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Research Article

Efficacy of majun e khabsul hadeed in iron deficiency anemia in reproductive age group: A randomised control study

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Abstract

Background and Objectives: Iron deficiency is a condition in which blood lacks adequate healthy red blood cells. Women of child bearing age are at high risk. In India incidence is 74% and prevalence is 30%. The goals of treatment are to restore changes in hemoglobin levels, red cell indices and peripheral smear. Aim of the study is to evaluate the effect of *majune khabsul hadeed* in iron deficiency anemia in women of reproductive age group.

Methods: A randomised standard controlled study, 60 patients were randomly allocated to test and control groups. *Majune khabsul hadeed* 5grams in test group and capsule fefol 1 in control group were given once daily for 3months. Subjective parameters viz. pallor, loss of appetite, reduced exercise capacity and fatigue were assessed at every follow up. Red cell indices, as objective parameters were assessed before and after treatment.

Results: Significant changes were observed in subjective parameters with $p<0.001$ at each assessment in both groups. On intergroup comparison there were no significant difference with $p>0.05$ except for reduced exercise capacity and fatigue. Objective parameters significantly improved in both groups after treatment with $p<0.001$. Five (16.7%) and 4(13.3%) patients were among responders, 10(33.3%) and 14(46.7%) partial responders and 13(43.3%) and 12(36.7%) non responders to treatment in test and control groups respectively. On intergroup comparison, there was no significant difference with $p>0.05$ suggesting that both groups had similar effect.

Conclusion: *Majune khabsul hadeed* is as effective as capsule fefol in the management of iron deficiency anemia in women of reproductive age group.

Keywords: Iron deficiency anemia; *majune khabsul hadeed*; women of reproductive age; RBC indices.

INTRODUCTION:

The world health organisation defines anemia as hemoglobin level below 130 g/l in men, 120 g/l in non-pregnant women and 110 g/l in pregnant women.[1]According to centres for disease control and prevention, iron deficiency is a condition resulting from too little iron in the body [2] and when the amount of available iron cannot complete the need of iron for the production of red blood cells.[3]It can be result from inadequate iron intake, decreased iron absorption, increased iron demand and increase iron loss.[4] it occurs in all ages but is especially common in women of child bearing age, in whom it is an important cause of chronic fatigue and ill health. during the reproductive life of the female several factors including menstruation, pregnancy, parturition and lactation significantly increases the physiological requirements of iron.[5]

Although more than 100 preparations containing iron are available but have immense gastro intestinal side effects that often effect the compliance of therapy.[6]However, due to the side effects of ferrous sulfate, some new formulations of iron supplement are under investigation and are being considered for the replacement of ferrous sulfate. One of these new agents is iron oxide.[7]

In unani medicine literature various single drugs are mentioned for iron deficiency anemia e.g. berberis vulgaris,ferraso ferric oxide(iron oxide),[8]cichorium intybus[9] etc. The goals of the alternative treatment are same as the conventional treatment i.e. to restore changes in hemoglobin levels, red cell indices and peripheral smear. In present study, a herbomineral formulation in jelly form *majunekhabsulhadeed* was considered for the management of iron deficiency anemia.

The main ingredient of this preparation if *khabsulhadeed* (ferraso ferric oxide / iron oxide), This therapeutic supplement has a widespread application, and previous studies have shown that in addition to providing blood iron (Fe), this agent can act as an antioxidant compound. Iron oxide plays a key role in biomedicine and can act as an iron supplement.[7]According to Unani literature *khabsulhadeed* possesses *Mawallid-e- Dam* (Heamatogenic)*Muqawwi-e-Medawa Kabid* (Stomachic and liver tonic) properties among others.[10]

Studies on different compositions of *khabsulhadeed* have been proved effective in IDA; *Safoofkhabsulhadeed*3 gm/day in capsule form was as effective as Capsule fefol in improving iron deficiency anemia during pregnancy in a study conducted by Jeelani et al., C. [11]similarly *MajoonKhabsul Hadeed* in a dose of 6 gm administered twicedaily for 60 days; showed Significant improvement in symptoms &signs and laboratory findings especially improved PCV, MCV and serumironwas observed in a study by Md Wasi Akhtar et al.[12]

In this formulation apart from *khabsulhadeed* (ferraso ferric oxide) other constituents like *amla* (Emblica officinalis), *baheda*(Terminalia bellerica), *balchar* (Nardostachys jatamansi), *soya* (Anethum sowa) are present which possess properties like hematopoietic, hepato-protective, hepato-stimulant and stomachic,[13-17]thereby gastrointestinal disturbance with this iron therapy are expected to be minimal. It also contains high amount of vitamin C which facilitates absorption of dietary non heme iron; hence may be recommended on priority.

MATERIAL AND METHODS

Study design: This randomised, single blind, standard control clinical trial was approved by the institutional ethical committee (IEC No. NIUM/IEC/2016-17/ANQ/03 dated 18-05-2017) and registered at CTRI (CTRI/2018/03/012759). The study was conducted at Department of Ilmul Qabalat wa Amraze Niswan, National institute of unani medicine hospital Bengaluru Karnataka from January 2018 to December 2018 among women of reproductive age group. Written informed consent prior to study was taken from all the participants.

Sampling method and randomisation: The sample size was calculated using the statistical formula, $n = 2 [(Z\alpha - Z\beta)\ \sigma / \mu 1 - \mu 2]^2$. [18]SD and mean of the hemoglobin of the previous study[19]were taken for the estimation of sample size. Estimated sample size was 30 in each group. Randomisation was done by using a computer-generated randomisation table.

Subject recruitment: The subjects were screened for the clinical study based on inclusion and exclusion criteria. A total 70 eligible subjects were screened and 60 met the inclusion and exclusion criteria. 10 patients were excluded because 3 of them had dimorphic anemia, 3 were known case of hypertension and 4 declined to participate in the study. Of the 60 recruited patients 30 were randomly assigned to test group and 30 to the control group.

Inclusion criteria: Patients within age group 18-45 years and hemoglobin in the range of 8-11.9 gm%

Exclusion criteria: Hemoglobin less than 8gm%, history of acute blood loss, systemic diseases, pregnant and lactating women

Study procedure: The patients fulfilling the inclusion criteria were enrolled after explaining the study in detail and receiving informed consent. In each patient, history was evaluated and complete physical examination including systemic examination was performed. Complaints with duration, personal history, past history, family history, clinical features and investigations were recorded in the CRF structured specifically for the study. Demographic details and socioeconomic status were assessed using kuppuswamy socioeconomic scale 2017.[20]

World health organization criteria for iron deficiency anemia: The WHO defines anemia as hemoglobin level below 130 g/l in men, 120 g/l in non-pregnant women and 110 g/l in pregnant women.

Scales and questionnaires used in the assessment of subjective parameters: Subjective parameters including generalized weakness, reduced exercise capacity, loss of appetite and fatigue.

For the assessment of pallor, **pallor scale** was used.

Pallor at any site was classified as being absent, mild, moderate or severe. The conjunctiva was considered pale if the anterior rim of the lower palpebral conjunctiva looked as pale as the deeper posterior rim. The tongue pallor was assessed on the dorsum of the tongue. Palmer pallor was assessed by the intensity of the colourof the palmer creases. Nail bed pallor was assessed by the colorof thenail.[21]

Pallor scale was arbitrarily divided into grades.

Grade 0: No pallor
Grade 1 (Mild): Pallor of conjunctiva and/or mucous membrane
Grade 2 (Moderate): Pallor of conjunctiva and/or mucous membrane + pallor of skin
Grade 3 (Severe): Pallor of conjunctiva and /or mucous membrane + pallor of skin+ pallor of palmer creases.[21, 22]

For the assessment of appetite **Council of Nutrition appetite questionnaire (CNAQ)** was used. It was developed by the council for nutritional strategies in long term care to examine major issues surrounding the diagnosis, prevention and treatment of under nutrition and the management of under nutrition in long term care.

Patient should be asked to complete the questionnaire by encircling the correct answer and then the results should be checked based upon the following numerical scales: a=1, b=2, c=3, d=4, e=5. The sum of the scores for the individual items constitutes the CNAQ score.

Score ≤ 28 indicates significant risk of at least 5% weight loss within six months.[23]

CNAQ scale: arbitrarily divided into grades.

Grade 0 (Total score 40)
Grade 1 (Total score 31-39)
Grade 2 (Total score 21-30)
Grade 3 (Total score 11-20)
Grade 4 (Total score 0-10)

Exercise capacity was assessed by using **Veterans specific activity questionnaire** (VSAQ):

VSAQ developed by Myers et al, is a very simple and easy questionnaire-based method that enables the evaluation of the exercise capacity and it has been used widely used.

The use of VSAQ allows the determination of different intensities of daily activities with corresponding MET in an increasing order. The scale ranges from 1 MET to 13 METs. The participants were asked to choose the MET that reflected the activity with the highest intensity that the participants are able to do routinely with minimal or no symptoms, such as shortness of breath, chest discomfort and fatigue and this MET was expressed as VSAQmaximum.[24, 25]

VSAQ scale: arbitrarily divided into grades.

Grade 0 (Total score 13)
Grade 1 (Total score 9-12)
Grade 2 (Total score 5-8)
Grade 3 (Total score 1-4)

Fatigue was assessed by using **Fatigue severity scale (FSS)**.It is a method of evaluating the impact of fatigue. The FSS is a short questionnaire and contains 9 statements that rate the severity of fatigue. 1 to 7 numbers should be encircled based on how accurately it reflects the patient's condition and extent to which she is agree or disagree to it. A low value indicates strong disagreement with the statement, whereas high value

indicates strong agreement.

Scoring of the result is done adding all the numbers. A total score less than 36 suggests that participant may not be suffering from fatigue. Score more than 36 suggests further evaluation.[26, 27]

FSS was arbitrarily divided into grades.

Grade 0 (Total score 9)
Grade 1 (Total score 10-23)
Grade 2 (Total score 24-43)
Grade 3 (Total score 43-63)

Objective parameters: including hemoglobin percentage, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration and peripheral smear.

Safety parameters: including **s**erum glutamic oxaloacetic transaminase activity (SGOT), serum glutamic pyruvic transaminase activity (SGPT), serum alkaline phosphatase activity, blood urea and serum creatinine

Monitoring and follow up: Once participants had fulfilled the inclusion criteria, written informed consent was obtained, and baselines scores for objective and subjective parameters were recorded. Information regarding duration and follow ups of the trial was given. Assigned intervention i.e. tests or control was given for 3 months. Patients were asked to come on every 15th day as for follow up and to get the intervention for the next 15 days. Subjective parameters were recorded on every 15 days for 3 months. Patient was asked for any adverse effect during each follow up. Objective parameters and safety parameters were reassessed after completion of the trial.

Interventions

In test group: *Majunekhabsulhadeed* a jelly form medicine was procured from Hamdard laboratory, a GMP certified company. Each 5gms of *majunekhabsulhadeed* contains *Emblica Officinalis*, *Nardostachys jatamansi*, *Terminalia Bellerica*, *Piper longum*, *Zingiber officinale*, *Plumbago zeylanica*, *Cyperus rotundus*, *Piper nigrum*, *Terminalia chebula*100 mg each, *Anethum sowa*, *Asphodelus tenuifolius* 45 mg each, clarified butter 100 mg, Ferraso ferric oxide 100 mg and Sugar 3650 mg. 75 gms medicine was dispensed in airtight container, sufficient of 15 days and patient instructed to take 5gms of *majunekhabsulhadeed* per day. The medicine was given for 3 consecutive months with following of once in 15 days.

The control drug capsule fefol was procured from nearby pharmacy, manufactured by GlaxoSmithKline Pharmaceuticals Limited and given in a dose of one capsule OD for 3 months.

Statistical analysis: The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance, with P values <0.005 considered statistically significant.

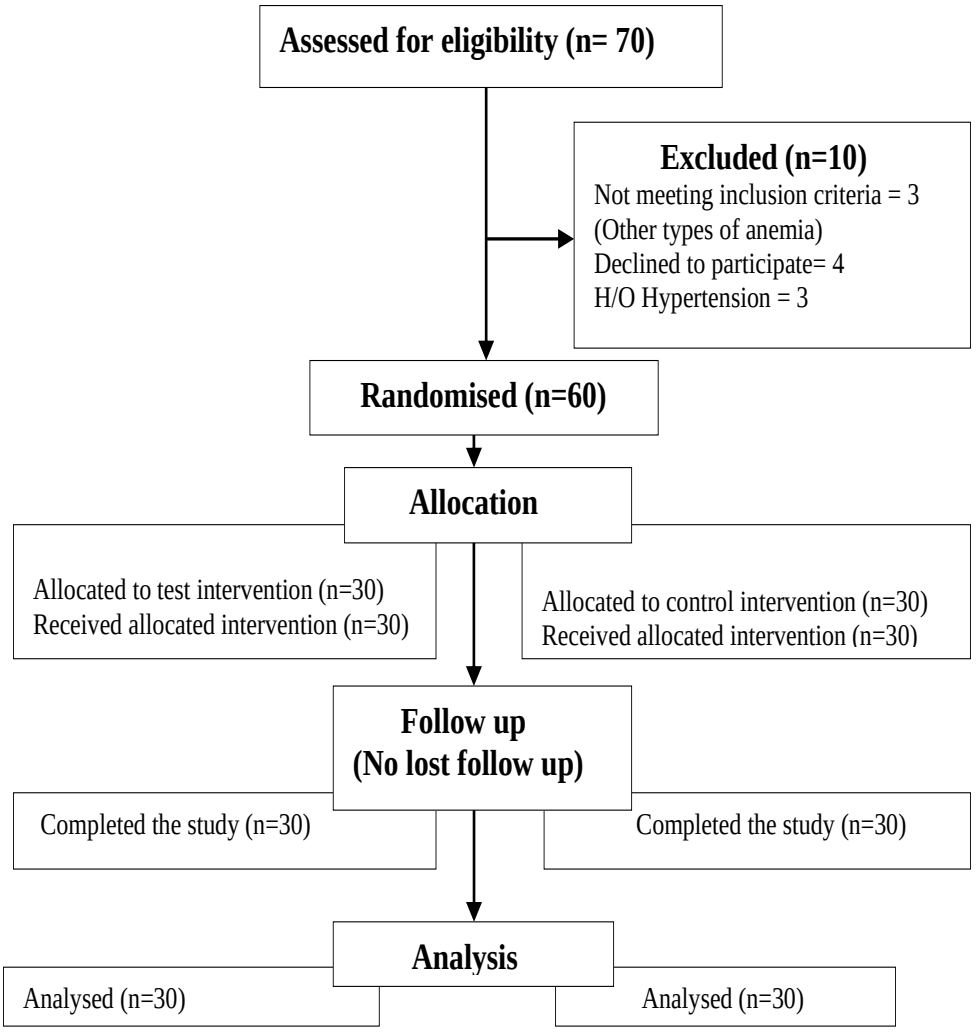

Figure 1: CONSORT Diagram

RESULTS:

A total 70 patients were assessed. 4 declined to participate and 66 meet the inclusion criteria. 6 did not meet the inclusion criteria, leaving 60 women to be randomly allocated, 30 patients in each group. (**Fig. 1**)

Both groups were comparable in base line characteristics namely age, socioeconomic status, marital status, diet, life style, habits, BMI and mizaj. All characteristics were insignificant with p value >0.05 except marital status and mizaj. This difference could be due to chance since sample size was modest. (**Table 1**)

Out of 60 patients all (30 in test and 30 in control group) were having pallor, reduced exercise capacity, loss of appetite and fatigue before treatment. The change in mean score of pallor scale, VSAQ, CNAQ and FSS, after treatment in test and control group were statistically significant (p<0.001) (**Table 2**) in all subjective parameters.

But on intergroup comparison test drug is more effective in alleviating reduced exercise capacity and fatigue as compared to control drug. (p>0.001) (**Table 2**)

Objective parameters viz. Hb%, PCV, MCV, MCH, MCHC, RBC count were also significantly improved in both the groups after treatment with p<0.001.

On intergroup comparison there were no statistically significant difference suggesting that the test drug to be as effective as control drug in improving objective parameters and alleviating IDA. **(Table 3)**

Before treatment 22 (73.3%) patients in test group and 19 (63.3%) in control group had microcytic hypochromic peripheral smear, 8 (26.7%) and 11 (36.7%) had normocytic hypochromic peripheral smear in test and control group respectively. After treatment 21 (70%) patients in test and 28 (93.3%) patients in control had normocytic normochromic peripheral smear, 8 (26.7%) &1 (3.3%) patients in test and control group had microcytic hypochromic peripheral smear and only 1 (3.3%) in each group had normocytic hypochromic peripheral smear. **(Table 4)**

Treatment outcome was categorized as responders, partial responders and non-responders; in test group 5 (16.7%), 10 (33.3%) and 13 (43.3%) were among responders, partial responders and non-responders respectively. Similarly in control group 4 (13.3%), 14 (46.7%) and 11 (36.7%) were among responders, partial responders and non-responders respectively. (**Table 5**)

Table 1: Baseline characteristics in two groups of patients studied

	Test Group (n=30) No. (%)	Control Group (n=30) No. (%)	P-value Test used
Age in years			
18-30	14 (46.7%)	18 (60%)	0.871
31-40	14 (46.7%)	11 (36.7%)	Student t-test
41-50	2 (6.6%)	1(3.3%)	
Socio Economic Status			
Lower	0 (0%)	1 (3.3%)	0.377
Lower Middle	9 (30%)	11 (36.7%)	Fisher Exact test
Upper	1 (3.3%)	2 (6.7%)	
Upper Lower	13 (43.3%)	14 (46.7%)	
Upper Middle	7 (23.3%)	2 (6.7%)	
Marital Status			
Married	17 (56.7%)	25 (83.3%)	0.024
Single	13 (43.3%)	5 (16.7%)	Chi-Square test
Diet			
Mixed	26 (86.7%)	28 (93.3%)	0.671
Vegetarian	4 (13.3%)	2 (6.7%)	Chi square/Fisher Exact test
Lifestyle			
Average	18 (60%)	25 (83.3%)	0.089
Sedentary	10 (33.3%)	3 (10%)	Chi square/Fisher Exact test
Laborer	2 (6.7%)	2 (6.7%)	
BMI (kg/m²)			
<18.5	5 (16.7%)	5 (16.7%)	0.687
18.5-25	19 (63.3%)	20 (66.7%)	Fisher Exact Test
25-30	5 (16.7%)	4 (13.3%)	
>30	1 (3.3%)	1 (3.3%)	

Table 2: Comparison of subjective parameters in two groups of patients studied

	Test Group Mean ± SD	Control Group Mean ± SD	P value Student t test (Two tailed, independent)	P value from day 0 { Student t test (Two tailed, independent)} *	P value from day 0 { Student t test (Two tailed, independent)} **
Pallor					
Day 0	2.90 ± 0.31	2.93 ± 0.25	0.647		
Day 30	2.23 ± 0.5	2.20 ± 0.41	0.779	<0.001	<0.001
Day 60	1.83 ± 0.59	1.93 ± 0.25	0.399	<0.001	<0.001
Day 90	1.30 ± 0.60	1.40 ± 0.56	0.507	<0.001	<0.001
Loss of Appetite					
Day 0	20.27 ± 6.29	20.03 ± 5.76	0.881		
Day 30	24.97 ± 4.79	25.43 ± 3.86	0.679	<0.001	<0.001
Day 60	28.97 ± 3.02	28.33 ± 1.56	0.312	<0.001	<0.001
Day 90	31.33 ± 2.35	30.53 ± 2.34	0.192	<0.001	<0.001
Reduced exercise capacity					
Day 0	2.53 ± 1.14	2.7 ± 0.99	0.547		
Day 30	4.30 ± 1.24	3.80 ± 1.03	0.094	<0.001	<0.001
Day 60	5.67 ± 1.69	4.83 ± 1.18	0.031	<0.001	<0.001
Day 90	6.80 ± 1.56	5.73 ± 1.39	0.007	<0.001	<0.001
Fatigue					
Day 0	57.00 ± 7.96	57.30 ± 5.00	0.862		
Day 30	48.00 ± 7.60	48.67 ± 5.31	0.695	<0.001	<0.001
Day 60	42.90 ± 8.08	45.93 ± 5.23	0.090	<0.001	<0.001
Day 90	36.00 ± 7.84	39.43 ± 4.90	0.046	<0.001	<0.001

*** Test group** **** Control group**

Table 3: Comparison of Objective parameters in two groups of patients studied

Hemoglobin (g/dl)	**Test Group (Mean ± SD)**	**Control Group (Mean ± SD)**	**P value Student t test (Two tailed, independent)**	**P value – from before treatment {Student t test (dependent)}***	**P value – from before treatment {Student t test (dependent)}****
Before Treatment	9.29 ± 0.8	9.57 ± 0.93	0.213		
After Treatment	11.62 ± 1.89	12.09 ± 1.29	0.266	<0.001	<0.001
Mean corpuscular volume(MCV)					
Before Treatment	70.58 ± 6.19	72.18 ± 9.47	0.443		
After Treatment	79.04 ± 11.02	83.06 ± 9.84	0.141	0.001	<0.001
Mean corpuscular hemoglobin (MCH)					
Before Treatment	22.22 ± 3.66	22.28 ± 3.37	0.945		
After Treatment	25.77 ± 4.89	27.42 ± 4.10	0.162	0.006	<0.001
Mean corpuscular hemoglobin concentration (MCHC)					
Before Treatment	30.11 ± 5.33	31.36 ± 2.25	0.243		
After Treatment	32.38 ± 2.06	32.91 ± 1.60	0.273	0.049	0.006
Packed cell volume					
Before Treatment	29.84 ± 2.55	29.44 ± 3.23	0.596		
After Treatment	36.19 ± 4.71	36.76 ± 3.29	0.591	<0.001	<0.001
Red blood cell count					
Before Treatment	4.26 ± 0.52	4.08 ± 0.59	0.224		
After Treatment	4.57 ± 0.36	4.45 ± 0.43	0.237	0.004	0.013

*** Test group** **** Control group**

Table 4: Comparison of Peripheral smear in two groups of patients studied

	Before treatment	After treatment
Test group (n=30)		
NN	0 (0.0%)	21 (70%)
NH	8 (26.7%)	1 (3.3%)
MH	22 (73.3%)	8 (26.7%)
Control group (n=30)		
NN	0 (0.0%)	28 (93.3%)
NH	11 (36.7%)	1 (3.3%)
MH	19 (63.3%)	1 (3.3%)
P value	0.405	0.011

Test group: P<0.001, Significant for 70.0% on paired Proportion test**

Control Group: P<0.001, Significant for 93.3% on paired Proportion test**

Table 5: Treatment outcome in two groups of patients studied

Treatment Outcome	Test Group (n=30)	Control Group (n=30)	Total
Responder	5 (16.7%)	4 (13.3%)	9 (15%)
Partial responders	10 (33.3%)	14 (46.7%)	24 (40%)
Non-responders	13 (43.3%)	11 (36.7%)	24 (40%)
Total	30 (100%)	30 (100%)	60 (100%)
P value = 0.721 (Fisher exact test)			

DISCUSSION:

In present study pallor, loss of appetite, reduced exercise capacity and fatigue were found in all the patients. The subjective parameters viz. pallor, loss of appetite, reduced exercise capacity and fatigue were assessed using scale for pallor, Council of nutrition appetite questionnaire (CNAQ), Veterans specific activity questionnaire (VSAQ) and Fatigue severity scale (FSS) respectively on D_0 through D_{30}, D_{60} to D_{90} and were found statistically significant with p<0.001 in both groups at each assessment. On intergroup comparison there were no significant difference with p>0.05 except for reduced exercise capacity and fatigue with p<0.05. It is very much consistent with the results of previous studies conducted by Nagesh CS et al., Meghna V, Abhishek.[28-30]

The objective parameters viz. Hb%, PCV, MCV, MCH, MCHC, RBC count were also significantly improved after treatment with p<0.001 in both groups.On intergroup comparison p >0.05 showed that there was no statistically significant difference between the two groups suggesting that test drug is as effective as control drug inthe improvement of objective parameters.These results are comparable with the studies conducted by Vaidya Meghna *et al.*[29]who showed significant increase in Hb%, MCV, MCH, MCHC and PCV with p >0.05 in intergroup comparison, using swarnmakshika 60 mg in one group and yashada & swarnmakshika 30 mg each in other group and Nagesh CS *et al.*[28] also showed significant increase in Hb%, MCV, MCH, MCHC and PCV, on inter group comparison with p >0.05, using capsule fefol in one group and *jawarish amla* and *qurskushtaefaulad* in other group.

Treatment outcome was categorized as responders, partial responders and non-responders; in test group 5 (16.7%), 10 (33.3%) and 13 (43.3%) were among responders, partial responders and non-responders respectively. Similarly, in control group 4 (13.3%), 14 (46.7%) and 11 (36.7%) were among responders, partial responders and non-responders respectively. On intergroup comparison p>0.05 (0.721) showed that both test and control drugs were similar in treatment of iron deficiency anemia in reproductive age group women.

Pharmacopeial formulation, "*Majunekhabsulhadeed"* a jelly form medicinecontains *amla khusk, balchar, baheda, peepalkalan, tukhmeshibt, tukhmgandana, zanjabeel, chitalakri, saad kufi, filfilsiyah, halelasiyah, ghee* and *khabsulhadeed mudabbar*.[31]

The improvement in the subjective and objective parameters seen in the present study as iron oxide per se provides blood iron (Fe) and act as an antioxidant compound, in addition to the supplementary effect of the chemical constituents of the ingredients of *majunekhabsulhadeed*viz. vitamin c, chromium, zinc, copper, tannin, gallic acid, [32, 33] furanocoumarin,[16]various enzymes like invertase, protease and other compounds like zeylinone, glucose, fructose, isozeylinone, droscrone, plumbaginol.[34]

According to unani system of medicine these drugs exhibit properties viz. *muqawwi-i-mi'da*(stomachic), *muqawwi-i-jigar*(liver tonic), *muqawwi-i-dimaghwaqalb*(brain and cardio tonic), *jadhib*(absorbent),*hadim*(digestive),*habis*(styptic),*mudammil-i-qurroh*(cicatrizant), *musaffi-i-khoon*(blood purifier), *mushtahi* (appetizer) etc. [8, 34]

Limitations of the present study: Required iron dosage not calculated, elemental iron content per dose not calculated, serum ferritin, transferrin saturation levels, total iron binding capacity was not evaluated. Post treatment follow up was not done. Test drug should be used with caution in individuals with respiratory illnesses, as itmay adversely affect the lungs.

Future recommendations: Investigations like serum ferritin,

transferrin saturation levels and total iron binding capacity should be included. Studies with larger sample size higher dosage should be carried out. Post treatment follow up should be done to look for recurrence symptoms of iron deficiency anemia. Phase three clinical trials can be carried out to confirm the efficacy and safety.

CONCLUSION

The findings gleaned from the present study demonstrated that *majunekhabsulhadeed* is as effective as capsule fefol in management ofiron deficiency anemia. Hence *majunekhabsulhadeed* can be recommended as an effective alternate in the management of iron deficiency anemia in women of reproductive age group. However, needs larger trials to confirm the same.

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Declarations:

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***Conflict of interest*:** None

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