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Research Article

CLINICAL VALIDATION OF UNANI PHARMACOPOEIAL FORMULATION *QURS-E-DĪDĀN* IN *DĪDĀN AL-AM'Ā'* (INTESTINAL WORMS)

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ABSTRACT

Qurs-e-Dīdān is an Unani Pharmacopeial formulation which is used since ancient period by Unani Physicians for the treatment of various intestinal worm infestation. The present study was carried out at Central Research Institute of Unani Medicine, Lucknow to scientifically validate the safety and efficacy of Unani Pharmacopeial formulation *Qurs-e-Dīdān* in *Dīdān al-Am'ā'* (intestinal worms) during the period 2015 to 2017. This was an open label, single arm, interventional study in which 68 subjects of either sex were randomly selected and given Qurs-e-Dīdān 250 mg. one tablet orally twice a day before meal for two weeks and the patients were observed weekly on the basis of subjective and objective clinical parameters which were recorded and the result was assessed on the basis of reduction in sign and symptoms on 4-point (0-3) scale and the presence or absence of ova, cyst or worms in the stool examination before and after the duration of protocol therapy and analyzed statistically using student's paired 't' test. The result was expressed as the Mean ± SD. The ova/cyst of worms passing in stools, recurrent abdominal pain, abdominal bloating, nocturnal perianal itching, odontoprisis, water brash were improved (P<0.01).

INTRODUCTION

Dīdān al- Am'ā' (intestinal worms) are parasites that populate the gastro-intestinal tract in humans and other animals. They can live throughout the body, but most of them prefer the intestinal wall. They 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.

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Unani Concept

According to Unani System of Medicine the main cause of formation of *Dīdān al-Am'ā'* (intestinal worms) in humans is *Balghami Rutūbāt* (Phlegmatic fluids) of small intestine. With the help of *Harārat Gharība* these *Rutubāt Balghamiyya* become putrefied (Muta'affin) leading to the formation of *Dīdān al-Am'ā'* (intestinal worms).[1,2] The *Balgham* (phlegm) due to its sweet taste and viscid nature get adhere to the wall of small intestine and becomes the main cause of formation of *Dīdān al-Am'ā'. Safrā'* (bile) does not favours the formation of *Dīdān al-Am'ā* because it is HārrYābis and bitter[1] and these conditions are unfavourable for the life, even *Safrā'* (bile) kills *Dīdān al-Am'ā',* so the bitter drugs are used for the treatment of *Dīdān al-Am'ā'*. Likewise *Sawdā'* (black bile) is BāridYābis which also does not favours the formation of *Dīdān al-Am'ā'*. *Tabī'at* does not allow Dam (blood) to take part in the formation of *Dīdān al-Am'ā'*. Hence

only *Balgham* (phlegm) is responsible for the formation of *Dīdān al-Am'ā'*. [3,4,5]

The worm infestation may be caused by the use of contaminated edibles and drinks especially pork, beef, vegetables, stagnant water and soil contact. In the classical literature of Unani medicine *Dīdān al-Am'ā'* (intestinal worms) are classified according to the external morphology into following three groups.[2,5]

A. ***Tiwāl*:** These worms are elongated, cylindrical and un-segmented. They are snake like in their appearance. They are called *Hayyāt* (roundworm). These worms are found in the upper part of intestine.[1,2]

B. ***Erāz*:** These worms are broad, flat and segmented. The segments resemble seeds of pumpkin (*Kaddu*), so they are called *Kaddu* Dane or *Habb* al-*Qara*' or *Mu*'*tarida* (tapeworm). They are found in the caecum. This group includes the following types of worms:
   - *Zaiyeg* or *Khinzīri* (*Taenia solium*) or pork tapeworm
   - *Mutawassit* (*Taenia saginata*) or beef tapeworm
   - *Arīz* and *Azīm* (*Diphyllobothrium* spp.) or fish tapeworm

C. ***Sighār*:** These worms are short in size and thread-like in shape. They are found in caecum, colon and rectum. This group includes the following worms:
   - *Dīdān-i-Khaliyya* or *Dūdul Khal* (Pinworm)
   - *Dīdān-i-Khaitiyya* or *Sighār* (Threadworm)
   - *Dīdān-i-Kullabiyya* or *Mustadīra* (Hookworm)

According to their internal morphology the intestinal worms are divided into the following groups:

- ***Mujawwafa*:** These worms have alimentary canal. This group includes *Hayyāt* (roundworm), *Dūdul Khal* (pinworm) and *Sighār* (threadworm).
- ***Musmata*:** In this group alimentary canal is absent. This group includes *Mu'tarida* (tapeworm) only.

The worms found in small intestine are: *Ascaris lumbricoides, Ancyclostoma duodenale, Strongyloides stercoralis,* and *Trichinella spiralis. Enterobius vermicularis* is found in large intestine and *Trichuris trichiura* is found in caecum and appendix. [6]

Ascaris lumbricoides (Roundworm)

It is commonly known as roundworm. It is worldwide in distribution and most common of all helminthes infesting man. The adult worm is located in the duodenum and jejunum. The disease caused is known as Ascariasis. The adult male worm measures 12 to 30cm x 2 to 4mm. Its posterior end is curved ventrally. The female measures 20-45cm x 3-6mm. A sexually mature female worm produces about 200000 eggs daily. The eggs contain the coiled up larvae which are infective to human beings. Such eggs when ingested with food such as raw vegetables and drinks, reach into the intestine. The adult worm may cause intestinal disturbances. Symptoms consist of intermittent colic pain, loss of appetite etc. [7]

Ancylostoma duodenale (Hookworm)

They are commonly known as hookworm. They differ from Ascaris nematodes by the absence of distinct lips. The anterior end of the worm is bent dorsally. Hence it is known as hookworm. The adult worms live in the intestinal canal of their hosts. Eggs are discharged in the faeces and complete their development in the soil. In size they are much smaller than roundworms. The male adult worm measures 8-12mm x 4-5mm. The female worm measures 12-15mm x 4-5mm. This worm infestation causes severe hypo-chromic microcytic anaemia. [7]

Enterobius vermicularis (Threadworm or Pinworm)

It is commonly known as thread worm or pin worm. It has a cosmopolitan distribution but is more common in temperate zones. The adult worm has three lips in the oral tip. The male worm measures 2-5mm x 1-2mm while the female worm measures 8-12mm x 0.3-0.5mm. Children are particularly susceptible. Commonly the recognizable symptoms are pruritus and itching over the perianal skin. There may be an eczematous condition around the anus and salpingitis in female. In children apart from pruritus common symptoms consist of restlessness, disturbed sleep, nocturnal enuresis and tiredness in the day time. On rare occasion, even there may be appendicitis. [7]

MATERIAL AND METHOD

The present study entitled "Clinical Validation of Unani Pharmacopoeial Formulation *Qurs-e-Dīdān* in the cases of *Dīdān al-Am'ā' (*Intestinal Worms), is an open label, single arm, interventional study, conducted at Central Research Institute of Unani Medicine, Lucknow, India to assess the safety and efficacy of Pharmacopoeial Formulation *Qurs-e-Dīdān* in *Dīdān al-Am'ā'* (Intestinal Worms). The patients were enrolled from the OPD. The Patient Information Sheet (PIS) containing information about the nature and objectives of the study and details of other study related procedures was explained and provided to each selected participant. When the patient becomes fully satisfied and willing to be the part of this study, he/she was screened and assessed for clinical and biochemical parameters. If they are found eligible for inclusion, they were enrolled in the study. He/she was asked to sign a consent form. A signed copy of Informed Consent Form (ICF) and PIS was given to the participants to keep their records. The detailed history was recorded and the patients were examined clinically in detail to record the various signs and

symptoms. Blood samples were collected for the pathological and biochemical investigations. The investigational drugs were dispensed as per the dosage schedule and patients were instructed to take the medicine as per the instructions. 98 subjects were selected for the study. Out of which 68 completed the two weeks protocol therapy. Irrespective of age and sex, patients were given *Qurs-e-Dīdān* (250gram) orally twice a day before meals with water for two weeks. And follow up assessment recorded after one week interval and no concomitant medication was allowed during the protocol therapy. Composition of trial Unani pharmacoepial formulation, mentioned in Table Number-1.[8]

Study Rationale

The epidemiological data indicates that nearly 2 billion people are infected by Soil transmitted helminthiasis worldwide and the children are most affected. The most affected regions of the worlds are Africa, South Asia and South America with 870 million children. India alone has nearly 25% of the total cases reported worldwide with 220.6 million children who need preventive measures.[9] Recent estimates suggest that roundworm (*Ascaris lumbricoides*), can infect over a billion, whipworm (*Trichuris trichiura*) 795 million and hookworm (*Ancylostoma duodenale*) 740 million people [10]. There are so many anti-helminthic drugs available for the treatment of *Dīdān al-Am'ā'* (intestinal worms) but there extensive use leads to developed resistance and various side effects from abdominal Discomfort to abdominal pain, loss of appetite, nausea, vomiting, drowsiness, headache and diarrhoea. All have some adverse effects.

There are so many single as well as compound Unani formulations which are safe and effective in the treatment of *Dīdān al-Am'ā'* (intestinal worms). A Unani pharmacopoeial formulation – *Qurs-e-Dīdān* has been used in the treatment of *Dīdān al-Am'ā'* (intestinal worms) since long by the eminent Unani physicians but the scientific data on its safety and efficacy are lacking. Therefore, this study is undertaken to validate the safety and efficacy of *Qurs-e-Dīdān* in the treatment of *Dīdān al-Am'ā'* (intestinal worms).

Subject Selection Criteria

Patients of either sex in the age group of 10-60 years were have *Dīdān al-Am'ā*' (intestinal worms) with and without any of the following associated signs & symptoms: *Ikhrāj-i-Dīdān* (Passage of worms, ova /cyst in stool), *Waja' al-Batn Mutakarrar* (Recurrent Abdominal Pain), *Nafkh al-Batn* (Abdominal Bloating), *Hikka al-Maq'adLaylī* (Nocturnal Perianal Itching), *Sarīr al-Asnān* (Odontoprisis), *Kasrat-i-IfrāzLu'āb-i-Dahan* (water Brash especially in the morning hours). Patients were excluded those not fitted in subject selection criteria. The patients of cardiac, hepatic or renal ailments, Patients taking Vitamin C, B-Complex and iron preparations, pregnant and lactating women, Patients having history of adverse reaction to any ingredient of the study drug were excluded.

Study Drug Details

Preparation and Administration of Drug

The drug was selected from National formulary of Unani Medicine, part -1,[8] which have the vermicidal and vermifugal action and therapeutically recommended in *Dīdān al-Am'ā'* cases. Prepared 250gm./tablet and supplied by the Pharmacy of Central Research Institute of Unani Medicine, Eragada, Hyderabad. 250mg. tablet was given orally twice a day before meals with water for 14 days.

Table 1: Composition of *Qurs-e-Dīdān*

S. No.	Ingredients	Botanical / Zoological Name	Quantity
1.	*PalaspapraMuqashshar*	*Butea monosperma*	1 Part
2.	*Maghz-e-Tukhm-e-Karanj*	*Pongamia pinnata*	1 Part
3.	*Nankhwah*	*Ptycotis ajowan*	1 Part
4.	*Qimbeel*	*Mallotus philippensis*	1 Part
5.	*Baobarang*	*Embelia ribes*	1 Part
6.	*Turbud*	*Operculina turpethum*	1 Part
7.	*QandSiyah*	*Saccharum officinarum*	1 Part

Ethical Considerations

The study was approved by Institutional Ethics Committee (IEC) of CRIUM, Lucknow and registered with The Clinical Trials Registry- India wide Reg. No. CTRI/2015/02/005544.

Laboratory Investigations

The each case of *Dīdān al-Am'ā'* (intestinal worms) selected for the study was subjected to the following pathological and biochemical investigations, conducted at baseline and after completion of the therapy.

- CBC (Hb%, TLC, DLC, ESR)
- Urine Examination: Routine & Microscopic
- Stool Examination: Routine and Microscopic for Ova/Cyst (for three consecutive days), Occult Blood
- Liver Function Tests: S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
- Kidney Function Tests: Serum Creatinine, Serum Urea
- Blood Glucose (Random): at the time of screening only

Assessment of Safety: Safety was assessed during clinical examination on the basis of adverse events and laboratory parameters like CBC, LFT, KFT, Urine Examination: Routine & Microscopic.

Assessment of Efficacy

Therapeutic efficacy of study drugs were assessed on the basis of reduction in signs and symptoms and grading was done on the basis of the following 4-point (0-3) scale.

- 0 = Not Present
- 1 = Mild
- 2 = Moderate
- 3 = Severe

Adverse Effects

No any known adverts effect was reported.

Statistical Analysis

Baseline and follow up values of clinical, pathological and biochemical parameters were statistically analyzed using student's paired 't' test. The result was expressed as the Mean ± SD. $P<0.05$ has been considered as statistically significant and $p<0.01$ and $p<0.001$ have been considered as statistically highly significant.

RESULT AND DISCUSSION

Mizaj of the patients of *Dīdān al-Am'ā'* (intestinal worms) was assessed on the parameter of *Ajnas e Ashra* - Assessment of *Mizāj*. It was observed that most of the patients 63.23% (43) were of *Balghami mizaj,* 19.12% (13) were *Safrawi*, 17.65% (12) patients were *Damwi mizaj*. This finding indicates that the patients of *Balghami* temperament are more susceptible for worm's infestation. All Unani physicians assert that the worms produced in intestine due to putrefaction of *Rutubat-i-balghamiya*. The sweet nature of *Rutubat-i-balghamiya* provides the worms best media to grow.

Table 2: *Mizaj* wise distribution of patients

Mizaj	**No. of cases**	**Percentage (%)**
Damvi	12	17.65
Balghami	43	63.23
Safrawi	13	19.12
Saudavi	--	--
Total	68	100

It was observed that young and adult population (10-20 (35.29%) and 21-40 (52.94%) years of age group either sex are equally susceptible for *Dīdān al-Am'ā'* (intestinal worms).

Table 3: Age Wise Distribution of patients

Age Group (In years)	**No. of cases**	**Percentage (%)**
10-20	24	35.29
21-40	36	52.94
41-60	08	11.77
Total	68	100
Mean±SD	27.25±12.94	

Table 4: Sex Wise Distribution of patients

Sex	No. of cases	Percentage (%)
Male	37	54.41
Female	31	45.59
Total	68	100

It was observed that low income group (7.65%) and persons having both dietary habits vegetarian and non vegetarian (63.24) were more affected to *Dīdān al-Am'ā'* (intestinal worms).

Table 5: Status wise Distribution of Patients

Status	No. of cases	Percentage (%)
Lower	46	67.65
Middle	22	32.35
Upper	--	--
Total	68	100

Table 6: Dietary wise distribution of patients

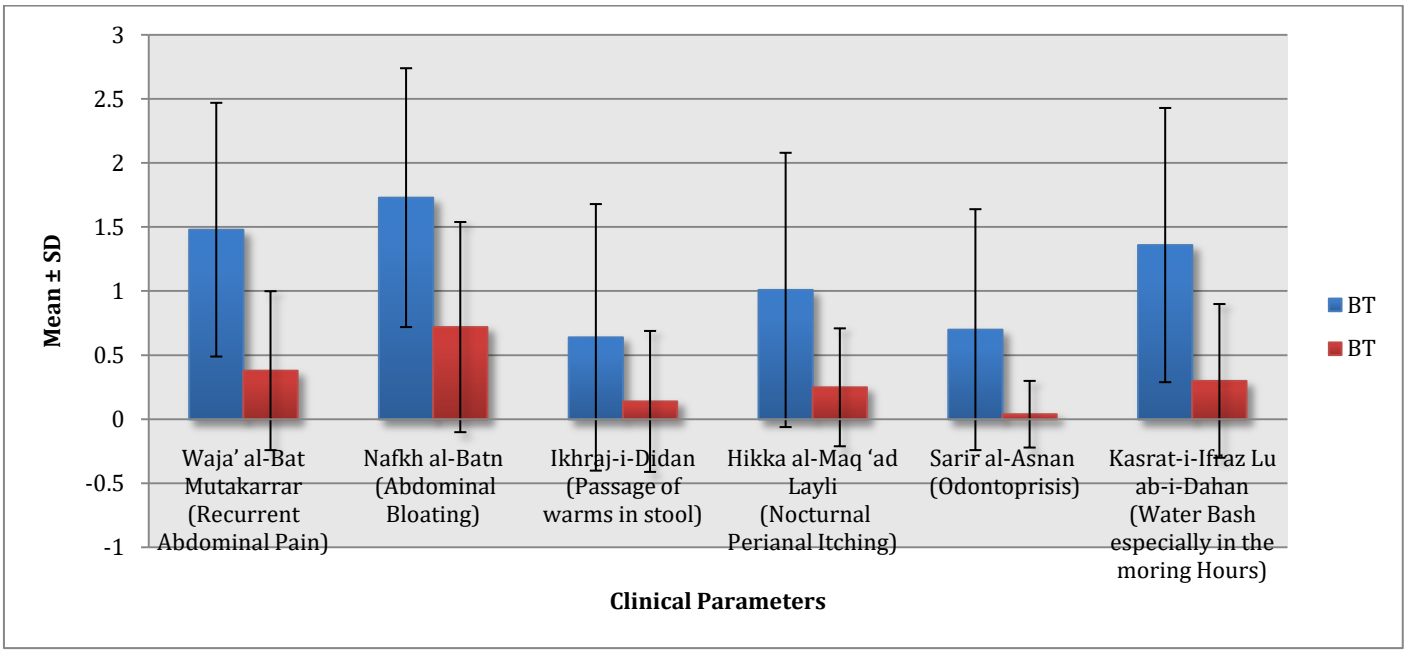
Diet	No. of cases	Percentage (%)
Veg	16	23.53
Non veg	9	13.23
Both	43	63.24
Total	68	100

Out of six clinical parameters studied, 74.32% improvement in *Waja' al-Bat Mutakarrar* (Recurrent Abdominal Pain), 58.72% in *Nafkh al-Batn* (Abdominal Bloating), 78.12% in *Ikhraj-i-Didan* (Passage of worms in stool), 75.24% in *Hikka al-Maq 'ad Layli* (Nocturnal Perianal Itching), 94.28% in *Sarir al-Asnan* (Odontoprisis) and 77.94% improvement in *Kasrat-i-Ifraz Lu ab-i-Dahan* (Water Bash especially in the morning Hours) was observed. The overall improvement was good. (Table .7).

Table 7: Effect of *Qurs-e-Dīdānn* on clinical parameters

Sr. No.	Clinical Parameters	Mean±SD		Efficacy (%)	P-Value	Result
		BT	AT			
1	*Waja' al-Bat Mutakarrar* (Recurrent Abdominal Pain)	1.48±0.99	0.38±.62	74.32	<0.0001	Extremely Significant
2	*Nafkh al-Batn* (Abdominal Bloating)	1.73±1.01	0.72±0.82	58.72	<0.0001	Extremely Significant
3	*Ikhraj-i-Didan* (Passage of warms in stool)	0.64±1.04	0.14±0.55	78.12	<0.0001	Extremely Significant
4	*Hikka al-Maq 'ad Layli* (Nocturnal Perianal Itching)	1.01±1.07	0.25±0.46	75.24	<0.0001	Extremely Significant
5	*Sarir al-Asnan* (Odontoprisis)	0.70±0.94	0.04±0.26	94.28	<0.0001	Extremely Significant
6	*Kasrat-i-Ifraz Lu ab-i-Dahan* (Water Bash especially in the morning Hours)	1.36±1.07	0.30±0.60	77.94	<0.0001	Extremely Significant

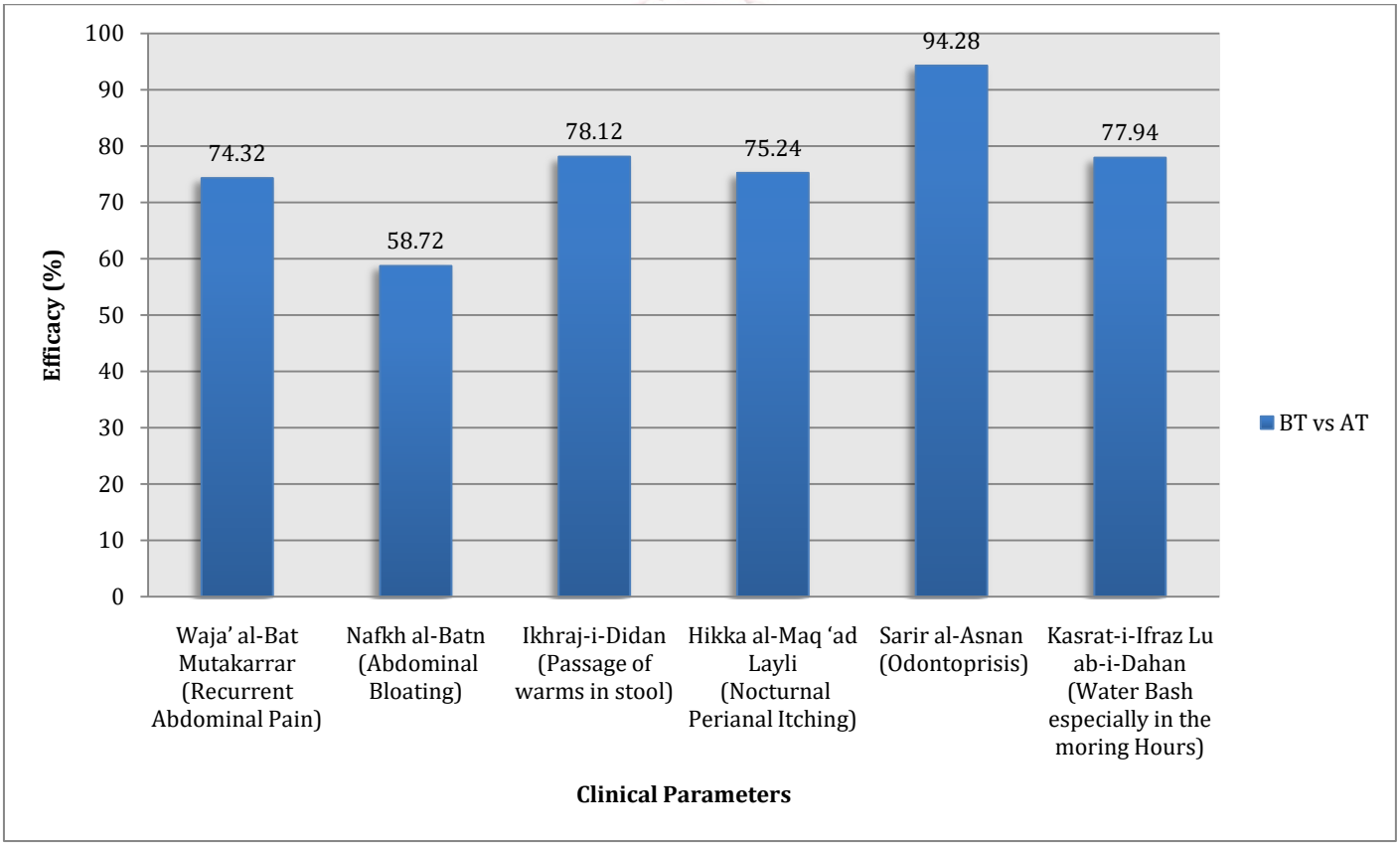
Figure 7.1: Effect of drugs on clinical parameters



BT=Before Treatment / AT=After Treatment

Figure 3: Efficacy (%) drugs on clinical parameters

Figure 7.2: Effect of drugs on clinical parameters



It was observed in the stool examination of the total 68 (100%) subjects at the baseline, 65 (95.58%) were found Ova of Ascaris lumbricoides in their stools while only 3.3 (4.41%) subject were found ova of Taenia saginata in there stools. It was noted after observation of result that the drug QDA has the antihelmenthic effect on worm infestation and shows more distinctive results on Ascaris lumbricoides. (Table 8.)

Table 8: Response in Stool Test

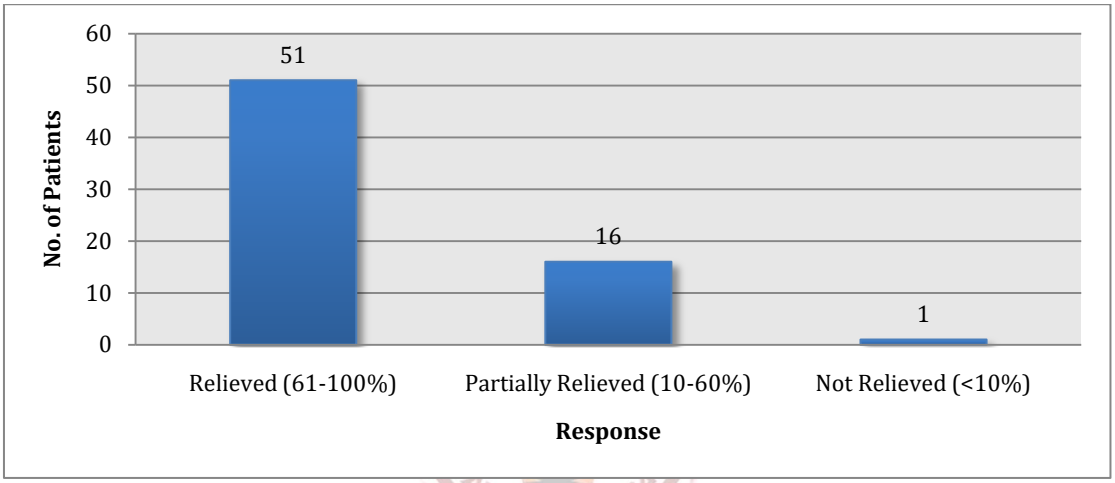
Worm	BF	AF	Percentage change (%)
Ova of Ascaris lumbricoides	65 (95.58%)	16 (23.52%)	72.06
Ova Of Taenia saginata	3 (4.41%)	2 (2.94%)	1.47

The general therapeutic response recorded out of 68 eligible subjects, 51 (75%) patients showed 61-100% relief in overall symptoms and signs, 16 (23.52%) patients showed 10-60% relief and 1(01.48%) patients showed less than 10% relief. (Table 9)

Table 9: General Therapeutic Response

Result	No. of cases	Percentage (%)
Relieved (61-100%)	51	75
Partially Relieved (10-60%)	16	23.52
Not Relieved (<10%)	1	01.48

Figure 9.1: General Therapeutic Response



The ingredients of poly herbal formulation QDA has the properties to kill and expel out the worms. It has the vermicidal and vermifugal actions[3] whether it is used alone or as compound formulation. They have various bio active constituents showing specific pharmacological properties by which they either kill worms or expels them out of the intestine. *Butea monosperma* (*Plaspapda*) is one of the drug which shown the significant Anthelmintic activity in aqueous extract as well as in ethanolic extract form. Its antihelminthic property is supposed to be due to the presence of alkaloid and tannins in the extract.[11,12,13] In one study, isolated constituent from B. frondosa, palasonin, was also screened and found to be effective against Ascaris lumbricoids.[14] Palasonin inhibited the glucose uptake and deplete the glycogen content in the presence of glucose that indicates that the palasonin arrests the energy producing mechanism. It also increases lactic acid which in turn inhibits the ATP production. This shows that the palasonin affects the parasite by two ways either by the inhibition of energy metabolism or modification in the motor functions of the parasites. [14]

Pongamia pinnata has effective vermicidal and vermifugal action.[3,15] Seeds are used as antihelmintic,[15] shows its effect against specific helminths, e.g. Ascaris lumbricoides in humans. The extract of *Trachyspermum ammi* shows the anthelminthic activity in a study that proves, it have the activity to hinder the metabolism of parasites through potentiating of ATPase activity and thus loss of energy reserves. Its cholinergic activity with peristaltic movement of the gut is also reported which helps in the expulsion of intestinal worms. It might be responsible for its antihelminthic activity.[16] Volatile oil, tannins, glycosides and steroidal substances are found in the alcoholic extract of the plant and the tannins are the compounds that are chemically phenolic in nature were shown antihelminthic activities. Tannin causes death of parasites by binding to the free proteins in gastrointestinal tract or glycoproteins on the cuticle. The aqueous extract /alcoholic of seeds of *Trachyspermum ammi* showed good anthelmintic activity and alcoholic extract of T. ammi normal concentration showed good anthelmintic activity. [17] Isolated resin from *Mallotus philippensis* shows the purgative effect on the oral dose of 120mg/kg in rats. So the antihelminthic effect of resin was found in albino rats infested from tapeworm. 60mg/kg & 120mg/kg dose of resin were found to be lethal on 35.69% and 78.21% population of tapeworms respectively. [18,19,20] Embelia ribes show good antihelmenthic activity as shows in vitro studies.[14] Operculina turpethum

traditionally used in various diseases. It has various medicinal properties like anti inflammatory, anti Spasmodic, antimicrobial and purgative actions. [21]

The most common effect of antihelmenthic drugs against worm is paralysis of the parasites muscular structure either by inhibition of the neuromuscular transmission or enzyme involved in energy production.

CONCLUSION

The oral administration of *Qurs-e-Dīdān* (250gram) twice a day before meals with water for two weeks was found to be effective in management of common complaints associated with helminthiasis such as recurrent abdominal pain, abdominal bloating, passage of worms with stool, nocturnal perianal itching, etc. The drug was found to be highly efficacious against Ascaris lumbricoides as evident from stool examination. Likewise the therapy was found to be safe and well tolerated as the safety parameters (Hb%, ESR, TLC, DLC, LFT and KFT) remained within the normal limits after the treatment. No unbearable side effects were seen and overall compliance to the trial drug was good. Thus, it may be concluded that *Qurs-e-Dīdān* is effective and safe in the management of *Dīdān al-Am'ā'* (Intestinal Worms).

Table 10: Effect of *Qurs-e-Dīdān* on Haemogram, LFT and KFT

	Name of the Parameters		No. of Observation (n)	Mean±SD		Percentage of Increase (↑) /Decrease (↓)		Paired "t" Test		Result
				BT	AT			Statistic value	P Value	
HAEMOGRAM	Hb (gm/dL)		68	11.39 ± 1.96	11.50 ± 1.87	00.96	↑	-3.50	0.00083	Result is significant at (P<.01)
	TLC (/mm)		68	9742.64 ± 1361.77	9683.82 ± 980.80	00.60	↓	0.52	0.60	Result is not significant at (P<.01)
	DLC	N (%)	68	59.57 ± 9.33	59.14 ± 7.56	00.72	↓	0.57	0.57	Result is not significant at (P<.01)
		L (%)	68	33.11 ± 7.71	35.08 ± 6.45	5.94	↑	-2.61	0.01	Result is not significant at (P<.01)
		E (%)	68	5.50 ± 5.47	04.27 ± 4.37	22.36	↓	02.65	0.01	Result is not significant at (P<.01)
		M (%)	68	1.66 ± 1.07	1.50 ± 1.47	9.63	↓	0.85	0.39	Result is not significant at (P<.01)
		B (%)	68	0 ± 0	0 ± 0	0 ± 0	--	--	--	--
LFT	S. Bilirubin (mg/100 ml)		68	0.64 ± 0.38	0.61 ± 0.56	4.68	↓	1.15	0.25	Result is not significant at (P<.01)
	SGOT (IU/L)		68	19.91 ± 7.68	22.27 ± 13.76	11.85	↑	-1.33	0.19	Result is not significant at (P<.01)
	SGPT (IU/L)		68	27.19 ± 23.10	26.49 ± 22.95	2.57	↓	0.34	0.73	Result is not significant at (P<.01)
	S. Alkaline Phosphatase (KA)		68	299.59 ± 162.02	284.16 ± 161.09	5.15	↓	1.91	0.06	Result is not significant at (P<.01)
KFT	S. Creatinine (mg/100 ml)		68	0.72 ± 0.16	0.71±0.13	1.38	↓	0.71	0.48	Result is not significant at (P<.01)
	S. Urea (mg/100 ml)		68	21.54 ± 6.23	21.67 ± 6.22	0.60	↑	-0.15	0.88	Result is not significant at (P<.01)

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