The Efficacy and Safety of a Unani Pharmacopoeial Drug Sharbat-E-Faulad in Cases of Anaemia

*[1]Radhey Shyam Verma, Shabana Parveen and Latafat Ali Khan

Regional Research Institute of Unani Medicine (CCRUM), Post Box No 70, Aligarh-202001, U.P, India

Abstract

naemia is defined as a decrease in the total amount of hemoglobin or the number of red blood cells. Iron deficiency anemia is a form of anaemia develops due to the lack of sufficient iron to form normal red blood cells. It is typically caused by inadequate intake of iron, chronic blood loss, digestive problem and other systemic and metabolic diseases. Present study was designed to evaluate the efficacy and safety of Unani drug Sharbat-e-Faulad in cases of anaemia. Haematological and biochemical studies were carried out to determine the efficacy and safety of the test drug. In haematological studies a significant increase in the level of haemoglobin (19.79%), Red blood corpuscles (18.94%), Total Leucocytes counts (15.6%) Packed Cell Volume (14.3%) and Mean Cell Haemoglobin Concentration (4.51%) (P<0.001) were observed. It was also found to reduce the level of Erythrocyte Sedimentation Rate (ESR) by 28.04% (P<0.001) (Table-2 & 3).

In Biochemical studies for liver function test, some patients showed decreased level of enzyme, while same enzyme was found increased in other patients but the deviation of either side was found within the normal range (Table-4, 5 & 6). Similarly, no significant change was observed on the two parameters of kidney function as the blood urea and serum creatinine levels were also found not to exceed the normal range.

It was, therefore, concluded that Sharbat-e-Faulad is a safe and effective haematinic drug and can be used in the patients of anaemia.

Keywords: Anaemia, Sharbat-e-Faulad, Haematinic

Introduction

Anaemia is one of the most common nutritional disorders and therefore has public health importance in developing countries like India where it is the most widespread nutritional problem specially in adolescents and women of reproductive age. As per WHO estimation the prevalence of anaemia in pregnant women is 14% in developed and 51% in developing countries while it is estimated to be 65-75% in India (Kalaivani, 2009; DeMayer and Adiels, 1998). As a result, about one-third of the global population (over 2 billion) is anaemic (Anonymous, 2004). In developed countries, the cause of anemia varies according to age and sex. In women of childbearing age excessive menstrual loss is the most frequent etiology, while in postmenopausal women

*[1] Author for correspondence

and in males, digestive diseases are the main cause (McIntyre and Long, 1993; Beutler *et al*., 2003; Yates *et al*., 2004).

The exact description of iron deficiency anaemia is not available in ancient Unani literature but Razi (Razes, 841-926 AD) and Abul Hasan Ahmad Bin Mohammad Tabri (10th century AD) have mentioned that Soo-e-*Mizaj Kabid Barid wa Ratab* (Deranged cold and wet temperament), leads to the development of features of iron deficiency anaemia, which they have described as Soo-ul-Qiniya (Kantoori, 1303; Tabri, 1995). Later, Kabiruddin (1950) simulated Soo-ul-Qiniya with that of '*Faqru-ddam', 'Qiliatut-Dam'* etc. He further described *Khizra* (chlorosis) as a type of *Soo-ul-Qiniya*, affecting the young girls and described its etio-pathology as the alteration in the constituents of blood and added that the size of RBCs becomes small (microcytosis) and their red substance decreases (hypochromia) with increased fibrous material in the blood. While mentioning the treatment he advised (*Kushta Foulad, Sharbat-e-Faulad, Sayyal-e- Faulad* etc.) (Table-1) iron supplement for a longer period with other haemopoietic, hepato-stumulant and hepato-protective drugs like *sharbat Anar*, *Kushta Marjan*, *Majoon Dabeeldul Ward*, *Jawarish Jalinoos* etc. As per description the involvement of liver appears to be inevitable in the causation of anaemia. Therefore the drugs frequently prescribed in this ailment contain ingredients that improve the digestion, liver function along with providing iron supplement. Sharbat-e-Faulad is an important preparation useful in anaemia irrespective of its cause and etiology. It improves digestion and nutrition and improves liver function on one hand and provides the required quantity of iron on the other. Therefore in the present study the efficacy of Sharbat-e-Faulad was studied in patients of anaemia. Since the drugs containing metallic ingredients have been reported to cause toxicity particularly in liver and kidney therefore the effect of Sharbat-e-Faulad was also studies on liver and kidney function.

Materials and Methods

Unani formulation Sharbat-e-Faulad was procured from Central Council for Research in Unani Medicine, New Delhi. The study was carried out at Regional Research Institute of Unani Medicine (RRIUM), Aligarh. Ninety patients aged 18-60 years of either sex were selected from the lot of patients attending the Out Patient Department (OPD) following the predesigned inclusive/exclusive criteria. Out of 90 patients 50 patients completed the study whereas 40 dropped out. The efficacy and safety of Unani drug Sharbat-e-Faulad was evaluated on the biochemical and haematological parameters.

Table 1 Ingradients of Sharbat-e-Faulad of each 10 ml.

S. No.	Name of ingredients	Quantity
1	Burada Faulad	120.0 mg
2	Tursha shora	0.3 ml
3	Tursha Namak shora	0.1 ml
4	Tursha Kibrit	0.1 ml
5	Sirka Jamun	3.0 ml
6	Sat Lemon	60.0 mg
7	Tukhm Karafs	6.0 mg
8	Badian	3.0 mg
9	Ajwain Desi	3.0 mg
10	Podina	3.0 mg
11	Tukhm Shibbat	3.0 mg
12	Hilteet	3.0 mg
13	Kashniz Khushk	3.0 mg
14	Filfil Daraz	3.0 mg
15	Kundar Gond	3.0 mg
16	Saad Koofi	3.0 mg
17	Tejpat	3.0 mg
18	Khurfa Siyah	3.0 mg
19	Taj Kalmi	3.0 mg
20	Balchhar	3.0 mg
21	Tukhm Halon	3.0 mg
22	Tukhm Piyaz	3.0 mg
23	Zanjabeel Khushk	3.0 mg
24	Filfil Siyah	3.0 mg
25	Zeera Safaid	1.5 mg
26	Qand Safaid	Q.S.

Selection criteria

Patients were enrolled on the basis of following inclusion and exclusion criteria:

Inclusion Criteria

Patients in the age group of 18-60 years of either sex having the signs and symptoms of anaemia.

1. Whitish or yellowish complexion of face and skin.
2. Pedal edema or generalized oedema
3. Haemoglobin in the range of 8.0-12.0 gm% in males and 8.0- 10 gm% in females.

Exclusion Criteria

1. Patients with Haemoglobin less than 8.0 gm%.
2. Patients with history of acute blood loss.
3. Patients with chronic diseases requiring long term treatment.
4. Pregnant and lactating women.

Diagnosis

The diagnosis was however confirmed when haemoglobin level was found in the range of 8.0-12 gm% in males and 8.0-10 gm% in females.

Collection of blood serum

Blood samples were collected by puncturing the vein at each investigation. 1.0 ml of blood with ethylene diamine tetra acetic acid (EDTA) was used for various haematological parameters and another 2.0-2.5 ml of blood sample was allowed to clot and serum was separated by centrifugation, which was used for various biochemical parameters. Biochemical and haematological investigations were carried out as follows:

Biochemical analysis

Serum Glutamate Pyruvate Transaminase (SGPT, E.C. 2.6.1.2) and Serum Glutamate Oxaloacetate Transaminase (SGOT, E.C. 2.6.1.1.) were done by the method described by International Federation of Clinical Chemistry (IFCC) (Bradley *et. al*., 1972), Serum Alkaline Phosphatase enzyme (S-ALP, EC.

3.1.3.1) by the method of Wilkinson *et. al*., (1969), Blood Urea by the method of Tiffany *et. al.,* (1980) and Serum Creatinine by Bowers (1980) method.

Haematological analysis

Haematological parameters were done according to the method described by Mukherjee (1990). It included Haemoglobin (Hb), Erythrocyte Sedimentation Rate (ESR), Total Leucocytes Counts (TLC), Red Blood Corpuscles (RBC) and Differential Leucocytes Counts (DLC): Polymorphs, Lymphocyte and Eosinophil Counts, Packed Cell Volume (PCV), Mean Cell Volume (MCV), Mean Cell Haemoglobin Concentration (MCHC), and Mean Cell Haemoglobin (MCH).

Dose and Mode of administration

Sharbat-e-Faulad was given in a dose of 12 ml orally to the patients twice a day after meal for a period of 90th-days. The haematological and biochemical investigation were conducted on day one and at the end of the study after 90 days. The findings were tabulated and compared statistically.

Statistical analysis

Data were analyzed statistically by one-way analysis of variance (ANOVA) followed by Dennett's' test. The values were considered significant when P-value was found less than 0.05.

Results and Discussion

Haematological Studies

Sharbat-e-Faulad significantly increased the level of haemoglobin by 19.79% ((P<0.001), Red blood corpuscles (RBC) by 18.94% (P<0.001), Total Leucocytes counts (TLC) by 15.6% (P<0.001) (Table-2), Packed Cell Volume (PCV) by 14.3% (P<0.001) and Mean Cell Haemoglobin Concentration (MCHC) by 4.51% (P<0.001) (Table-3), when compared with the values of pre and post treatment. Sharbat-e-Faulad significantly reduced the level of Erythrocyte Sedimentation Rate (ESR) by 28.04% (P<0.001) (Table-2). The findings of haematological study clearly indicated that Sharbat-e-Faulad increased the level of RBCs, Hb, PCV and MCHC suggesting that it helped in improving the anaemia.

Biochemical Studies

(i) Liver Function Tests

The effect of Sharbat-e-Faulad was found to vary from individual to individual in patients of anaemia. Out of 50 patients, 20 patients showed decreased level of SGPT (3.53% to 76.94%), 29 patients showed increased level of SGPT (5.56% to173.27%) and one patient showed no change in SGPT level. 21 patients showed decreased SGOT level (3.88% to 69.44%), 27 patients showed increased level of SGOT (1.04% to 144.36%) and 2 patients showed no change in SGOT level. 23 patients showed decreased level of serum alkaline phosphatase (S-ALP) (1.68% to 41.92%), 27 patients showed increased level of S-ALP (0.8% to 64%) (Table-4 & 5), when pre-treatment findings were compared with that of post treatment values. Since decrease or increases in the level of enzymes were not found to be significant therefore it can be inferred that it did not induce any negative or favourable response. The safety of the drug is though confirmed but at the same time it also indicated that Sharbat-e-Faulad does not possess hepatprotective or hepato stimulant effect as described in Unani literature. The findings suggested further that the haematinic effect was induced probably by the presence of iron in the compound formulation. The role of other ingredients however should be ascertain evoking certain other parameters.

(ii) Kidney Function Tests

A slight increase in the level of blood urea (5.62%) was observed but it was not found significant statistically. No change in serum creatinine level was observed in anaemic patients (Table-6). The two parameters of kidney function were found to be within the normal limit suggesting that test drug did not induce any untowards effect on kidney and thus can be used safely in the patients of anaemia.

Table 2 Effect of Unani drug Sharbat-e-Faulad on the levels of Haemoglobin, R.B.C. count, Total Leucocyte count (T.L.C.), Erythrocyte Sedimentation Rate (E.S.R.), Polymorph, Lymphocyte and Eosinophil count in anaemia patients.

Parameter → Group ↓	Haemo-globin (gm %)	R.B.C. ($10^6/mm^3$)	T.L.C. ($10^3/mm^3$)	ESR (mm/hr)	Poly-morphs (%)	Lympho-cyte (%)	Eosino-phil (%)
(Pre-treatment)	9.7 ± 0.09	3.22 ± 0.04	5.00 ± 0.12	38.48 ± 1.64	68.00 ± 1.03	29.0 ± 0.92	3.00 ± 0.42

Parameter → Group ↓	Haemo-globin (gm %)	R.B.C. (10^6/mm^3)	T.L.C. (10^3/mm^3)	ESR (mm/hr)	Poly-morphs (%)	Lympho-cyte (%)	Eosino-phil (%)
End follow-up (90th-days)	11.62 ± 0.98***	3.83 ± 0.05***	5.78 ± 0.16***	27.69 ±1.64***	69.00 ± 0.82	28.00 ± 0.76	3.00 ± 0.30

***P<0.001 highly significant and P is not being significant

Table 3 Effect of Unani coded drug sharbat-e- Faulad on the level of Packed Cell Volume (PCV), Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) and Mean Cell Haemoglobin Concentration (MCHC) in anaemia patients.

Parameter → Group ↓	PCV (%)	MCV (µ3)	MCHC (%)	MCH (P.gm)
(Pre-Treatment)	34.69 ± 0.55	108.43 ± 1.30	27.92 ± 0.32	30.1 ± 0.13
End Follow-up (90th-days)	39.65 ± 0.62***	103.58 ± 0.95**	29.18 ± 0.23***	30.05 ± 0.09

**P<0.01 significant, ***P<0.001 highly significant and P is not being significant

Table 4 Effect of Unani drug Sharbat-e-Faulad on the levels of SGPT, SGOT and Serum Alkaline Phosphatase (S-ALP) in anaemia patients.

Parameter →	SGPT (IU/L)			SGOT (IU/L)				Serum Alkaline-phosphatase (IU/L)			
Group →	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up 90th days)	
S. No		De-crease value	% De-crease			De-crease value	% De-crease			De-crease value	% De-crease
1	53.04	51.27	3.53%	1	30.06	26.52	11.78%	1	150.0	134.6	10.27%
2	17.77	14.14	20.43%	2	22.98	21.22	7.66%	2	64.03	58.60	8.48%
3	22.98	5.30	76.94%	3	30.06	26.52	11.78%	3	71.08	62.67	11.83%
4	56.58	24.75	56.26%	4	35.81	15.91	55.57%	4	86.54	68.53	21.81%
5	30.06	26.52	11.78%	5	50.56	17.68	65.03%	5	184.8	180.6	2.27%
6	24.75	19.45	21.41%	6	33.59	24.75	26.32%	6	146.2	84.92	41.92%
7	10.16	8.82	13.19%	7	21.22	12.38	41.66%	7	54.80	43.60	20.44%
8	28.29	22.38	20.89%	8	25.75	24.75	3.88%	8	88.72	76.49	13.79%
9	28.29	18.91	33.16%	9	26.52	21.22	20.00%	9	79.49	73.25	7.85%
10	37.13	26.24	29.33%	10	40.66	30.96	23.86%	10	72.94	67.85	6.98%
11	36.58	33.59	8.17%	11	35.36	15.91	55.01%	11	64.84	60.09	7.33%
12	33.59	20.76	38.2%	12	28.29	24.12	14.74%	12	99.84	96.86	3.00%
13	37.13	30.42	18.06%	13	26.52	20.52	22.62%	13	110.01	108.16	1.68%

Parameter →	SGPT (IU/L)			SGOT (IU/L)				Serum Alkaline-phosphatase (IU/L)			
Group →	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up 90th days)	
S. No		De-crease value	% De-crease			De-crease value	% De-crease			De-crease value	% De-crease
14	28.29	18.91	33.16%	14	22.98	20.62	10.27%	14	134.3	102.6	23.60%
15	33.59	30.06	10.51%	15	33.59	31.06	7.53%	15	87.96	78.06	11.26%
16	53.04	46.06	13.16%	16	35.36	32.18	9.00%	16	86.82	81.93	5.63%
17	37.13	22.81	38.57%	17	54.81	50.91	7.12%	17	112	110.26	1.55%
18	37.13	16.42	55.78%	18	47.74	24.9	47.84%	18	97.67	89	8.88%
19	28.29	22.98	18.77%	19	26.52	20.62	22.25%	19	75.68	69.18	8.59%
20	76.02	23.98	68.46%	20	26.52	19.45	26.66%	20	114.8	112.8	1.74%
				21	63.65	19.45	69.44%	21	206.7	150.2	27.33%
								22	104.2	98.16	5.8%
								23	77.59	66.47	14.33%

Table 5 Effect of Unani drug Sharbat-e-Faulad on the levels of SGPT, SGOT and Serum Alkaline Phosphatase (S-ALP) in anaemia patients.

Parameter →	SGPT (IU/L)			SGOT (IU/L)				Serum Alkaline-phosphatase (IU/L)			
Group →	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up 90th days)	
S. No		De-crease value	% De-crease			De-crease value	% De-crease			De-crease value	% De-crease
1	19.45	24.75	27.25%	1	22.43	54.81	144.36%	1	79.49	80.58	1.37%
2	22.98	28.29	23.11%	2	10.61	24.75	133.27%	2	68.37	87.36	27.78%
3	15.91	22.98	44.44%	3	30.06	32.13	6.89%	3	48.0	63.48	32.25%
4	21.22	28.29	33.32%	4	29.75	30.06	1.04%	4	63.48	78.68	23.95%
5	19.45	38.9	100%	5	24.75	30.59	23.6%	5	80.03	107.2	33.95%
6	31.82	33.59	5.56%	6	21.22	38.90	83.32%	6	97.67	160.18	64%
7	19.45	42.43	118.15%	7	31.82	33.59	5.56%	7	60.67	69.45	14.47%
8	26.52	31.06	17.12%	8	26.52	30.06	13.35%	8	51.55	52.9	2.62%
9	19.45	22.98	18.15%	9	20.76	28.75	38.49%	9	70.54	71.08	0.8%
10	15.91	24.75	55.56%	10	17.68	22.98	29.98%	10	63.48	64.57	1.72%
11	15.91	21.22	33.38%	11	26.92	30.06	11.66%	11	65.11	85.46	31.26%
12	14.14	38.64	173.27%	12	24.75	40.5	63.64%	12	78.12	113.9	45.8%
13	30.06	67.18	123.49%	13	24.75	32.13	29.82%	13	71.72	72.71	1.38%
14	24.75	26.41	6.71%	14	30.06	34.7	15.44%	14	82.75	88.7	7.19%
15	19.45	30.06	54.55%	15	17.68	22.98	29.98%	15	66.47	90.07	35.51%
16	12.38	24.62	98.87%	16	21.46	22.98	7.08%	16	93.87	100.5	7.06%
17	14.14	17.68	25.04%	17	26.52	31.06	17.12%	17	54.53	70.5	29.29%
18	21.22	35.36	66.64%	18	19.45	22.98	18.15%	18	55.35	65.92	19.10%
19	21.22	25.70	21.11%	19	26.52	28.72	8.30%	19	66.2	72.2	9.06%

Parameter →	SGPT (IU/L)			SGOT (IU/L)				Serum Alkaline-phosphatase (IU/L)			
Group →	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up (90th days)		S. No	Pre-treat-ment	End-follow-up 90th days)	
S. No		De-crease value	% De-crease			De-crease value	% De-crease			De-crease value	% De-crease
20	22.98	26.54	15.49%	20	21.22	25.12	18.38%	20	79.76	82.76	3.76%
21	17.68	28.56	61.54%	21	15.91	30.24	90.06%	21	54.53	66.2	21.4%
22	10.61	17.68	66.64%	22	21.22	26.52	24.98%	22	258.9	290.18	12.08%
23	15.91	18.92	18.92%	23	16.28	18.24	12.04%	23	80.03	108	34.95%
24	12.38	14.62	18.10%	24	26.52	30.2	13.88%	24	59.69	62.48	4.65%
25	24.75	28.41	14.79%	25	20.06	24.26	20.94%	25	91.97	98.66	7.27%
26	21.22	38	79.08%	26	26.52	36.06	35.97%	26	93.06	94.92	2.00%
27	19.45	22.18	14.04%	27	22.98	44.62	94.17%	27	67.28	72.46	7.70%
28	14.14	18.12	28.15%								
29	14.14	34.44	143.56%								

Table 6 Effect of Unani drug Sharbat-e-Faulad on the levels of blood Urea and Serum Creatinine in anaemia patients.

Parameter → / Group ↓	Blood Urea (mg/dl)	Serum Creatinine (mg/dl)
(Pre-Treatment)	21.90 ± 0.86	0.86 ± 0.02
End Follow-Up (90th-days)	23.13 ± 0.89□	0.87 ± 0.02□

□P is not significant

Conclusion

In the light of the above findings and the observations it can be concluded that Sharbat-e- Faulad possesses significant haematinic effect. It can also be inferred that the drug is safe as it did not induce any toxic effect, particularly on liver and kidney functions.

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