Original Article

Evaluation of Feconomics® versus traditional techniques for diagnosis of intestinal parasitic infections among schoolchildren in Sohag, Egypt

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ABSTRACT

Background: Intestinal parasitic infections (IPIs) still stand as the foremost obstacles in public health of schoolchildren in developing countries. Rapid accurate diagnosis is essential for implementation, and monitoring of programs for community control of IPIs.
Objective: To assess the efficacy of Feconomics® technique in comparison with traditional techniques i.e., direct wet mounts, and formalin ethyl acetate concentration technique (FECT) for the diagnosis of IPIs in school children.
Subjects and Methods: A cross-sectional study was conducted on 100 schoolchildren aged 6 to 12 years. Demographic data were collected using a structured questionnaire. All stool samples were microscopically examined by direct saline and iodine wet mounts, FECT, and Feconomics® technique. Concentrated stool samples were stained with Kinyoun's acid-fast method.
Results: The detection rate of intestinal parasites by direct wet mounts, FECT and Feconomics® technique were 16%, 34 %, 58% respectively. The most prevalent parasite detected by Feconomics® was *Cryptosporidium* spp. (18%) followed by *G. lamblia* (15%), *H. nana* (13%), *E. histolytica/dispar* complex (9%), *E. coli* (7%), *C. cayetanensis* (2%), *E. vermicularis* (2%), and 1% for each of *Blastocystis* spp., intestinal *Microsporidium* and *A. lumbricoides*. The detection rate of IPIs was not significantly associated with age, sex, residence or family size but was significantly higher in autumn than winter (P<0.03). The sensitivity, specificity, positive and negative predictive values (PPV, NPV) of Feconomics® compared with direct wet mounts as gold standard were 100%, 50%, 27.6% and 100% respectively with an accuracy of 58% and area under curve (AUC) of 0.750. Sensitivity, specificity, PPV and NPV of Feconomics® compared with FECT as gold standard were 91.2%, 59.1%,53.4%, and 92.9%, respectively with an accuracy of 70% and AUC of 0.751.
Conclusion: Use of Feconomics® is suggested for the routine diagnosis of IPIs in developing countries especially since a centrifuge is not required and it eliminates large stool particles.

Keywords: diagnostic accuracy; direct wet smear; Egypt; Feconomics®; intestinal parasitic infections; schoolchildren.

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INTRODUCTION

In Egypt, IPIs represent a significant public health alert due to their high morbidity and mortality. Individuals of all ages are affected by IPIs; however, children are the most commonly predisposed, which is linked to their poor hygienic practices, and weak immune status[1]. In children, IPIs cause a number of negative health outcomes such as malnutrition, anemia, impaired growth and cognitive development[2]. Early detection of the causative intestinal parasites plays a significant role in implementing timely and correct treatment, which relieves the patients' symptoms and also prevents recurrences[3].

Microscopic examination of stool specimens is essential for diagnosis of intestinal parasites. The direct wet smear and the concentration techniques were considered as the most common techniques used in detecting intestinal parasites. Concentration of stool samples allows detection of low numbers of parasites in the specimen that might be missed using the wet smear only[4]. There are two types of stool concentration methods, sedimentation and flotation, that are designed to isolate protozoa, larvae or eggs of helminths by centrifugation or variation in the specific density of the microorganisms[5]. Besides, FECT was commonly used in laboratories owing to its ability to isolate parasites from fresh and preserved fecal samples[6]. However, the concentration methods are labor intensive, time consuming, and often necessitate centrifugation[5,7].

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Owing to these drawbacks, a new, simple, and fast concentration Feconomics® technique is an alternative for fecal concentration in routine laboratory practice being ready-to-use and eliminating the need for centrifugation and floatation[3,5,8]. The present study aimed to evaluate the performance of Feconomics® in comparison with traditional methods.

SUBJECTS AND METHODS

This descriptive analytical study was conducted in Medical Parasitology Department, Faculty of Medicine, Sohag University from June 2022 to January 2023.

Study design: A cross-sectional study was carried out to assess the efficacy of Feconomics® technique in comparison with traditional techniques, i.e., direct saline and iodine wet mounts, FECT, and Kinyoun's acid-fast stain.

Study area: This study was conducted in Sohag Governorate, Upper Egypt. Sohag is situated in the southern region of the country about 467 kilometres to the south of Cairo. It extends into the Nile Valley with a total size of 1547 km^2 with an estimated population of 5,706,510.

Study population: The randomized sampling population included 100 schoolchildren aged 6-12 years of both genders attending El-Emary and El-Sadat primary schools.

Laboratory examination: Stool samples were collected in clean, dry, wide-mouth containers with tight-fitting lids. Each collected sample was divided into two parts; the 1st part was examined macroscopically, and microscopically by direct wet mounts, and FECT and then stained with Kinyoun's acid-fast method; the 2nd part was concentrated by Feconomics® technique. according to the manufacturer's instructions. Feconomics® is manufactured by Salubris Inc, Boston, USA with a patent-pending product application number of 2010/07549. It consists of a plastic cup containing about 10 ml sodium acetate acetic acid formalin (SAF) solution and a small plastic bag containing absorbent beads of 1 to 3 mm in diameter (Fig. 1). About two grams of stool were added to this cup then the absorbent beads were added to the mixture and homogenized by shaking manually. After 3 minutes (time needed for beads to absorb the excess solution and leave the concentrate behind), one drop of the concentrate was mixed with iodine and examined under a microscope then stained with Kinyoun's acid-fast method to assess the presence of intestinal coccidia[3,5].

(A) (B)

Fig. 1. Feconomics® Kit; **(A)** Stool sample mixed with SAF. **(B)** Package of absorbent beads added to sample.

Statistical analysis: Data were analyzed using IBM SPSS Statistics for Windows version 25 and Medcalc version 15.8.0 25.0, expressed as mean ±SD, number and percentage. Sensitivity, Specificity, PPV, NPV, and accuracy were calculated for evaluated Feconomics® considering direct wet mounts or FECT as gold standard. Cohen's kappa and its significance were calculated to assess the agreement among the studied diagnostic techniques with the level of significance set using the following criteria: ≤0 = poor, 0.01–0.20 = slight, 0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = substantial and 0.81–1 = almost perfect. Significance was considered at $P< 0.05$.

Ethical considerations: The study was approved by Medical Research Ethical Committee (MREC) of the Faculty of Medicine, Sohag University, Egypt with the IRB registration No. Soh-med-22-04-17. This study was registered at ClinicalTrials.gov under registry No. NCT05360472 from September 2022 to January 2023. It followed the tenets of the Declaration of Helsinki. Written informed consent was obtained from each child's parents after explaining the process and the purpose of the study.

RESULTS

A total of 100 fecal samples from school children were collected and examined for intestinal parasites using direct wet mounts, FECT and Feconomics®. Their ages ranged from 6 to 12 (8.94±2.004) years. Male children constituted 50%; those living in rural areas were 58%; those with family size ≥ 5 members were 71%; those with no symptoms were 77%; and those who had diarrhea 14%, colic 3% and both colic and diarrhea 6%.

The detection rate of IPIs by direct wet mounts, FECT and Feconomics® were 16%, 34%, 58% respectively among the children (Table 1). The most common detected parasites by Feconomics® were *Cryptosporidium* spp.18 (18.0%) followed by *G. lamblia* 15(15.0%), *H. nana* 13 (13.0%), *E. histolytica/E. dispar* complex 9 (9.0%), *E. coli* 7 (7.0%), *C. cayetanensis* 2 (2.0%), *E. vermicularis* 2 (2.0%), 1 (1%) for each of *Blastocystis* spp., intestinal *Microsporidium*, and *A. lumbricoides*.

The IPIs weren't significantly associated with age, sex, residence or family size (Table 2). The infection

was significantly associated with the season where the detection rate proved to be higher in October (autumn) (51.2%) than in December (winter) (25%) (P<0.03) (Table 3).

The sensitivity, specificity, PPV & NPV of Feconomics® compared with direct wet mounts as gold standard were 100%, 50%, 27.6%, 100% respectively with an accuracy of 58% and AUC of 0.750. Kappa value was 0.242 indicating fair agreement between both diagnostic methods with statistically significant difference (P<0.0001) (Table 4, Fig 2). The sensitivity, specificity, PPV and NPV of Feconomics® compared with FECT as gold standard were 91.2%, 59.1%, 53.4% and 92.9% respectively with an accuracy of 70% and AUC of 0.751. Kappa value was 0.429 that indicate moderate agreement between both diagnostic methods with statistically significant difference (P<0.0001) (Table 5, Fig 3).

Table 1. The detection rate and distribution of IPIs detected by direct wet mounts, FECT and Feconomics® (n =100).

	Direct wet mounts		FECT		Feconomics®		Statistical analysis	
	No,	%	No,	%	No,	%	X^2	*P* value
Pathogenic protozoa								
Cryptosporidium spp.	0	0	11	11.0	18	18.0	18.857	<0.001*
G. lamblia	8	8.0	12	12.0	15	15.0	2.394	0.302
E. histolytica/E. dispar complex	2	2.0	6	6.0	9	9.0	4.614	0.100
C. cayetanensis	0	0	1	1.0	2	2.0	2.020	0.364
Blastocystis spp.	0	0	0	0	1	1.0	2.007	0.367
Intestinal *Microsporidium*	0	0	0	0	1	1.0	2.007	0.367
Non-pathogenic protozoa								
E. coli	1	1.0	1	1.0	7	7.0	8.247	0.016*
Helminths								
H. nana	5	5.0	6	6.0	13	13.0	5.163	0.076
E. vermicularis	0	0	0	0	2	2.0	4.027	0.134
A. lumbricoides	0	0	0	0	1	1.0	2.007	0.367
Total positive	16	16	34	34	58	58		

Table 2. The detection rate of IPIs by FECT among 100 outpatients according to sociodemographic risk factors.

	Positive IPIs (n=34)	Negative IPIs (n=66)	*P* value
Age			
6-9 years	16 (47.05%)	26 (39.39%)	0.46
9-12 years	18 (52.94%)	40 (60.6%)	
Gender			
Boy	19 (55.88%)	31 (46.97%)	0.4
Girl	15 (44.12%)	35 (53.03%)	
Residence			
Rural	21 (61.76%)	37 (56.06%)	0.58
Urban	13 (38.24%)	29 (43.94%)	
Family size			
< 5 members	9 (26.47%)	20 (30.3%)	0.69
≥ 5 members	25 (73.53%)	46 (69.7%)	

Table 3. Seasonal detection rate of IPIs in studied samples using FECT.

	Autumn (Oct.) No. = 39		Winter (Dec.) No. = 28		Statistical analysis
	No,	%	No,	%	
***Cryptosporidium* spp.**	6	15.4	3	10.7	***X2* = 4.6** ***P* = 0.03**
G. lamblia	5	12.8	2	7.1	
H. nana	4	10.3	1	3.6	
***E. histolytica/E. dispar* complex**	3	7.7	1	3.6	
E. coli	1	2.5	0	0	
C. cayetanensis	1	2.5	0	0	
Total positive	20	51.2	7	25	

Table 4. Efficacy of Feconomics® in comparison with direct wet mounts.

Feconomics®	Direct wet mounts		Total	Statistical analysis
	Positive	Negative		
Positive	16	42	58	
Negative	0	42	42	
Sensitivity%	100			**Kappa= 0.242**
Specificity%	50			**P= 0.0001***
PPV%	27.6			
NPV%	100			
Accuracy%	58			
AUC	0.750			

***:** Significant

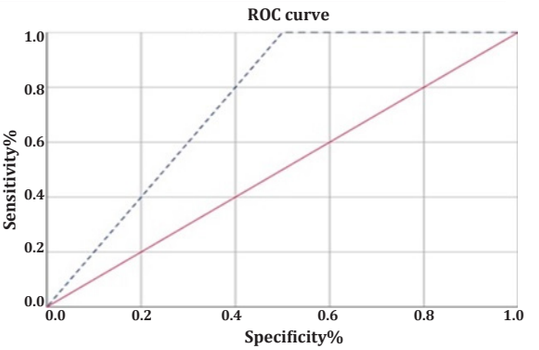

Fig. 2. ROC curve analysis of Feconomics® compared to direct wet mounts in detection of parasites. ROC curve showed AUC=0.750 and *P*= 0.002. ROC, receiver operating characteristic; AUC, area under the curve.

Table 5. Efficacy of Feconomics® in comparison with FECT.

Feconomics®	FECT		Total	Statistical analysis
	Positive	Negative		
Positive	31	27	58	
Negative	3	39	42	
Sensitivity%	91.2			**Kappa= 0.429**
Specificity%	59.1			**P= 0.0001***
PPV%	53.4			
NPV%	92.9			
Accuracy%	70			
AUC	0.751			

***:** Significant

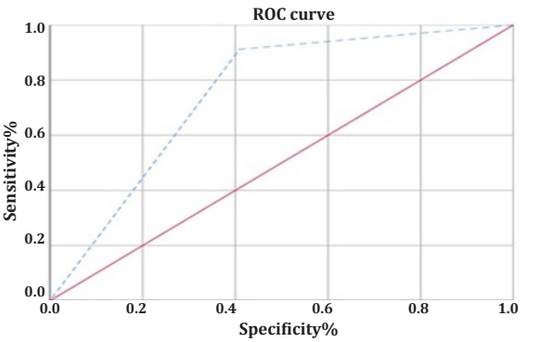

Fig. 3. ROC curve analysis of Feconomics® compared to FECT in detection of parasites. ROC curve showed AUC=0.751 and P =0.0001. ROC, receiver operating characteristic; AUC, area under the curve.

DISCUSSION

Masses of schoolchildren are at high risk for infection with protozoan and helminthic parasites[9]. Hence, accurate and rapid diagnosis is crucial in abating parasitic infections[10]. Drawbacks of the standard concentration techniques encouraged the development of commercial products such as Feconomics®. These are new ready to use kits for concentration of stool samples in parasitological diagnosis[8].

In the present study, the microscopic examination showed that detection rate of IPIs of schoolchildren by direct wet mounts, FECT and Feconomics® were 16%, 34%, 58% respectively. In addition, Feconomics® revealed that *Cryptosporidium* spp. (18%) was the most common parasite followed by *G. lamblia* (15%), *H. nana* (13%), *E. histolytica/E. dispar* complex (9%) and *E. coli* (7%). Besides, Feconomics® showed distinctive higher sensitivity for detection of all parasites and also for individual parasites when compared to direct wet mounts and FECT and showed significant difference in detection of *Cryptosporidium* spp. and *E. coli* when compared to results of direct wet mounts and FECT (*P*<0.001, *P*<0.016, respectively). Our results were close to results attained by Kurt *et al.*[5] in which Feconomics® identified higher number of parasites (38.2%) compared to FECT (32.2%), and *Blastocystis* spp. was found to be the most common parasite, followed by *G. lamblia*. The study conducted by Koltas *et al.*[3] also confirmed high prevalence with Feconomics® of 15.9% in comparison to 13.3% with FECT and 9.8 % with direct wet mounts examination, detecting *Blastocystis* spp. (4%) *G. lamblia* (3.8%) and *E. coli* (1.6%). Moreover, our results agreed with a report by Abdel-Gaffar *et al.*[8] in which Feconomics® significantly showed better results as compared to other methods regarding detection of all parasites, and *Cryptosporidium* spp. was the most commonly detected parasite (25.7%) followed by *G. lamblia* (16.2%) and *E. histolytica/E. dispar* complex (12.5%).

In our study, the detection rate of IPIs was higher among the age group of 9-12 (52.94%), in male patients (55.88%), in those living in rural areas (61.76%) and in groups of family size ≥ 5 members (73.53%); however, there were no significant statistical differences observed regarding age or gender or residence or family size. In this respect we

agreed with El-Nadi *et al.*[11] who didn't find significant relation between infection and children age groups or gender in Sohag; but disagreed with them[11] and with Dyab *et al.*[12] in reporting significantly higher IPIs for those living in rural areas and having large families of more than 5 members (P<0.05, P<0.006 respectively). Discrepancies in reports probably occur according to standard of living and hygienic conditions.

Regarding the seasonal variation effect we recorded a higher detection rate of IPIs in October (51.2%) more than in December (25%) with significant statistical differences (P<0.03). A similar study from Jordan[13], reported that the prevalence of different parasites showed the highest rate of infection (62%) during the summer months with a peak in September, and statistically significant difference (P<0.05) to the recorded rate in winter, November–February (16%), with a peak in January.

In the current study, the sensitivity and specificity of Feconomics® compared with direct wet mounts were 100% and 50%, respectively while the sensitivity and specificity compared with FECT were 91.2% and 59.1%, respectively. This result was supported by Kurt *et al.*[5] who reported a sensitivity and specificity of Feconomics® of 92 and 85% respectively. Also, the results were confirmed by Koltas *et al.*[3] who reported higher sensitivity and specificity of Feconomics® over FECT and direct wet mounts, (96 and 97%, respectively). In addition, the results agreed with the study of Abdel-Gaffar *et al.*[8], as they verified that Feconomics® showed distinctive higher sensitivity for detection of all parasites (96%) and also for individual parasites when compared to all other methods. It was suggested that the false-negative results of FECT may be attributed to low parasite counts in the stool sample, in spite of the centrifugation step included in the preparation of the specimen[5], and a false positive result may be due to that the presence of debris. The superiority of Feconomics® may be attributed to the absorbent beads that help homogenization and concentration of the samples leading to clarity of sediment and lack of debris. The technique replaces centrifugation by using absorbent beads that help in concentrating parasites' eggs and cysts, as well as in maintaining characteristic morphology. It was also emphasized that it might be possible to conduct further molecular studies such as PCR using the fecal sample concentrated by Feconomics®. However this requires additional valuation[3,5].

Our current results showed that Feconomics® is an effective new tool in the concentration of stools without sediment or debris in the examined sample. In addition to eliminating the need for centrifugation, and flotation, it is more time saving than FECT. Another advantage is working in a closed system which is less hazardous to the working personnel. However, the limitations of this study were the small sample size because of high cost of Feconomics®, and the tests employed for the diagnosis of intestinal parasites did not include more accurate methods such as PCR.

In conclusion, Feconomics® is simple, rapid, highly sensitive, and can be used to yield rapid results for outbreak situations, for screening proposals and for massive assays in endemic areas where large numbers of samples need to be analyzed.

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Conflict of interest: There are no conflicts of interest.

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