR,B.

226

Principal Investigator Pieter Speelman

Trainee Investigator (if any) _____

Application No. 80-049(P)

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Giardiasis in an out-

Project status:

patients clinic in Dacca, Bangladesh:

- (X) New Study
- () Continuation with change
- () No change (do not fill out rest of form)

retrospective study

Give the appropriate answer to each of the following (If Not Applicable write NA).

Source of Population:

- (a) Ill subjects Yes No
- (b) Non-ill subjects Yes No
- (c) Minors or persons under guardianship Yes No

Does the study involve:

- (a) Physical risks to the subjects Yes No
- (b) Social Risks Yes No
- (c) Psychological risks to subjects Yes No
- (d) Discomfort to subjects Yes No
- (e) Invasion of privacy Yes No
- (f) Disclosure of information damaging to subject or others Yes No

Does the study involve:

- (a) Use of records, (hospital, medical, death, birth or other) Yes No
- (b) Use of fetal tissue or abortus Yes No
- (c) Use of organs or body fluids Yes No

Are subjects clearly informed about:

- (a) Nature and purposes of study Yes No
- (b) Procedures to be followed including alternatives used Yes No
- (c) Physical risks Yes No
- (d) Sensitive questions Yes No
- (e) Benefits to be derived Yes No
- (f) Right to refuse to participate or to withdraw from study Yes No
- (g) Confidential handling of data Yes No
- (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No

5. Will signed consent form be required:

- (a) From subjects Yes No
- (b) From parent or guardian (if subjects are minors) Yes No

NA

6. Will precautions be taken to protect anonymity of subjects Yes No

NA

7. Check documents being submitted herewith to Committee:

Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).

X Protocol (Required)

X Abstract Summary (Required)

Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)

Informed consent form for subjects

Informed consent form for parent or guardian

Procedure for maintaining confidentiality

Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

NA

I agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

80-049(P)

Rec'd.

30.12.80

SECTION I - RESEARCH PROTOCOL

1. Title: Giardiasis in an outpatients clinic in Dacca, Bangladesh; a retrospective study
2. Principal Investigator: Dr. Pieter Speelman
Co Investigator: Dr. Majid Molla
3. Starting Date: December 1980
4. Completion Date: January 1981
5. Total Direct Cost:
6. Scientific Program Head:

This protocol has been approved by the Working Group.

Pathogenesis and Therapy

Signature of Scientific Program Head:

W.B. [Signature]

Date:

30/11/80

7. Abstract Summary:

The purpose of this limited study is to review the charts of patients, visiting the outpatients department of ICDDR,B from January the first till December 31st 1980. The available data will be collected from all patients with giardia cysts and or trophozoites in their stools.

The reason for examining these data is to describe the population of patients with giardiasis, to find out which concomitant parasitic infections they have, to explore if there is any specific stool-picture and to find out if there is any seasonal variation.

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective:

The objective of this retrospective study is to learn more about giardiasis among the patients consulting the outpatients clinic of ICDDR,B.

2. BACKGROUND:

Giardia Lamblia is a cosmopolitan parasite with worldwide distribution. Incidences vary between 2 and 25 to 30 percent ¹⁾ Frequently the incidence rate is under-estimated because only a single stool specimen is examined.

Most patients harbouring this parasite are asymptomatic; in tropical countries, but also in moderate climates.

Giardiasis has become a common parasitic cause of water-borne outbreaks of disease. Beavers have been incriminated as an animal reservoir. Food and drinks, prepared with contaminated water, are probably frequent sources of infection. High rates of infection are found among children in nurseries and institutions most likely a result of hand to mouth transmission²⁾.

During the last years increasing clinical and epidemiological evidence has been produced that G. Lamblia may be an important pathogen in man. Why some people develop symptoms and others do not, is not understood.

The incubation period of symptomatic giardiasis is usually about 2 weeks. The most common complaint is diarrhoea (sometimes with explosive onset), or loose stools which may be bulky foul-smelling and are often passed only in the mornings.

The stools may contain mucus, but blood and pus are absent. Other symptoms include abdominal distention and discomfort (upper epigastric

cramps), weakness anorexia, nausea, vomiting, flatulence, weightloss, depression and in children failure to thrive. The acute stage may last from a few days to several months. Some people may have subacute symptoms lasting for months or years³⁾.

Parasitologic confirmation of the diagnosis may be difficult. Stool examination can give false negative results. The presence of G. Lamblia - cysts or trophozoites-may be irregular and unpredictable⁴⁾.

Intermittent passage of parasites in the stool may be related to periods of active multiplication⁵⁾. Probably related to the intermittent passage of parasites is the fact that examination of stools on alternate days has provided an increased yield of positive specimens. Stool examination using a concentration method will kill the trophozoites. A false negative result can be obtained if the stool contains these forms only.

One stool examination only is diagnostic in 50⁶⁾-76⁵⁾%. Utilizing direct smear and formol-ether concentration-tests 76% were positive on the first specimen, 90% were confirmed with two specimens and 97% of the cases were determined to be positive with three specimens⁵⁾ ⁶⁾

Delays of several months between the onset of symptoms and the diagnosis are common⁷⁾.

Studies from a number of centers have reported malabsorption with giardiasis d-Xylose and fat-malabsorption have been reported from India ⁸⁾ ⁹⁾ and North America ¹⁰⁾ ¹¹⁾ ¹²⁾ ¹³⁾

In overland travellers with symptomatic giardiasis impaired Xylose and fat absorption has been shown in 58% and 38% of patients but unlike other groups, they found abnormal absorption of Vit B₁₂ in 50% of patients¹⁴⁾.

Abnormalities of the jejunal mucosa are found in association with malabsorption.¹⁵⁾

The extent to which secretory immunoglobulin contributes to eradication is not known, but it has been recognized for some time¹⁶⁾ that deficiency of humoral activity is associated with an increased prevalence of giardiasis, suggesting that immunoglobulin is important.

However in generally healthy individuals, giardiasis is not etiologically related to relative immunoglobulin deficiencies¹⁷⁾. Hypochlorhydria or achlorhydria have been shown to facilitate *Giardia* infections¹⁸⁾.

Serum antibody to G. lamblia has been found^{19) 20) 21)} showing that parasite antigen is absorbed through the intestinal epithelium. There is still doubt if and how often giardia invades the tissue. Possibly cell-mediated hypersensitivity may contribute to mucosal damage.

In giardiasis, like in tropical sprue, colonization of the small intestine with enterobacteria has been found²²⁾.

At this moment several drugs are used in the treatment of giardiasis, quinacrine, metronidazol, furazolidine and tinidazol.

B. SPECIFIC AIMS:

1. To describe the population (number, age, sex) of patients with giardiasis, diagnosed at the outpatients clinic.
2. To find out how many times these patients have giardiasis only and how many times there are concomitant parasitic infections.
3. To explore if there is any seasonal variation.
4. To correlate a quantitative assessment of cysts and tr trophozoites in the stools (+ -> 4 +) with the stoolpicture (WBC, RBC, blood, mucus, pH).

C. METHODS OF PROCEDURE

1. Review of charts.

The charts, made by the laboratory during ME-stool examinations, will be reviewed to find the patients with giardiasis.

2. From these charts available data will be recorded in the data sheet, attached with the protocol for entering onto computer discs, so that questions can be asked for interrelationships and interpretations.

D. SIGNIFICANCE

Examination of charts in this retrospective review will provide valuable information on the magnitude of the problem of giardia infections among the patients consulting our outpatients clinic.

Probably this study will form the basis for a new prospective study of giardiasis in the near future.

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SECTION III - BUDGET

PERSONNEL SERVICES:

			<u>Salary</u>	
<u>Name</u>	<u>Position</u>	<u>% Effort</u>	<u>Taka</u>	<u>Dollars</u>
1. Dr. P. Speelman	Investigator	25% x 2 mths	-	1016
2. Dr. M. Milla	Co Inverstigator	10% x 2 mths	-	350
3.	Statistician	10% x 2 mths	2000	-
4.	Coding Assistant	100% x 2 mths	4000	-
5.	Clerk	20% x 2 mths	620	-
Sub Total :			6620	1366

BUDGET SUMMARY

<u>Category</u>	<u>Taka</u>	<u>Dollar</u>
1. Personnel	6620	1360
2. Supplies	Nil	-
3. Equipment	Nil	-
4. Hospitalization cost	Nil	-
5. Travel	Nil	-
6. Animal Resources	Nil	-
7. Logistic Support	Nil	-
8. Printing / Reproduction	Nil	-
9. Computer Service 10 hours	10,000	-
10. Key Punch	2,000	-
Total :	18,620	1360

Tk. 18,620 = US \$ 1240

Total US dollars 2600

Data Sheet

Information

Code list

Card plan

Study No.

1. Date

day month year

/ / / /
1 3
/ / / / / / / /
4 9

2. Patient No.

/ / / / / / / /
10 14

3. Age

day month year

/ / / / / / / /
15 20

4. Sex

 1 2
male female

/ /
21

5. Location

/ / / / / / / /
22 27

6. Consistency

Watery	<u> 1 </u>
liquid	<u> 2 </u>
loose	<u> 3 </u>
soft	<u> 4 </u>
formed	<u> 5 </u>
not available	<u> 9 </u>

/ / /
28

7. pH

 1 2
alkaline acid

/ / /
29

8. Blood

No blood	<u> 1 </u>
trace	<u> 2 </u>
positive	<u> 3 </u>

/ / /
30

9. Mucus

No mucus	<u> 1 </u>
trace	<u> 2 </u>
1 +	<u> 3 </u>
2 +	<u> 4 </u>

/ / /
31

10. WBC range (number)	<u> </u>	<u> </u>	<u> / / / / </u>	<u> / / / / </u>
	lower limit	upper limit	32 34	35 37
11. RBC range (number)	<u> </u>	<u> </u>	<u> / / / / </u>	<u> / / / / </u>
	lower limit	upper limit	38 40	41 43
12. Macrophage (number)	<u> </u>	<u> </u>	<u> / / </u>	<u> / / </u>
	lower limit	upper limit	44	45
13. Giardia	<u>cysts</u>			
	Not present	<u> 9 </u>		
	+	<u> 1 </u>		
	1 +	<u> 2 </u>		<u> / / </u>
	2 +	<u> 3 </u>		46
	3 +	<u> 4 </u>		
	4 +	<u> 5 </u>		
	<u>trophozoites</u>			
	not present	<u> 9 </u>		
	+	<u> 1 </u>		
	1 +	<u> 2 </u>		
	2 +	<u> 3 </u>		<u> / / </u>
	3 +	<u> 4 </u>		47
	4 +	<u> 5 </u>		
14. Entamoeba histolytica veg.	<u> 1 </u>	<u> 2 </u>		<u> / / </u>
	yes	no		48
15. Entamoeba histolytica veg+RBC	<u> 1 </u>	<u> 2 </u>		<u> / / </u>
	yes	no		49
16. Entamoeba histolytica cysts	<u> 1 </u>	<u> 2 </u>		<u> / / </u>
	yes	no		50

17.	Entamoeba Coli veg.	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{51}$
18.	Entamoeba Coli cyst	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{52}$
19.	Trichomonos hominis	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{53}$
20.	Helminths	absent	$\frac{1}{\quad}$	
		strongyloides larvae	$\frac{2}{\quad}$	$\frac{\quad}{54}$
		others	$\frac{3}{\quad}$	
21.	Ova			
	Ascaris lumbricoides	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{55}$
	Trichuris trichiura	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{56}$
	Hookworm	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{57}$
	Strongyloides stercoratis	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{58}$
	Hymenolepis nana	$\frac{1}{\text{yes}}$	$\frac{2}{\text{no}}$	$\frac{\quad}{59}$
22.	Neutral fat			
		absent	$\frac{1}{\quad}$	
		1 +	$\frac{2}{\quad}$	
		2 +	$\frac{3}{\quad}$	$\frac{\quad}{60}$
		3 +	$\frac{4}{\quad}$	
		4 +	$\frac{5}{\quad}$	