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Clinical Evaluation of Herbal Formulation for the Treatment of Intestinal Worms

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Abstract: Present research work was conducted to study the clinical efficacy of coded herbal medicine Kemol in comparison with Piperazine for treatment of intestinal worm infestation. One hundred patients with intestinal worm infection were randomly assigned into two groups, 50 in each group. Test group was treated with Kemol and control group was treated with Piperazine. The effect of both drugs for treatment of intestinal worm infestation was observed before and after treatment. Comparison of data recorded by physician relating to these variables showed significant differences between test and control groups ($p<0.05$). The efficacy of the test treated medication (Kemol) was superior as $p = 0.03$. Kemol is more effective than the Piperazine in the treatment of intestinal worms.

Key words: Intestinal worm infestation, herbal medicine, piperazine

INTRODUCTION

There are number of worms that can live within the human body. The worms live in the digestive tract, especially in the intestines, from where they obtain their nutrition. Worm infestations are present in people of all ages but they are much more of a problem in children. Roundworms are the parasitic, invertebrate worms belonging to the phylum Nematoda. These worms have unsegmented elongated bodies that are pointed at the ends. Certain roundworms are microscopic whereas some can be visible to the naked eye. Pinworm, hookworm and whipworm are the three major types of roundworms. As they are parasites, they can be found anywhere, in the soil, in bodies of animals as well as humans. Roundworm infection is most common in hot or tropical climates. Roundworms in humans are found in the intestines, the gastro-intestinal tract and sometimes even in the lungs. They are intestinal parasites. Roundworm infection is most commonly observed in children than in adults. Eggs of roundworms (never the mature worms) enter human body through contaminated food, water and soil. Children are more prone to getting infected with roundworms as they play in the dirt and mud and are not aware of the importance of maintaining hygiene. Most parasites require some host to complete their life cycle. Animals can also serve as the host (Bethony, 2001).

Roundworm: The roundworm, also known as Ascaris lumbricoides or the large intestinal human roundworm, is more common in areas of the world with an appropriate climate, a high population density and where sanitation is a problem. The World Health Organization (WHO) estimates that about 25% of the world's population is infected with roundworm. The Ascaris causes an infection known as ascariasis. Living worms are pale pink in colour and have a bright red stripe of their bodies. The female roundworm typically ranges in size from 16-33 cm inches and can grow to the thickness of a pencil. The male roundworm is smaller than its female counterpart (Cox, 2008).

Upto approximately one hundred riundworms can infect a single human host. The female roundworm can lay as many as 200,000 to 300,000 eggs a day. The eggs of the roundworm have an incredibly thick shell and are very resistant to variations in temperature and humidity in the environment. They are coated with a jelly-like substance with a lumpy surface that allows the eggs to stick to almost anything. Although it takes about two to three weeks for them to become infective, roundworm eggs will remain infective in the soil for some time. This infection usually occurs via the faecal-oral route. Once someone ingests infective eggs, usually after contact with infected food or hands, then the eggs are carried to the lower intestines where they hatch into larvae. The larvae then migrate through the body, passing through the intestinal wall and are carried by the blood or the lymphatic system to the lungs. Once in the lungs, the roundworm larvae break out of the pulmonary capillaries into the air sacs, ascending into the throat and descending into the small intestine again. After about two months in the small intestine the roundworms mature into adults. The roundworm adults remain in the small intestine feeding on the contents of the intestine.

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They do not actually feed on the human host as many of the other nematodes do.

Types of roundworm infections: There are many types of roundworms that can cause different health problems in human beings. Symptoms of roundworms in humans also vary according to the type of roundworm which actually causes the infection. The most common type of roundworm infection called ascariasis caused by the large intestinal roundworm known as Ascaris lumbricoides. These roundworms can grow up to 14 inches in length. Once the eggs of these roundworms reach the intestine, larvae are released, which in turn perforate the intestinal wall and enter the liver and lungs through the bloodstream or the lymphatic system. Once inside the lungs, these worms can cause cough, chest pain, breathing trouble, etc. From the lungs, they travel to the airways and the back of the mouth, where they are ingested to the stomach along with saliva. They reach the intestine and grow.

Enterobius vermicularis is another type of roundworm which is known as pinworm and causes enterobiasis. Pinworms are small and thread-like in appearance. They inhabit the colon and rectum of humans, especially children.

Causes and transmission modes of intestinal worms: Parasites can get into the intestine by going through the mouth from uncooked or unwashed food, contaminated water or hands, or by skin contact with larva infected soil. When the organisms are swallowed, they move into the intestine, where they can reproduce and cause symptoms (Park, 2008).

Children are particularly susceptible if they are not thoroughly sterilized after coming into contact with infected soil that is present in environments that they may frequently visit such as sandboxes and school playgrounds. People in developing countries are also at particular risk due to drinking water from sources that may be contaminated with parasites that colonize the gastrointestinal tract (Matienzo and Velez, 1954).

There are several ways in which intestinal worms can be caused in human beings. The most prominent mode of transmission is through any kind of contact with the feces of an infected person. This can be when human excrement is used as fertilizer in farms, or when clothes of infected people and soiled diapers of children are washed. People who are in contact with the soil that contains human feces (like farmers) stand a high chance of getting infected with intestinal worms. Eating food that is contaminated with the worms is another common way of transmission. Worms can exist on the outer layers of the food. Hence people consuming foods without washing them thoroughly are prone to intestinal worms. Raw meats, milk and eggs can contain worms that can cause intestinal infections. Meats like beef, pork and fish that are undercooked contain live worms. People maintaining poor hygiene habits can not only get themselves infected with intestinal worms, but they can also pass on the infections to other people. Worms like hookworms enter the human body through the soles of the feet. Hence people who move around on the open ground with bare feet have a very high degree of getting infected with hookworms (Maldonado, 1956).

Sign and symptoms of intestinal worms: There can be mild or severe signs of roundworms in humans, depending on the type of worm and its number in the human body. The most frequent symptom from roundworm is upper abdominal discomfort. Other symptoms are asthma, eye pain, insomnia and rashes due to the secretions or waste products from the worms. In large numbers they can cause blockages in the intestinal tract, hemorrhages when penetrating the intestinal wall, appendicitis, peritonitis, abscesses in the liver, hemorrhagic pancreatitis, loss of appetite and an insufficient absorption of digested foods. Adults grow to 15 inches long. Hookworm larvae penetrate the skin. When hookworm reach adulthood, they can sap the victim's strength, vitality and overall well-being. Young worms use their teeth to burrow through the intestinal wall and feed on blood. Symptoms from hookworm are iron deficiency, abdominal pain, loss of appetite, craving to eat soil, protein deficiency, dry skin and hair, skin irritations, edema, distended abdomen, stunted growth, delayed puberty, mental dullness, cardiac failure and death. In case of pinworm infection, vaginal or anal itching along with abdominal pain is experienced. Whereas in case of hookworm and whipworm infection, there may be blood in stools or black colored stools. The person may be rashes if infected with hookworm or whipworm. In case of severe roundworm infection in children, the worms are even found in bed or during passing of stools (Burrows, 1950).

Roundworm infections are more common in warm climates and usually result from the lack of proper hygiene or sanitary conditions. The pinworm is the most common of all roundworm infections in the US. Because it infects children most often and is easily spread, infections will be found mainly where humans gather like in families, day cares, camps and schools. Other more common roundworm infections in humans include: Enterobius vermicularis, the pinworm that causes enterobiasis (not very dangerous but does cause a great deal of itching around the anus which is then spread from dirty fingernails). *Ascaris lumbricoides*, the large intestinal roundworm that causes ascariasis Necator and Ancylostoma, two types of hookworms that cause ancylostomiasis causes intestinal blockage, abdominal swelling and severe pain and shortness of breath). Trichuris trichiura, the whipworm that causes trichuriasis (can cause severe anemia and rectal prolapse). Strongyloides stercoralis, that causes strongyloidiasis (an intestinal infection that persists because of the worm's ability to go virtually unnoticed. It may replicate for decades). *Trichinella spiralis* that

causes trichinosis (also called Trichinellosis is caused by eating undercooked meat infected with the worm. It can cause severe flu-like symptoms with diarrhea that can last for months, eye swelling, joint pain and coordination may be affected (Shah and Zargar, 2006).

Diagnosis: The majority of internal parasites are diagnosed by microscopic examination of the feces for eggs that are released by the adult parasites. The two primary methods of fecal analysis are direct observation and fecal flotation. In direct observation a smear is made of some fecal material on a microscope slide and the slide is analyzed for parasite eggs. It is used to detect eggs that don't show up well during the fecal flotation. Fecal flotation is the most accurate way to detect most internal parasites. A sample of fresh feces is put into a special solution that causes any eggs that might be present to float to the top and adhere to a cover slip. The cover slip is put on a microscope slide for analysis. This concentration of eggs substantially increases the chance of finding any eggs that might be present. The flotation solution is added to the fecal container and a cover slip is placed on the top to collect any eggs that float to the surface after a 5 min wait. The cover slip is put on a microscope slide and carefully scanned for the eggs of any parasite. Diagnosing roundworm infection involves identifying the species of worm causing the infection. Steps in diagnosis may include: Physical exam, Stool and urine samples identify microorganisms in the stool and urine, Blood tests detect infection in the blood, Muscle or skin biopsy find infections that affect the muscle or skin, Ultrasound reveals worms in lymph nodes, X-ray reveals large worms in abdominal region, Sampling of contents of small intestine may reveal the presence of roundworms (Massara and Enk, 2004).

Treatment: Roundworm can lay as many as 200,000 to 300,000 eggs a day, but it takes a couple of weeks for an infection to set in in a host. Mebendazole is used for those older than 2 years. It is given twice a day for 3 days and is not repeated unless there is evidence that it needs to be. Pyrantel pamoate is a non-prescription medicine used mainly for pinworm infections. Two doses are usually needed and given 2 weeks apart since it kills the adult worms but not the eggs it has laid. Piperazine is given as a single dose and often combined with senna. This is a good combination since piperazine paralyzes the worms while senna expels them. Levamisole paralyzes the worms but is not used in some countries. It is used only when other medications have not worked. Antiparasitic medications are the primary treatment for roundworm infections. The medication prescribed depends on which specific roundworm infects the person. Surgical procedures may sometimes be needed, but they are not always readily available in areas where roundworm infections are common. Roundworm infections can cause inflammation in the intestines and reduce the absorption of essential nutrients, including vitamins A and B6. Vitamin A deficiencies are believed to increase the risk of parasitic infection (Bradley and Jackson, 2004).

MATERIALS AND METHODS

Study design: This case controlled examination based study was conducted at Shifa-ul-Mulk Memorial Hospital for Eastern Medicine on the patient living in the rural areas of 27-70 villages surrounding Madinat-ul-Hikmah Hamdard University, Karachi. The study has been conducted according to the principles of good clinical practice that is, an informed consent was obtained from the patients before enrollment and proper history and clinical examination were recorded on each follow up. The study was carried out in the period 2007-2009. Chi-square test and exact fisher test were used to analyze the statistical difference.

Patients and dosage form design: The study was carried out on the patients of ages between 5-16 years. The trial was conducted on 100 patients irrespective of socioeconomic status at outpatient department in Shifaul-Mulk-Memorial Hospital. The patients were divided in control and test group. Controlled group received Piperazine and the test group received herbal medicine Kemol Tab. 500 mg (three times per day orally). Kemol is a herbal coded formulation of compound drugs with their synergistic action of herbal drugs design and calculated according to herbal pharmacopoeia, monographs of Unani medicine on scientific basis. Each 500 mg Kemol tablet contains *Embelia ribes* Burm. f 125 mg, *Mallotus philippinensis* Muell 125 mg, *Butea monosperma* Lam 125 mg, *Mentha arvensis* Linn. 125 mg. The Kemol as such comprises of four different types of botanical drugs the quantity of which were considered on the basis of ethnomedical information as well as pointed out in Hamdard Pharmacopoeia and Tibbi Pharmacopoeia (Said, 1969). Furthermore Piperazine 500 mg (three times a day) is a recommended dosage form as given in Pharma guide. The patients suffering from diabetes, hypertension, renal impairment and other musculoskeletal disorders were excluded from this study. As such it was monitored that patients were not suffering from any other serious disease or ailment. The literature search very clearly displayed that Piperazine is not involved in any way with the food interaction such as vegetables and meat (chicken and fish).

Setting: The therapeutic evaluations of these medicines were conducted at Shifa-ul-Mulk Memorial Hospital, for Eastern Medicine, Hamdard University. The patients were registered from the general O.P.D. and hospitalized to the clinical Research ward of the Hospital. All the patients selected for the study, were thoroughly examined and clinical history was recorded.

Sample selection: The sample was selected from the out patient department registered and enrolled in Shifa ul Mulk Memorial Hospital and on the basis of diagnosis of intestinal worm infestation and inclusion and exclusion criteria the patient fulfilling the intestinal worm infestation criteria as candidates were selected. The study period include was from 2007-2009. Among this population all the patient suffering from intestinal worm were interviewed immediately and upon their consent to participate they were grouped as test and control groups.

Data collection: Data collected for this research work included filling of clinical trial proforma through personal interview, personal observation and use of case record, file and documents. The designed clinical trial proforma specified the clinical feature and information to be filled by the physician for record and utilized in statistical assessment.

Statistical analysis: Statistical analysis were performed using SPSS and excel software, the Chi Square Test was determined. All differences were considered statistically significant by generating a 'p-value' from test statistics. The significant result with 'p-value' less than 0.05 was considered as statistically significant.

Inclusion criteria:
The cases suffering from intestinal worms were selected on the following lines:
The patients suffering from intestinal worms.
Patients living in Gadap Town, Karachi.
Patients having no obvious pathological finding on routine examination
All socioeconomic classes including lower middle and higher.
Male and female patients between 5 to 16 years of age.

Exclusion criteria: The major exclusion criteria for this trial were:
Patients belonging to the distant area outside Karachi were excluded because of inherent difficulty in follow up.
Chronic and secondary infectious cases were excluded.
Patients having chronic infections e.g. tuberculosis, leprosy or neoplastic events in the medical history were considered reason for exclusion.
Patient having history of adverse reaction to any of the study drugs as or contraindicated for their use.

Patient characteristics: The mean age of 27 male patients prescribed Kemol as calculated was 9.92 and standard deviation was 3.13 as shown in Table 1. The mean age of 23 female patients prescribed Kemol as calculated was 9.60 and standard deviation was 3.10 as shown in Table 1. The mean age of 50 patients (both male and female) prescribed Kemol as calculated was 9.78 and standard deviation was 3.09 as shown in Table 1. The mean age of 26 male patients prescribed Piperazine as calculated was 9.62 and standard deviation was 3.20 as shown in Table 1. The mean age of 24 female patients prescribed Piperazine as calculated was 9.31 and standard deviation was 2.87 as shown in Table 1. The mean age of 50 patients (both male and female) prescribed Piperazine as calculated was 9.46 and standard deviation was 3 as shown in Table 1.

Table 1: Mean distribution of age

Treatment group	Sex	Mean	No. of patients	SD
Test drug (Kemol)	Male	9.92	27	3.13
	Female	9.60	23	3.10
	Total	9.78	50	3.09
Control drug (Piperazine)	Male	9.62	26	3.20
	Female	9.31	24	2.87
	Total	9.46	50	3.00
Total	Male	9.92	53	2.99
	Female	9.61	47	3.11
	Total	9.62	100	3.03

SD = Standard deviation

Table 2: Distribution of age

	Treatment group		
Age group	Test (n)	Control (n)	Total (n)
5-8 years	22	25	47
9-12 years	15	14	29
13-16 years	13	11	24
Total	50	50	100

Treatment assignment and follow-up: One hundred patients consented to participate in the study. Pretreatment clinical and laboratory parameters (stool D/R). for the treatment groups were noted. The two treatment groups were comparable in efficacy results and side effects of the medicine administered. All subjects were clinically studied and completed the assigned therapy during the period 2007 to 2009.

RESULTS

According to the statistical analysis a significant difference was observed between two treated groups ($p<0.05$) at the end of therapy. All differences that were equal to or more than the set cut-off values were considered clinically significant. The evaluation of treatment is significantly improved in the test group compared with control group at the end of therapy. So it can be concluded that the efficacy of the Kemol is highly significant when patient is treated at least for 1 week and although the efficacy of the Kemol is slow but it has long lasting effects.

Significance of the results: A significant difference was identified, concluding that associated symptoms of intestinal worms were significantly reduced when treated with Kemol. The data offered support to the experimental hypothesis and therefore null hypothesis was rejected.

Table 3: Intestinal worms in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Intestinal worms	Yes	50	50	100	1.00
	No	00	00	00	
	Total	50	50	100	

Table 4: Improvement in reducing sign and symptoms of intestinal worms at end of therapy

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Intestinal worms	Complete improvement	47(94%)	40(80%)	87	0.037
	No improvement	3(6%)	10(20%)	13	
	Total	50	50	100	

Table 5: Abdominal pain in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Abdominal pain	No	44	43	87	0.755
	Yes	7	7	14	
	Total	50	50	100	

Table 6: Abdominal pain in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Abdominal pain	Improved	10(83.33%)	7(46.67%)	17	0.049
	Not improved	2(16.67%)	8(53.33%)	10	
	Total	12	15	27	

Table 7: Abdominal bloating in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Abdominal bloating	Absent	43	45	88	0.538
	Present	7	5	12	
	Total	50	50	100	

Table 8: Abdominal bloating in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Abdominal bloating	Improved	6(85.71%)	1(20%)	7	0.02
	Not improved	1(14.29%)	4(80%)	5	
	Total	7	5	12	

Table 9: Blood in stool in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Blood in stool	No	41	39	80	0.617
	Yes	9	11	20	
	Total	50	50	100	

94% of patients had complete improvement using Kemol and 80% of patients using Piperazine had complete improvement at end of therapy.

Abdominal pain: 83.33% of patients prescribed Kemol had complete improvement and 46.67% of patient prescribed Piperazine had complete improvement.

Abdominal bloating: 85.71% of patients prescribed Kemol had complete improvement and 20% of patients prescribed Piperazine had complete improvement.

Blood in stool: 88.89% of patients prescribed Kemol had complete improvement and 54.45% of patients prescribed Piperazine had complete improvement.

Table 10: Blood in stool in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Blood in stool	Improved	8(88.89%)	5(54.45%)	13	0.042
	Not improved	1(11.11%)	6(54.55%)	7	
	Total	9	11	20	

Table 11: Bed wetting in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Bed wetting	No	44	43	87	0.766
	Yes	6	7	13	
	Total	50	50	100	

Table 12: Bed wetting in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Bed wetting	Improved	5(83.33%)	2(28.57%)	7	0.048
	Not Improved	1(16.67%)	5(71.43%)	6	
	Total	6	7	13	

Table 13: Nausea and vomiting in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Nausea and vomiting	No	26	29	55	0.546
	Yes	24	21	45	
	Total	50	50	100	

Table 14: Nausea and vomiting in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Nausea and vomiting	Improved	22(91.67%)	14(66.67%)	36	0.036
	Not improved	2(8.33%)	7(33.33%)	9	
	Total	24	21	45	

Table 15: Weight loss in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Weight loss	Yes	13	10	23	0.476
	No	37	40	77	
	Total	50	50	100	

Table 16: Weight loss in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Weight loss	Improved	11(84.62%)	4(40%)	15	0.025
	Not improved	2(15.38%)	6(60%)	8	
	Total	13	10	23	

Table 17: Itching around the anus in total patients at baseline

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Itching	Yes	10	12	22	0.629
	No	40	38	78	
	Total	50	50	100	

Table 18: Itching around the anus in total patients at after treatment

		Treatment group			
Complaint at baseline		Test (Kemol)	Control (Piperazine)	Total (n)	p-value
Itching	Improved	9(90%)	6(50%)	15	0.044
	Not improved	1(10%)	6(50%)	7	
	Total	10	12	22	

Bed wetting: 83.33% of patients prescribed Kemol had complete improvement and 28.57% of patients prescribed Piperazine had complete improvement.

Nausea and vomiting

Weight loss: 84.62% patients prescribed Kemol showed improvement in weight loss and 40% of patients prescribed Piperazine had complete improvement.

Itching: 90% patients prescribed Kemol showed improvement in itching around the anus while 50% patients prescribed Piperazine showed improvement in Itching.

DISCUSSION

The human body especially the stomach and the intestine is home to a number of parasites such as hookworms, roundworms, flatworms, etc. These parasites are helpful in the digestive process. However, at times, the parasites also create several problems. There are various causes for the problems caused-contaminated food, dirty fingers and food, faulty living, etc. Some of the symptoms observed in people suffering from intestinal worms are nausea and vomiting, foul breath, dark circles under the eyes, inflammation of the intestine and lungs, nausea, vomiting, anaemia and nutritional disorders and loss of weight. Although allopathic drugs are commonly used for treatment of intestinal worms. These drugs have side effects like nausea, vomiting and muscle tremors. In order to overcome this problem, there is a great need to find new medicinal agents which have good efficacy and less adverse effects. Herbal medicine could be choice to treat intestinal worms and considering this option a formulation has been designed based on literature citation. Therefore, one of the good combinations could be a coded herbal formulation Kemol. It has been previously reported that *Embelia ribes* has antihelmentic effect and is commonly used for the treatment of intestinal worms. A previous study (Said, 1969; Chopra and Nayarand, 1956) demonstrated that *Embelia ribes* has a mild laxative activity and clinical studies have shown that extracts are effective against ascarides. So by taking advantage the coded herbal formulation Kemol, contains a total four ingredients in which *Embelia ribes* and *Butea monosperma* are the basic chief ingredients and others such as *Mallatus philipinensis*, *Menthus avernusi* will be function for the treatment of intestinal worms. This unicenter trial has been conducted, for comparing the efficacy and safety of herbal coded formulation Kemol as a test drug with Allopathic medicine Piperazine as control drug for the treatment of intestinal worms. Study was under taken as an observational paradigm in which objectives have been defined as comparative to evaluate herbal and allopathic medicine so as to asses their efficacy in helmintic patients. This study shows high prevalence of intestinal worms in Gadap Town. In accordance with previous study has been found that intestinal worm infection is high in children than in adults.

Conclusion: Kemol is more effective than the Piperazine in the treatment of intestinal worm infection as determined by p value <0.03. Therefore, control drug showed lesser efficacy than the test drug in its compliance to treat intestinal worm infection. The control drug exhibited side effects like gastrointestinal intolerance nausea and vomiting, where the test drug did not display or show any untoward manifestation associated with the use of this medication and found acceptability by all treated patients.

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