Management of anaemia in geriatrics patients through *Opuntia elatior* Mill.: An Open labelled clinical study.

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INTRODUCTION

Any knowledge system grows and develops through continuous research and evolution. Ayurveda, the oldest traditional health care system also follows the same path. Since ancient times, including Ayurveda, some traditional folk medicines are also being practiced, to treat many diseases. As reported by WHO, about 70-80% of the world populations, particularly in the developing countries, rely on non-conventional medicine in their primary healthcare[i]. Iron deficiency is a very common nutritional disorder worldwide and is known to affect approximately one third of the global population. Nutritional iron deficiency is the most common cause of anaemia in India[ii]. A prominent diagnostic feature of *Pandu roga* is the pallor on the skin which occurs due to the quantitative and qualitative deficiency of *raktu dhatu* (~blood tissue) caused either in the form of deficiency of haemoglobin and/ or red blood cells (RBCs). Considering *Panduta* (pallor) as the predominant sign, the disease is termed as *Pandu Roga*. The nearest correlation of Iron Deficiency Anaemia (IDA) can be made with *Pandu Roga*, because of the predominance of *Panduta* or pallor in the whole body.

Opuntia elatior Mill., a folklore medicinal plant, is being used by the local people of Gujarat, to treat anaemia, and general debility[iii]. Its fruit is also very rich source of nutrients and vitamins and are eaten fresh, dried or preserved in jams, syrups or processed into candy like products.[ivv] Fruit of *O.elatio*r is reported for its hematinic, analgesic and anti-asthmatic activity including its safety reports during acute toxic study[vi].

MATERIALS AND METHODS

Drug: The fruit of *O. elatior* in its ripened condition was collected following good collection practice from nearby areas of Jamnagar.

Study design: Open labelled clinical study.

No.	Subject	Details
1.	**Drug**	Fruit of *O.elatior*

2.	Part used	Ripen fruits
3.	Form	Fruit juice
4.	Dose	20 ml per day in two divide dose with equal quantity of lukewarm water
5.	Route	Oral
6.	Time	In empty stomach, during early morning and evening.
7.	Duration	30 days

Inclusion criteria:

1. Patients between sixty to eighty years of geriatric age with classical symptoms of *pandu* and nutritional deficiency irrespective of sex.

Exclusion criteria:

1. Patients suffering from any systemic disease like hypertention, diabetes and tuberculosis etc.

2. Age below sixty and above eighty years.

3. Severe case of *pandu* with complication

Approval of institutional ethical committee: The clinical study was carried out after obtaining permission from institutional ethics committee- IEC (No.PGT/7-A/Ethics/2013-14/1767 Dt.10/09/2013) and being registered in CTRI (CTRI/20014/11/005217).

Laboratory investigations: HB%, total RBC,MCV, MCH, MCHC, PCV, Platelet,TLC, ESR

Assessment criteria: Assessment was mainly based on the improvement observed in the subjective parameters before treatment and after treatment & haematology and biochemical parameters.

Assessment of total effect of therapies: result of the treatment has been assessed on the basis of increase in HB%, total RBC,MCV, MCH, MCHC, PCV, Platelet count, ESR, improvement in signs and symptoms of the *pandu roga* and for subjective parameters especially on Ayurvedic symptoms, suitable scoring pattern has been developed.

Grading of clinical features:

No.	Symptoms	Score
1.	***Panduvarna* (pallor) of *twaka* (Skin), *Anana*(Face), *Netra* (Sclera), *Nakha* (Nail)**	
	Panduta absent in these region	**0**
	Panduta present in any one region	**1**
	Panduta present in any two region	**2**

	Panduta present in any three region	**3**
	Panduta present in all four region	**4**
2.	*Daurbalya* **(General weakness)**	
	No feeling of *daurbalya* during daily activities	**0**
	Sometimes feeling of *daurbalya*, but performs daily activities	**1**
	Often feeling of *daurbalya*, but hampers daily activities	**2**
	Always feeling *daurbalya* and unable to perform daily activities even postural movement, bathing, feeding etc	**3**
3.	*Hridspandana* **(Palpitation)**	
	No *hridspandana*	**0**
	Hridspandana during mild exertion	**1**
	Hridspandana for sometimes during normal activities	**2**
	Hridspandana frequently during normal activities	**3**
	Hridspandana persistant during normal activities	**4**
4.	*Bhrama* **(Vertigo)**	
	No *bhrama*	**0**
	Occasionally present (e.g. 1-2 times per week)	**1**
	Frequently present (1-2 times per day)	**2**
	Persistant (throughout day)	**3**
5.	*Pindikodwestana* **(calf muscle cramp)**	
	No leg cramps	**0**
	Mild leg cramps only at night	**1**
	Leg cramps present in night or an exertion	**2**
	Leg cramps present in night or an exertion, needs medication	**3**
	Leg cramps present throughout the day	**4**
6.	*Shrama* **(fatigue)**	
	No *shrama* except hard work	**0**
	Shrama after moderate work for a certain time	**1**
	Shrama after light work for a certain time	**2**
	Shrama after routine activities for a certain times	**3**
7.	*Shwasa* **(exertional dyspnoea)**	
	No *shwasa*	**0**

	Shwasa after heavy work, relieved soon, tolerable		1
	Shwasa after moderate work, relieved soon, tolerable		2
	Shwasa after light work, relieved later, tolerable		3
	Shwasa after light work, relieved later, intolerable		4
8.	*Jwara* (Fever)		
	No *jwara*		0
	Mild		1
	Moderate		2
	severe		3

Overall assessment of result: was calculated on the basis of average improvement in the percentage relief of following scoring pattern:

1. Complete remission: 100%

2. Marked improvement: 76-99%

3. Improvement: 51-75%

4. Mild improvement: 26-50%

5. Unchanged: below 25%

Analysis of data and use of statistical methods: Paired 't' test was used to assess the effect of therapy within group in subjective as well as objective parameters. Unpaired 't' test was applied to compare the effect of therapies in both the male and female groups.

OBSERVATIONS AND RESULTS

Chief complaints wise distribution of 30 patients of *Pandu*.

Chief complaints	No. of patients	%
Panduta	21	67.74
Bhrama	18	58.06
Dourbalya	28	90.32
Hridspandana	2	6.45
Pindikodwesthana	14	45.16
Shrama	18	58.06
Shwasa	17	54.84
Jwara	0	0

Effect of treatment on chief complaints (pair 't' test) of patients of *pandu*.

Chief complaints	Mean	Diff.		P	S

	BT	AT		% Change		
Panduta	1.71	0.905	0.81	↓47.22%	<0.001	S
Bhrama	1.28	0.67	0.61	↓47.83%	<0.001	S
Dourbalya	2.37	1.3	1.07	↓45.31%	<0.001	S
Hridspandana	1.5	1.5	0.0	0000	-	NS
Jwara	0	0	0	0000	-	-
Pindikodwesthana	1.77	1.14	0.64	↓36%	0.002	S
Shrama	1.77	0.94	0.82	↓46.67%	<0.001	S
Shwasa	2.56	1.38	1.19	↓46.34%	<0.001	S

↓= decrease

Significant improvement was observed in all chief complaints except hridspandana. The highest (47.83%) improvement was seen in bhrama followed by panduta (47.22%).

Effect of treatment on haematological parameters (Pair 't' test)

Parameter	Mean		Difference	% change	P value	S
	BT	AT				
Hb	12.10	12.31	0.21	1.76↑	0.008	S
TLC	6783.33	7000	216.67	3.19↑	0.199	IS
Total RBC	4.244	4.296	0.052	1.23↑	0.467	IS
Platelet	290.80	297.1	6.33	2.18↑	0.330	IS
MCV	85.94	85.35	0.59	0.69↓	0.324	IS
MCH	28.79	28.89	0.11	0.37↑	0.688	IS
MCHC	33.48	33.65	0.18	0.53↑	0.215	IS
PCV	36.16	36.56	0.40	1.10↑	0.112	IS

S= significant, IS= Insignificant, ↑= Increase, ↓= decrease

Total effect of therapy:

	Unchanged (0-25%)	Mild improvement (26-50%)	Improvement (51-75)	Marked improvement (76-99)	Complete remission (100%)
Total	9	18	3	0	0

Change %	30	60	10	0	0

Adverse effect: during whole trial and 30 days follow up there is no any adverse reaction noted.

DISCUSSION & CONCLUSION

The most important presenting sign of *panduroga* is *panduta* or *pallorness* where lusture of the skin is lost. The sign is the most conclusive sign of the disease because whenever any patient comes across, the thing first observed is the appearanc3e.regarding the effect of therapy significant result seen with 47.22% improvement. The result were found significant (P<0.001). The drug having madhura rasa predominance and *snigdha guna* dominant which led to pacification of rukshata of vata and tikshnata of pitta thereby replenishing rasa dhatu. Also giddiness or bhrama was found in 53.33% patients showing very common presenting symptoms. Maximum relief was observed 47.83% which was significant (P<0.001) other symptoms like daurbalya, shrama, pindikodwesthana and shwas also shows significant improvement.

Haematological values which considered to see the effect of drug in case of panduroga were HBgm%, total RBC, MCV, MCH, MCHC and ESR. After treatment, trial drug was found to be effective in increasing the HB gms% is statistically significant(P= 0.008). in haematological parameters. TLC, Total RBC, Platelet, MCH,MCHC, PCV showed marked imcrease but changes ware non-significant. Haemoglobin count has been observed to increase significantly which suggests the possible role of *O.elatior* as a haematinic. The claim can be further explored using a greater sample size.

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