

SCIENTIFIC STUDY OF UNANI FORMULATIONS IN THE CASES OF OSTEOPOROSIS

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ABSTRACT

Osteoporosis is a worldwide concern; 20 October is remembered every year as the world osteoporosis day. Osteoporosis occurs either due to failure to achieve the peak bone mass or excessive rate of remodeling of bone. WHO defined that the BMD of -2.5 measured by DEXA scan is osteoporosis. Objective: The aim of this study to evaluate the safety and efficacy of Unani formulations in enhancing the BMD to normal level with evidences of increase in BMD by measurement with DEXA scan. Material and Methods: This clinical study is based on single blind trial. Patients as per inclusion and exclusion criteria were selected for the study. Consent of the patient recorded. Formulations are used in females: Kushta-e-Sadaf 350mg once in a day - Abhal (Juniperuscommunis) 150 mg + Asghand (Withania somnifera) 50mg + Persiaoshan (Adiantum capillus) 150 mg, two times daily. In males: Kushta-e-Sadaf 350mg once in a day-Asghand (Withania somnifera) 150mg+Bozidan (Pyrethrum indicum) 150mg, two times daily after checking their purity. Emphasis is also given on daily diet regarding that patient must have balance diet with milk, fruits, and vegetables. The study conducted in two groups. Group A is given Unani formulations by oral route. In-group B along with Unani formulations exercise and cupping, a classical method of Unani applied as a part of treatment to observe the effect in increasing the BMD in relation to duration of treatment was used. Results: In-group A which included 60 patients (48 females & 12 males), 30 patients (50%) became normal and the Osteopenia was near to normal in 17 patients (28%). Out of 30 normal cases, 27 became normal in the duration of 8-9 months and 13 patients attained the Osteopenia near to normal in the same period. In-group B of 80 patients (62 females 18 males), 52 patients (65%) became normal and the Osteopenia was near to normal in 24 patients (30%). Out of 52 normal cases, 39 patients became normal in duration of 6 to 6.5 months. To rule out any side effects and toxicity on the vital organs of the body the blood sugar, LFT, KFT, lipid profile, S. alkaline phosphates and Hb% were done before starting the treatment then it was repeated on every month till the end of treatment. The above enzymes and biomarkers values remain within normal limits or near to normal on repeated examination on every month in the cases that became normal except in the cases where Osteopenia/osteoporosis continued and not responded with the treatment. In some patients, having osteoporosis with T score -4.5 or above the S. alkaline phosphates level was slightly higher and continued to be higher on repeated blood examination during the treatment in these cases showing very slow response and not becoming normal. Conclusion: The sample size of groups A & B is not the same; however, the cure rate in-group A is 50% while in-group B, the cure rate is 65%. The average duration of treatment in-group A is 8-9 months while in-group B is 6-6.5 months. This shows that regular exercise and application of Hejama (Cupping) reduce the duration of treatment. The duration of treatment of any of the disease is an important factor because medicine should be use for a shorter period. The above study validates the effectiveness of Unani formulation in increasing the BMD to normal level and no significant signs or side effects were observed even after use the formulations for months together.

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Introduction

Osteoporosis is characterized by low bone mass and density (BMD) with micro architectural deterioration of bone tissue leading to enhanced bone fragility. This increases the susceptibility to fracture. Osteoporosis is a silent disease, (remain without any pain

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or discomfort) reflected in low bone density until a fracture occurs [1]. It is the most common reason in elderly of typical fragility fracture occurs in the vertebral column, ribs, hip and wrist. Technically Osteoporosis is defined as bone mineral density of 2.5 and standard deviation below that of a younger adult typically measured by Dual Energy X-ray Absorptiometry (DEXA) at the hip. WHO's definition of osteoporosis at present is only applicable when BMD is measured by DEXA scan. DEXA scan is not allowed during pregnancy. The WHO guidelines for clinical diagnosis is based on T score of DEXA scan. T score of less than 1.0 is defined as Osteopenia. T score of less than 2.5 is defined osteoporosis [2].

Osteoporosis is increasing in India and the victims of this disease are old men and women, they may suddenly suffer from fracture of bone and may be disabled for longtime and become burden on family/society. In the west, osteoporotic fractures are major cause of morbidity and mortality in elderly. With the increasing longevity in age of Indian population, it is now being realized that, as in west, osteoporotic fractures will be a major cause of morbidity and mortality in old women and men in India.

Even conservative estimate suggests that of these, 20% of women and about 10-15% of men would be osteoporotic. The total affected population would, therefore, be around 25 million [3]. It is estimated that 10% of the Indian population is above 65 years of age and at least five crore people are at risk of osteoporotic fractures. One in every third postmenopausal women is at the risk of fracture [4]. Osteoporosis is not only preventable but also treatable; however, most of the cases remain undiagnosed and remain untreated and therefore possibility of the fracture increases.

In India, it is generally believed that osteoporosis affects the females only while medical data shows that ratio in women is 1:4 while in man it is 1:8 above the age of 40.

In finding out effective formulations of Unani medicine, it is necessary to take an account the various risk factors of osteoporosis disease. Some causes are Non modifiable like advanced age, race, heredity and build where as some are Potentially modifiable comprising alcohol, smoking, malnutrition, high animal protein diet, underweight/inactive person, heavy metals, soft drinks, diseases and Drugs.

Patients and Methods

This is a clinical study based on single blind trial. The cases of osteoporosis as per WHO definition is where the BMD measured by DEXA scan and BMD T score found -2.5 admitted in the study as per the following inclusion and exclusion criteria.

Inclusion Criteria:

Patients of the osteoporosis of both the sexes around the age of 40 years with or without the symptom of osteoporosis or fracture but having BMD T score -2.5 on DEXA scan.

Exclusion Criteria:

Patients of osteoporosis (BMD T score -2.5) but suffering from (I) Secondary hypertension, tuberculosis of any organ, thyroid or any hormonal disorders. (II) Ischemic heart disease, coronary bypass operation, oophorectomy, liver or kidney insufficiency, pregnancy and type-1 diabetes. Type-2 diabetics with blood sugar above (Fasting 110-130/mg/dl--PP 140-200/mg/dl) excluded from the study.

As per inclusion and exclusion criteria, the patients selected for the study. History of the patient and consent of the patient were taken and recorded.

Unani formulations used in the study:

There are number of Unani medicine mentioned in Unani text as chondro protective or to strengthen the bones or to unite the bone when there is a fracture in the bone but no evidence based study was available that they increase the bone mineral density. This is the first evidence based scientific study in relation to improvement in BMD on the examination with Dexa scan.

To treat the Osteopenia or osteoporosis Kushta-e-Sadaf, a natural source of calcium processed in the form of kushtha along with some known chondro protective, anti-inflammatory and analgesic drugs combination as below:

In females: Kushta-e-Sadaf 350mg once in a day

Abhal (Juniperus communis) 150mg+Asgand (Withania somnifera)

150mg+Persiaoshan (Adiantum capillus) 150mg, two times daily

In males: Kushta-e-Sadaf 350mg once in a day

Asgand (Withania somnifera) 150mg+

Bozidan (Pyrethrum indicum) 150mg, two times daily

The Sadaf was procured from the Dawakhana Tibbiya College, Aligarh, identified, cleaned and then Kushta-e-Sadaf was prepared as per standards prescribed in National Formulary of Unani Medicine- Part I Ministry of Health, GOI [5].

The single drugs Abhal (Juniperus communis) [6-7], Mushktramashi (Persiaoshan) (Adiantum capillus) [8-9], Asghand (Withania somnifera) [10-11-12], Bozidan (Pyrethrum indicum) [13-14] were procured from Dawakhana Tibbiya College Aligarh identified, checked for quality and their Safoof (fine powder) prepared as per the standard Unani pharmacopoeial method in our department of Saidla (Unani pharmacy) faculty of Unani medicine AMU Aligarh.

Along with the above medicines, emphasis also given on diet. The patient advised to take milk and their products, seasonal fruits and vegetables, which provide good amount of potassium, magnesium, beta-carotene and fiber in daily diet. Such diets in all ages and sex particularly affect bone mass by providing alkaline environment which is helpful for absorption of the calcium and minerals.

The selected patients divided into group A-B. The group-A (60 patients) were given the Unani formulations only orally as per gender. In-group B (80 patients) along with the Unani formulations, Unani Regimanal therapy method i.e. Hejama or cupping was applied in every patient. Hejama (Cupping) is an Unani classical method of treatment that has been used in the prevention and management of different diseases in the body. Cupping is a therapy in which cups applied on the surface of skin and a vacuum created through suction in result cups adhere on the surface of the body. (Fig.1) It improves blood circulation (Hyperemia) locally and draws the healing force to the diseased part of the body. Cupping therapy is used in musculo-skeletal pain, sciatica, arthritis, etc [15]. It acts by increasing the blood supply of the affected parts and oxygen perfusion locally, decreasing the blood viscosity, increasing absorption of essential substances locally and in result resolving the inflammation [16].



Fig. 1 Hejama (Cupping)

The cups were applied on the back (Lumber region) of the patient for half an hour daily in first seven days, then once in a week for three months, then once on every fifteen-day till the treatment is given.

Secondly Exercise was also included in treatment schedule for treating osteoporosis because low physical activity leads to increased bone loss, decreased BMD and in results increase fracture risk. Number of studies has proved the role of exercise in improving the BMD in the process of age related osteoporosis decline [17].

To get the benefits of exercise including increased BMD throughout life, there is a need to evolve a regular exercise programme at least 5 hours per week [18,19].

Therefore, along with the Unani treatment, lumber flexion and extension exercises for 30-35 minutes per day are advised as a part of the treatment (Fig. 2-3).



Fig. 2 Spinal Flexion Exercise



Fig. 3 Spinal Extension Exercise

To rule out any undesirable effect of the formulations/Regimanal methods on the patient LFT, KFT, general haemogram, blood sugar and Hb% were done before starting the treatment, then it was repeated on every month till the end of the treatment.

Further, response of medicine is also observed by clinical examination of patients to find out any new changes in any system of the body or skin etc.

Results, Findings and observations:

In Group A, 60 patients of osteoporosis of both the sexes, of various age were selected and included in study as per inclusion criteria.

The efficacy of Unani formulations in terms of deposition of calcium and minerals in bone i.e. increase in BMD measured by DEXA scan before starting treatment and after the treatment (5-11 months). Results of the DEXA scan in relation to age and sex of the patient recorded for analysis.

In Group A, the observation and result surmised in the tables and graphs below and analyzed as under:

Table 1: Gender wise data

Gender	No of Patient	Percentage
Female	48	80%
Male	12	20%
Grand Total	60	100%

Table 2: Age group distribution

Age Group	No of Patient
25-29	1
35-39	2
40-44	1
45-49	6
50-54	15
55-59	13
60-64	10
65-69	5
70-74	6
75-80	1
Grand Total	60

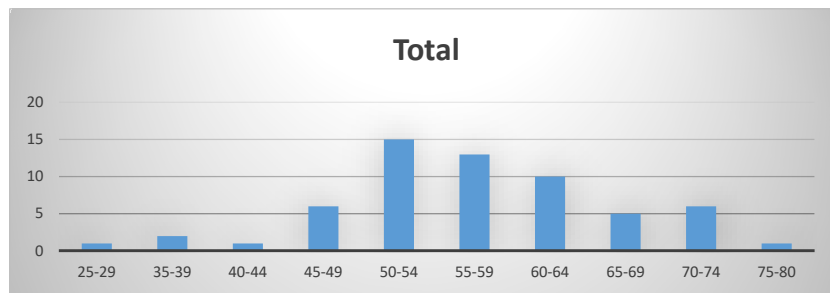


Fig4.

The Table 2 and Fig. 4 show that the age group of 50-54 years have the maximum number of patients 15 (25%) then the age group 55-59 have 13 patients (22%) while in the age group 60-64, there are 10 patients (17%) only. In remaining age groups, the numbers of patients were very less.

Table 3: Age group with gender wise distribution

Age Group	Gender		Grand Total
	Female	Male	
A 25-34	1		1
B 35-44	3		3
C 45-54		20	21
D 55-64		18	23
E 65-74		6	11
F 75-85		1	1
Grand Total	48	12	60

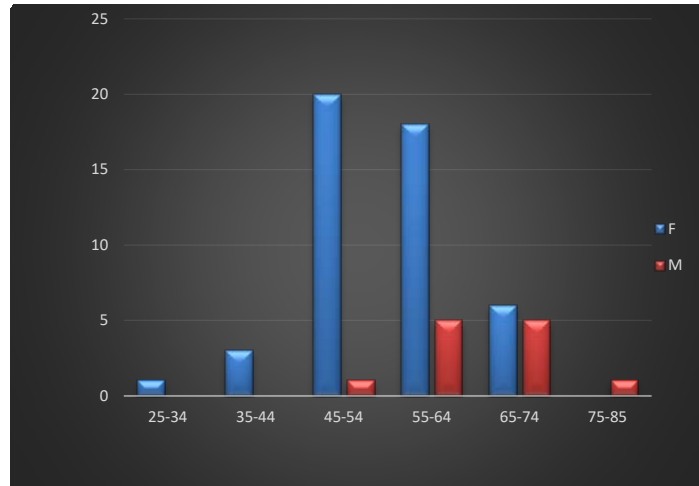


Fig. 5

The above Table-3 and Fig.5 show that in various age groups the gender wise distribution of the disease also varies. Out of 48 female patients in the age group of 45-54, the female patients were 20 (42%) while in the age group of 55-64, the female were 18 (37%). Moreover, in the age group, 65-74, the females were 6. out of 12 male patients, group C has 01, group D and E 05 each and group F 01 male only.

Table 4: Result Distribution

Observation	No of Patient	Percentage
Normal	30	50.0%
Osteopenia	17	28.3%
Osteopenia*	10	16.7%
Osteoporosis	3	5.0%
Grand Total	60	100%

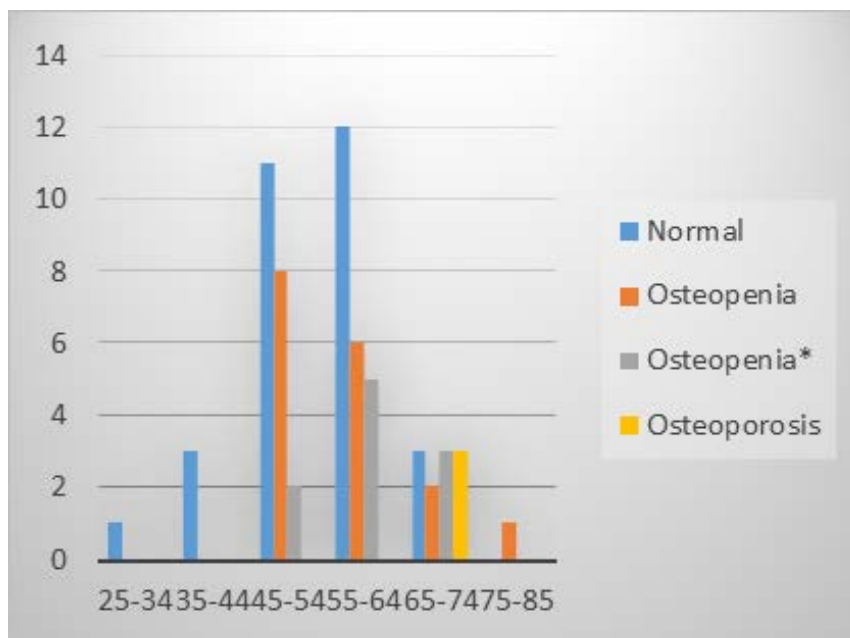


Fig. 6

Table 4 Fig. 6 indicate that out of 60 patients, 30 patients (50%) were become cured while 17 patients (28%) responded well and reached to the level of Osteopenia near the normal. 10 patients (18%) improved very slow and the Osteopenia* in these patients was marked. The 3 patients (5%) did not improve and remained osteoporotic (BMD more then -2.5).

Table-5: Age wise result

Age Group	Result				Total patients
	Normal	Osteopenia	Osteopenia*	Osteoporosis	
25-34	1				1
35-44	3				3
45-54	11	8	2		21
55-64	12	6	5		23
65-74	3	2	3	3	11
75-85		1			1
Grand Total	30	17	10	3	60

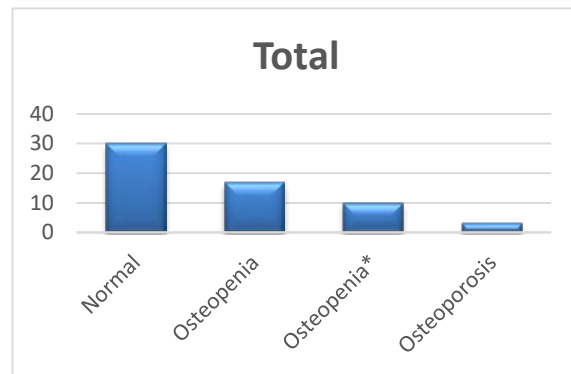


Fig. 7

Table-5 Fig. 7 indicate that in early age group 25-34, there was only 01 patients, who became normal and in the age group 35-44, there were 03 patients and 03 became normal which indicate the very good response in early age. In the age group of 45-54, out of 21, 11 patients became normal, 08 patients improved well and Osteopenia was near to normal while in 02 of the patients, the Osteopenia was marked. In the age group of 55-64, out of 23, 12 patients become normal and 06 improved well and Osteopenia was near to normal but in 05 patients, the Osteopenia was marked. This shows that above four groups responded well to the treatment.

Table 6: Response of treatment in term of months

Treatment Duration, months	Result				Total patients
	Normal	Osteopenia	Osteopenia*	Osteoporosis	
6		1			1
7	1	1			2
8	15	11	10	3	39
9	12	2			14
11	2	2			4
Grand Total	30	17	10	3	60

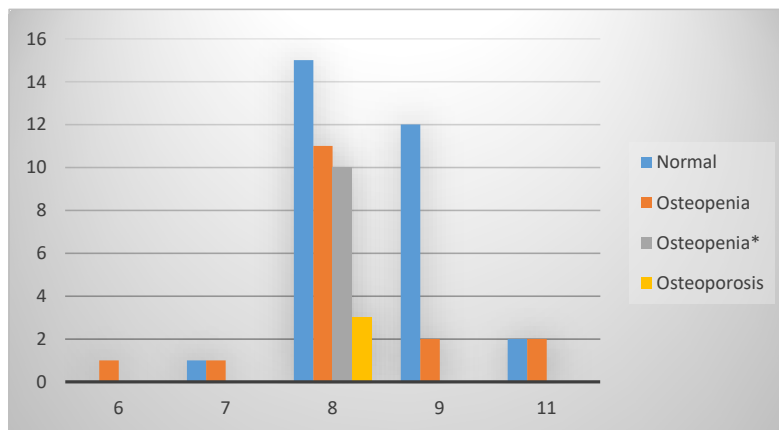


Fig. 8

The above Table 6 and Fig. 8 shows that in-group A, one patient became normal and 01 improved near to normal (Osteopenia) in 07 months. 15 patients became normal and 11 patients improved near to normal (Osteopenia) in 08 months. 12 patients became

normal and 02 improved near to (Osteopenia) normal in 09 months. Two patients became normal in 11 months and two improved near to normal (Osteopenia) in 11 months. The above results indicate that out of 30 normal patients, 27 patients became normal in 8-9 months.

In Group B, 80 patients of osteoporosis of both the sexes, of various age groups were selected and included in study as per inclusion and exclusion criteria. In this group along with the use of Unani formulations, the (i) Exercise (Reyazat) (ii) Hejama (Cupping) were integral part of treatment and patients followed the instructions. The efficacy of Unani formulations in term of deposition of calcium and minerals in bone i.e. increase in BMD measured by DEXA scan before starting treatment and after the treatment the results in relation to age and sex of the patient recorded. In this Group B, the observation and result surmised in the following tables and graphs and analyzed as under:

Table-7: Gender wise data

Gender	No of Patient	Percentage
Female	62	77%
Male	18	23%
Grand Total	80	100%

Table-8: Age group distribution

Age Group	No of Patient
35-44	7
45-54	13
55-64	51
65-75	9
Grand Total	80

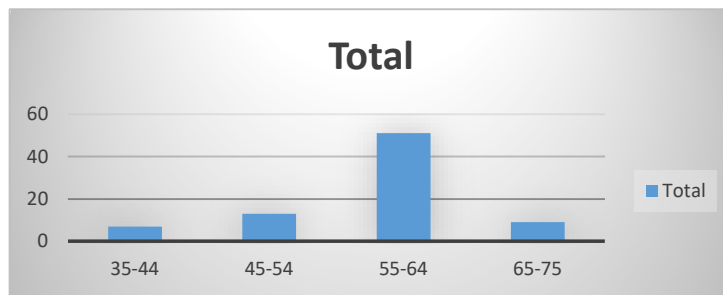


Fig. 9

The above Table 8 and Fig. 9 show that the age group of 55-64 years have the maximum number of patients 51 (64%). The age group, 45-54 have 13 (16%) patients while the age group 65-75, there are 09 (11%) patients only and in age group of 35-44, there are only 07 (9%) patients.

Table-9: Age group with gender wise distribution

Age Group	Gender		Total patients
	Female	Male	
35-44	6	1	7
45-54	10	3	13
55-64	42	9	51
65-75	4	5	9
Grand Total	62	18	80

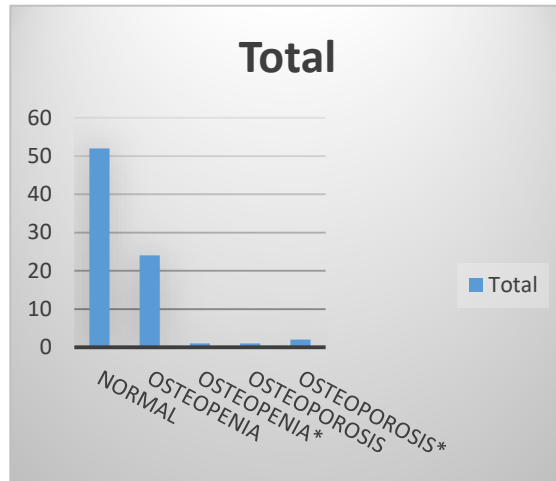


Fig. 10

The above Table 9 and Fig.10 show that in various age groups, the gender wise distribution of the disease also varies. Out of 62 female and 18 male patients in the age group of 35-44, the female patients were 6 and male 1. In age group of 55-64, the female patients were 42 and male were 09 while in the age group of 45-54 the females were 10 and 03 males. Moreover, in the age group, 65-75 the females were 4 and males were 05 while in the age group 35-44, the females 06 and males 01.

Table-10: Result Distribution

Observation	No of Patient	Percentage
Normal	52	65.00%
Osteopenia	24	30.00%
Osteopenia*	1	1.25%
Osteoporosis	3	3.75%
Grand Total	80	100.00%

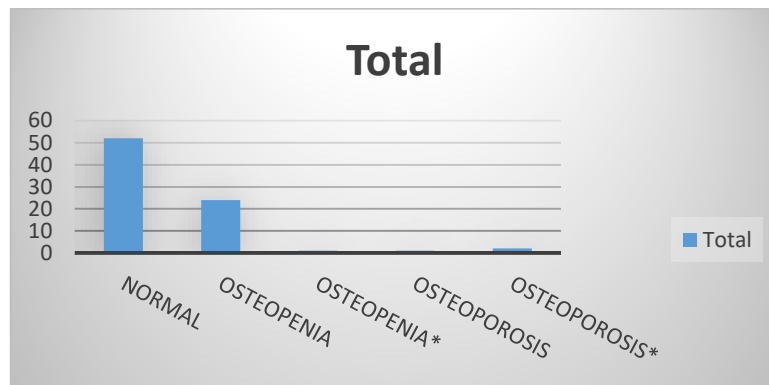


Fig. 11

The above Table-10 Fig.11 shows that out of 80 patients, 52 (65%) patients became normal while 24 (30%) patients responded well and reached to the level Osteopenia near the normal. One patients improved very slowly and the Osteopenia* in this patient was marked. 03 (4%) patients did not improve and remained osteoporotic (BMD more then -2.5).

Table-11: Age wise result

Age Group	Result				Total patients
	Normal	Osteopenia	Osteopenia*	Osteoporosis	
35-44	6	1			7
45-54	10	3			13
55-64	30	18	1	2	51
65-75	6	2		1	9
Grand Total	52	24	1	3	80

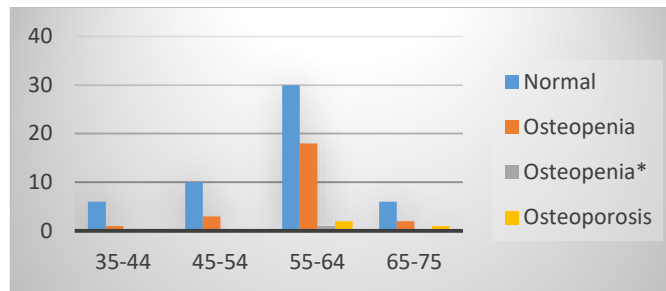


Fig. 12

Table 11, Fig. 12 show that in the early age group 35-44, there were 07 patients in which 06 became normal and 01 reached Osteopenia near to normal. In the age group, 45-54, there were 13 patients, 10 became normal, and 03 Osteopenia near to normal which indicate the good response in these age groups. Out of 51 patients in the age group of 55-64, 30 patients became normal, 18 patients improved well and Osteopenia was near to normal, in 01 patient, Osteopenia was marked, while osteoporosis continued in 02 patients. In the age group of 65-75, out of 09 patients, 06 became normal, 02 improved well and Osteopenia was near to normal while in one patient, osteoporosis continued.

Table-12: Effect of duration of treatment on observation

Treatment Duration, months	Result				Total patients
	Normal	Osteopenia	Osteopenia*	Osteoporosis	
5.5	1	2			3
6	15	5		1	21
6.5	24	8	1	2	35
7	9	9			18
7.5	3				3
Grand Total	52	24	1	3	80

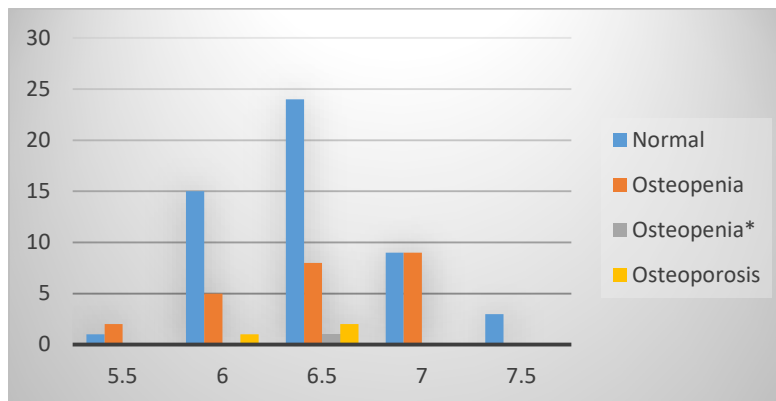


Fig. 13

Table 12, Fig 13 show the results in group B, one patient became normal and 02 improved near to normal (Osteopenia) in 5.5 months. 15 patients became normal and 05 patients improved near to normal (Osteopenia) and one remained osteoporosis in 6 months. In 6.5 months, 24 patients become normal and 08 improved near to normal (Osteopenia) and 01 patients had marked Osteopenia and in two patients osteoporosis continued. In 07 months out of 18 patients, 09 became normal and 09 improved near to normal (Osteopenia). In 7.5 months out of 03 patients, 03 become normal. This indicate that in group B out of 52 normal patients, 48 patients became normal from 6 to 7 months' duration.

Discussion

In this study, the selected patients as per inclusion and exclusion criteria were divided in-groups A and B. In-group A, patients were treated with Unani formulations only as per male and female formula. In-group B along with the above Unani, formulations as per gender, patient followed the lumbar flexion an extension exercises 30-35 minutes per day as part of treatment. Further Hejama (Cupping) an Unani Classical method of treatment was also applied to enhance the BMD of bones. It is encouraging observation that in both groups, after few days of administration of Unani formulation those patients having pain and stiffness in lumbar region and hip get relieved which indicate that these formulations have some analgesic effect also.

In-group A, there were 60 patients (48 females 12 males) and majority of the patients were 50 to 64 years of age. Out 60 patients, in 30 (50%) patients BMD became normal and patients were cured and the Osteopenia was near to normal in 17 (28%) cases. Out of 30 normal cases, 27 became normal in the duration of 8-9 months and 13 patients attained the Osteopenia near to normal

in the same period. In-group B of 80 patients (62 females 18 males), the majority of the patients were 45 to 60 years of age. Out of 80 patients, in 52 (65%) patients, BMD became normal and the Osteopenia was near to normal in 24 (30%) patients. Out of 52 normal cases, 39 patients became normal in duration of 6 to 6.5 months. Cure rate in-group A is 50% while in-group B the cure rate is 65%. The average duration of treatment in-group A is 8 to 9 months while in-group B is 6 to 6.5 months. The sample size of groups A & B is not same; however, an inference can draw that Unani formulations are effective in improving the BMD to a normal level in both of the groups. In-group B, intervention with cupping and exercise reduces the duration of treatment. The duration of treatment of any of the disease is an important factor because medicine should be used for a short duration as far as possible. In group A, in age group 25-34, there was 01 patients and 01 became normal. In age group 35-44, there were 03 patients and 03 became normal. In age group 45-54 and 55-64, out of 44 patients, 23 became normal. In-group B, in the age group 35-44, out of 07 cases, 06 became normal, in age group of 45-54, out 13 patients, 10 became normal. In the age group of 55-64, out of 51 patients, 30 became normal. The findings suggest that in both of the groups the Unani formulations are more effective in early and middle age 35 to 55 years of age. In some female patients above the age 50, the Hb% was below normal, in such cases haematinics also given. To rule out any side effects or toxicity on the vital organs of the body in both groups A and B, the blood sugar, LFT, KFT, lipid profile, S. alkaline phosphates and Hb% were done before starting the treatment then repeated on every month till the end of treatment. The levels of the above biomarkers and enzymes in blood were found within normal limits or near to normal on repeated examination on every month in the cases cured except in the cases where Osteopenia/osteoporosis continued and not responded with the treatment. In some patients, having osteoporosis with T score -4.5 or above the S. alkaline phosphates level was slightly higher and continued to be higher on repeated blood examination during the treatment and these cases showed very slow response and did not become normal.

Conclusion

This study validated the effectiveness of Unani formulations in improving the BMD to normal and curing the osteoporosis. No significant signs and side effects noted even after use the formulations for months together, except some patient complained about indigestion, which was subsided within some days by changing in the diet schedule. This study helped in providing effective, safe and evidence based alternate treatment by Unani medicine for the osteoporosis, which will help in preventing sudden fragility fracture in old patients and will, decrease the burden on the family and health care system of the states.

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*YNM= Year Not Mentioned