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Efficacy of unani formulation on systolic and diastolic blood pressure

Mursaleen Naseer, Abdul Mannan and Mohd Kashif

Abstract
The term hypertension or *Zightul-Dam-Qavi* has not been mentioned in any of the classical Unani literature. But most of the Unani scholars were familiar to manifestation of hypertension, as they have described most of its symptoms such as headache, palpitation, vertigo and epistaxis, due to *imtala* (repletion). The present study was novel step towards finding a safe cost effective treatment for raised blood Pressure and to validate Unani drugs scientifically following a standardised protocol. The study designed was an open and randomized clinical trial with standard control. The 60 patients were taken and divided equally to both test as well as control groups. The duration of protocol was 90 days and assessment either subjective or objective, made at every 30th day. Test drug formulation *Qurs-e-Pudina* as well as control drug atorvastatin both showed statistically significant improvement, with a little better improvement by test drug. The test drug formulation produced significant blood pressure lowering effect without any side/ adverse effect, and it is proposed to study the same formulation for a longer period to get better results to declare it as antihypertensive formulation.

Keywords: High Blood Pressure, Systolic Blood Pressure, Diastolic Blood Pressure, Unani

Introduction
Hypertension, the "silent Killer" is considered to be a major health problem throughout the globe. This is due to high prevalence and its association with increased risk of cardiovascular complications [1]. In spite of increasing public awareness and a rapid advancement of anti-hypertensive medications, hypertension still remains one of the leading cause of cardiovascular morbidity and mortality [2].
The *Zightul-Dam-Qavi* has not been mentioned in any of the classical Unani literature. The term hypertension was coined by Harry Gold Ballet in 1934 and the term *Zightul-Dam-Qavi* was used by Unani scholars contemporary to Indian period. Although, there exists no mention of the disease with its present term, that does not mean at all that the Unani scholars were not obvious of the disease. In fact there is an explicit description of the typical manifestation of hypertension in Unani literature eg *ghashi, duar, ruaf* under the heading of *imtela-e-ba hasbul auyeah* [3, 4] that can precisely be equated with the contemporary term hypertension.

Etiology and *Pathophisiology*
The most important cause of hypertension is Imtila-e-Dam, which is of two types:
1. Imtila-e-dam bahasbul auiya
2. Imtila-e-dam bahasbul quwa

In Imtila-e-dam bahasbul auiya there is raised blood volume resulting in increased vascular pressure. This type of imtila is due to excess accumulation of metabolic products, whether mahmooda (beneficial) or ghair mahmooda (harmful), and this type of congestion is common in obese people [5].
In Imtila-e-dam bahasbul quwa, faculties like quwwat-e-nafsaniya, quwwat-e-mudabbara badan and quwwat-e-tabia of body are disturbed. Among them, disturbance of quwwat-e-tabia leads to altered digestion resulting in production of harmful by-products. Similarly disturbed quwwat-e-nafsaniya and quwwat-e-mudabbira badan also weaken body systems at the level that a small quantity of toxin/ harmful by-products may produce symptoms of imtila [6].

Line of Management [7]
A general guideline for the management of hypertension should be as follows:

A. Non- pharmacological Salt restricted diet
1. Weight reduction of obese and overweight
3. Regular physical activity
4. Cessation of alcohol intake and smoking
5. Stress reduction and to provide happy environment

B. Pharmacological
1. Musakkin or Moaddile Jazbat (Tranquilizers): Khashkhash, Bekh-e-Asrol, Tukhm-e-Kahu, Kishneez
2. Mudir-e-baul (Diuretics): Khar-e-Khasak, Tukhm-e-Gazar, Tukhm-e-Turab, Tukhm-e-Khayarain, Sharbat-e-Bazoori, Sharbat-e-Anannas
3. Musaffy/ Moaddile Dam (Blood Purifiers): Sandal, Chiraita, Unnab,
4. Mufatteh urooq (Vasodilators): Asrol, Kasni, Karafs, Revand chini
5. Muqawwi Qalb (Cardiotonic): Abresham, Yashab, Marwareed
6. Muqawwi Quwa Mudabbira badan wa quwa tabiya: Marwareed, Gauzaban

Need of the study

Since the drugs which are available in the Western Medicine are known to have various adverse effects therefore, there arises a need to find an alternate solution for this life threatening disease. Unani system of medicine is enriched with drugs that are being used in hypertension for century with great efficacy. The present study is a novel step towards finding a safe cost effective treatment for hypertension and to validate Unani drugs scientifically following a standardised protocol.

In the treatment of hypertension, compound drugs in natural forms are preferred over single drugs. Because a compound formulation produces desired type of effects and encompass many complexities of the disease. To evaluate clinical efficacy of drugs in hypertension, *Qurs-e- Pudina* was chosen. This drug for hypertension is proposed keeping in mind the side effects that directly arise after the administration of the drug for relatively longer period.

Material and Methods

The present study is randomized open study with standard control and was conducted in department of Moalejat, Ajmal Khan Tibbiya College, Hospital, AMU, Aligarh. It comprised of 60 patients which were equally divided in two groups i.e. Test group (Group A) and Control group (Group B). All the patients were taken from AKTC Hospital, either from IPD or OPDs and grouped randomly.

Duration of study was eighteen months, started from January 2015 and duration of protocol for both groups as 90 days with follow up every 30th day. A total of 67 patients were enrolled in the study but 7 patients did not complete the duration for unknown reasons. After the completion of 60 patients as proposed for the study, further more patients were not included in the trial. The patients were selected on the basis of inclusion and exclusion criteria. Only those who fulfilled following criteria were enrolled in this study.

Inclusion criteria

It includes subjective as well as objective parameters as given below:

Subjective parameters

- Palpitation
- Breathlessness

Objective parameters

Any level of blood pressure associated with symptoms.

Exclusion criteria

It includes

- Patients of age below 30 years and above 60 years
- Patients having liver diseases and renal diseases
- Thyroid disorders
- Pregnant and lactating women
- Diabetes Mellitus
- Alcoholics
- Patients who failed to follow up

After fulfilling the above mentioned criteria, a written informed consent was signed by each patient and then started the proposed trial as per the protocol.

Drug and Dosage

Test Drug

Two tablets of *Qurs-e-Pudina* (each of 775 mg) twice a day before meal for 90 days was given.

The drug was purchased from market, a product of Hamdard laboratory and ingredients of drug are as follows:

S. No.	Name of Drug	Botanical/Chemical/English Name	Weight (in grams)
1.	Ajwain desi	*Ptycotis ajowan*	200
2.	Badyan	*Foeniculum vulgare*	200
3.	Pudina khushk	*Mentha arvensis*	200
4.	Darchini	*Cinnamomum zeylanicum*	25
5.	Zanjabeel	*Zingiber officinale*	200
6.	Zeera Siyah	*Carum carvi*	150
7.	Zeera Sufaid	*Cuminum cyminum*	150
8.	Filfil siyah	*Piper nigrum*	80
9.	Gond	Resin	125
10.	Namak siyah	Himalayan Black Salt	200
11.	Naushadar	Ammonium chloride	80
12.	Shakar Sufaid	*Saccharum officinarum*	700
13.	Sang Jarahat Saeeda	Hydrated Magnesium Silicate	25
14.	Magneshia Fahmi	Magnesium Sulphate	5

Control Drug

One tablet of Atorvastatin (10 mg) after dinner for 90 days was given. This was also purchased from the market with a brand name Atorvakind-10, a product of Mankind Pharma Ltd.

Assessment

Subjective and objective assessments were made by every 30th day.

Evaluation of the results

Observations were noted in case report form, all the data were tabulated and evaluated statistically by using paired t-test.

Observations and Results

According to age patients were distributed into six age groups i.e. 30-35, 35-40, 40-45, 45-50, 50-55 and 55-60. Maximum number of cases (14) were found in 40-45 years age group followed by 13 each in 35-45 years and 45-50 years age groups, 9 cases in age group of 30-35 years, 8 in between 50-56 years and only 3 patients belonged to age group of 55-60 years (Table No. 1)

During the study, patients were divided into males and females according to their gender and observations mentioned in table no. 3. Males contributed only 11 (18.33%), 6 in test group and 5 in control group while females contributed in greater ratio i.e. 49 (81.67%), 24 in test group and 25 in control group out of 60 cases (Table No.2)

The effect on systolic blood pressure was found very significant in both the groups ($p<<0.05$). Data is tabulated in table no. 3 with statistical calculations. Before treatment mean systolic BP was 129±10.51 for test group while 128.87±8.43 for control group and after treatment it remained 126.2±6.67 and 126.13±6.21 for test and control groups respectively (Table No. 3)

A highly significant ($p=0.001$) reduction in diastolic BP was observed after the treatment in test group and very significant ($p<<0.05$) reduction in patients of control group. As recorded in table no. 16, mean diastolic BP in test group was 84.6 ± 6.69 and in control group was 84.4 ± 6.73 before treatment, which reduced to 81.33 ± 3.34 in test group and 81.33 ± 3.5 in control group after treatment (Table No. 4)

Table 1: Distribution of the Patients according to Age

Age Group	Test Group		Control Group		Total	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
30-35	7	23.33	2	6.67	9	15
35-40	5	16.67	8	26.67	13	21.67
40-45	6	20	8	26.67	14	23.33
45-50	7	23.33	6	20	13	21.67
50-55	3	10	5	16.67	8	13.33
55-60	2	6.67	1	3.33	3	5
Total	30	100	30	100	60	100

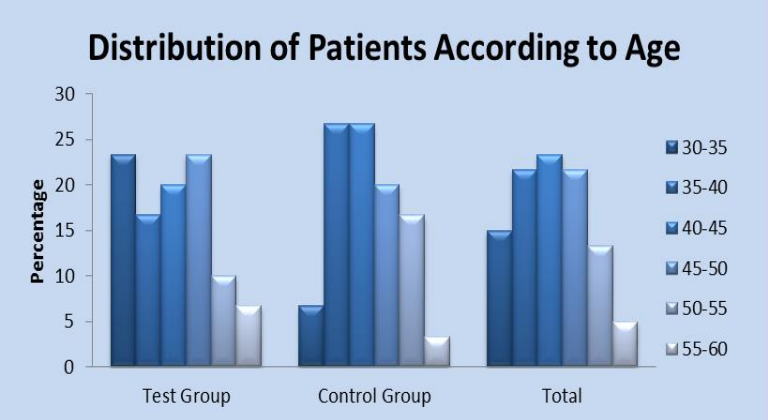


Table 2: Distribution of Patients according to Sex

Sex	Test Group		Control Group		Total	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
Male	6	20	5	16.67	11	18.33
Female	24	80	25	83.33	49	81.67
Total	30	100	30	100	60	100

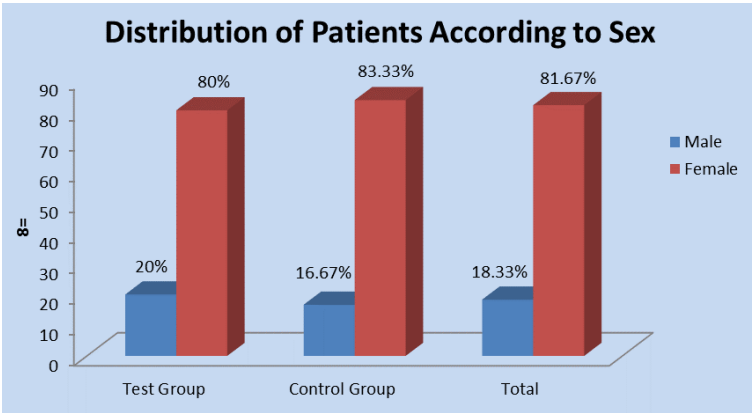


Table 3: Effect of Drugs on Systolic BP (mm of Hg)

Systolic B.P. (Mean ± SD)	Test Group				Control Group			
	B. Tt.	After treatment			B. Tt.	After treatment		
	0 day	30 days	60 days	90 days	0 day	30 days	60 days	90 days
	129 ± 10.51	127.6 ± 8.08	127.06 ± 6.45	126.2 ± 6.69	128.87 ± 8.43	127.33 ± 6.97	126.07 ± 6.18	126.13 ± 6.21
t & p values	t = 2.98, p = 0.0058 (p<<0.05)				t = 3.52, p = 0.0014 (p<<0.05)			

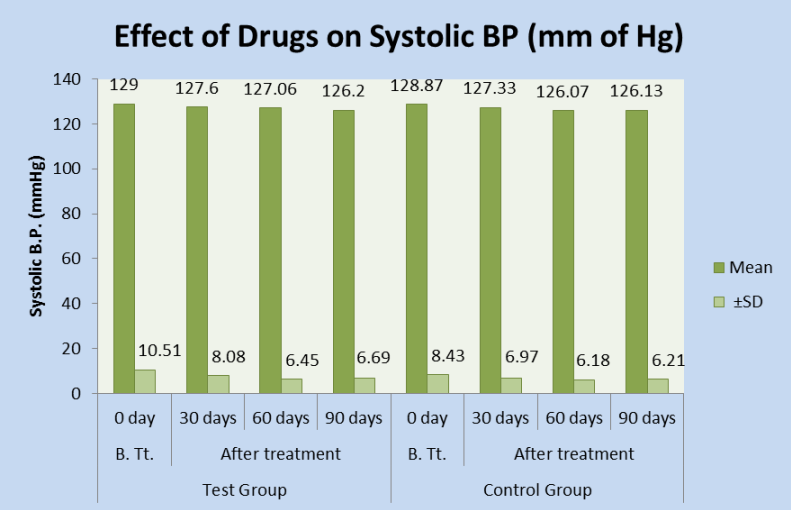
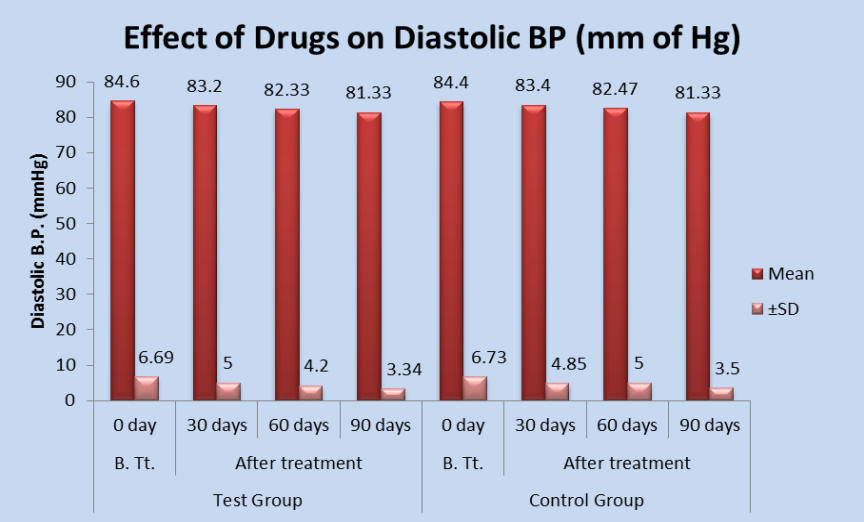


Table 4: Effect of Drugs on Diastolic BP (mm of Hg)

Diastolic B.P. (Mean ± SD)	Test Group				Control Group			
	B. Tt.	After treatment			B. Tt.	After treatment		
	0 day	30 days	60 days	90 days	0 day	30 days	60 days	90 days
	84.6 ± 6.69	83.2 ± 5.00	82.33 ± 4.20	81.33 ± 3.34	84.4 ± 6.73	83.4 ± 4.85	82.47 ± 5	81.33 ± 3.5
t & p values	t = 3.66, p = 0.001 (p<<0.05)				t = 3.27, p = 0.0028 (p<<0.05)			



Discussion

The test drug also exerted significant blood pressure lowering effect on both systolic and diastolic blood pressures. In unani literature, it is mentioned that the blood vessels become narrow if a person suffers from siman-e-mufrat [8, 9]. As the drug is found beneficial in this disease, it should also effect the blood vessels and may reflect a dilatory effect on them, which helps in lowering the blood pressure. Other reason might be the ingredients, most of them like Ajwain Desi (*Tachyspermum ammi* Linn.), Badiyan (*Foeniculam vulgare*), Pudina (*Mentha arvensis* Linn), Darchini (*Cinnamomum zeylanicum*), Zeera Siyah (*Carum carvi* Linn), Zeera Safaid (*Cuminum cyminum*) and Naushadar (Ammonium chloride) functions as diuretics and by this diuretic effect they can lower the blood pressure [10, 11, 12, 13]. The Studies on Ajwain desi (*Tachyspermum ammi* Linn.) proved its hypotensive property [14]. Similarly animals studies have been confirmed the blood pressure lowering effect of Zanjabeel (*Zingiber officinale*) [15]. Therefore, this effect is justified to a greater extent. Significant effect in reducing systolic and diastolic blood pressure in control group may be due to the atorvastatin

used as a control drug, has well known hypolipidemic effect.

Conclusion

To conclude, it may be deduced that the effect of the drugs on blood pressure was significant statistically. The drugs were well tolerated and have no serious ill effect. Further advanced studies and research for better drugs combination need to be carried out for more precise effect.

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