

A STANDARDISED CLINICAL STUDY TO EVALUATE THE EFFICACY OF DRAKSHA GHRITA IN GARBHINI PANDU W.S.R TO ANAEMIA IN PREGNANCY

Deepashri T¹Suchetha Kumari²

¹PG Scholar ²Associate Professor

Dept of PrasootiTantra and StreeRoga, ShriDharmastala Manjunatheshwara College of Ayurveda, Udupi, Karnataka, India

Email: Deepa.s.tikare@gmail.com

ABSTRACT

Background: Pregnancy is a state, where there is progressive anatomical, physiological and biochemical change not only confined to the genital organs but also to all the system of body. In under-developed countries due to nutrient deficiency anaemia has become major contributing factor for mortality and morbidity. **Objective:** This study was carried out to know the efficacy of *Draksha Ghrita* in *GarbhiniPandu* (Anaemia in Pregnancy). **Methods:** A single blind clinical study of two groups consisting of 15 patients each in control and trial group. Group A was administered with Ferrous sulphate in the dose of 200mg once daily for the period of 30 days. Group B was administered with *Draksha Ghrita*, 18ml morning and evening in an empty stomach with Luke warm water for the period of 30 days. **Results:** The study revealed a substantial efficacy of *DrakshaGhrita* in *GarbhiniPandu* (Anaemia in Pregnancy) with respect to subjective parameters. *DrakshaGhrita* has got a vital role in the pregnancy which has shown successful result in symptomatic relief. **Conclusion:** The drug is proved to be safe, easily available and cost effective and no adverse effect has seen.

Keywords: Anaemia in Pregnancy, *DrakshaGhrita*, Ferrous sulphate, *GarbhiniPandu*

INTRODUCTION

“Life starts from the moment of Conception”. Pregnancy is a physiological process which may turn up into pathology if neglected, may lead to complicate events of Pregnancy, Labor and Puerperium. One among such disease is *Pandu* (anaemia) which occurs due to

*Rasavahasrotodhusti*¹ (vitiation of rasa carrying channels).

According to standard laid down by WHO anaemia in pregnancy is present when haemoglobin concentration in the peripheral blood is 11gm/100ml or less. Incidence of disease

ranges from 40-80%. It is a universal problem and occurs for any age².

There is no direct reference of *Garbhini Pandu* (anaemia in pregnancy), though *Pandu* (anaemia) has been explained elaborately. This might be due to our *Acharyas* gave more emphasis on *Garbhini Paricharya* (regimens to be followed during pregnancy) which is not being followed in the present era.

As said by *Acharya Charaka*³, *Garbhini* (pregnant women) should be treated like *Poornameva Tailapatram* (pot filled with oil) hence, *Shodhana karma* (purification therapy) is contraindicated in pregnancy and only *Shamanaoushadhas* (medication therapy) are advised. *Kashyapasamhita*⁴ quoted that the features of *jwaradirogas* (fever etc diseases) of *annada* are considered to be the same for *Garbhini*.

So, considering the necessity to have a drug beneficial in *Panduroga*, safe and cost effective *Draksha Ghrita* which is having properties like *Hridayabalaprada* (that strengthens the heart), *Raktaprasadana* (blood soothers), *Mutrala* (diuretic), *Jeevaniya* (supporting life), *Balya* (supporting life), *Brmhana* (nutritive), *Pushtiprada* (improves body nourishment), *Medhya* (that increases memory), and *Shothahara*⁵ is considered for the research .

OBJECTIVE OF THE STUDY:

To evaluate the effect of *Draksha Ghrita*⁶ in *Garbhini Pandu*.

MATERIALS AND METHODS:

The study was initiated after obtaining the Institute's Human Ethic Committee Permission (Ref. no. SDMCA/ACA49/EC46/14-15 Date-23.4.15)

- The patients were selected regardless of their Age, Religion, Socio economic status

etc. fully satisfying the clinical criteria for diagnosis of Anaemia in Pregnancy. Minimum 30 Patients attending OPD & IPD of SDM Ayurveda Hospital, Udupi, fulfilling the inclusion and exclusion criteria of disease were selected for study

Method of collection of data:

- Selected patients were randomly distributed into 2 groups consisting of 15 patients each.
- A special Proforma was prepared with details of history taking, physical signs and symptoms, lab investigation as mentioned in *Ayurvedic* classics and allied sciences.
- Parameters of signs and symptoms & investigations was scored on the basis of standard method and analysed statistically.

Design of the study

- Single blind clinical study of two groups consisting of 15 patients each with pre-test and post-test.
- Group A were administered with Ferrous Sulphate in the dose of 200mg (containing 60mg of elemental iron) once daily for the period of 30 days.
- Group B were administered with *Draksha Ghrita*, 18ml⁷ morning and evening in an empty stomach with luke warm water for the period of 30 days.

Inclusion criteria

- Hb % between 8 to 10 g%
- Primi & multi *gravida*
- Patients within age group of 18 to 35 years.
- Patients in 2nd trimester of pregnancy

Exclusion criteria

- Hb% below 8g%
- Anaemia due to other pathology like Bleeding piles, APH, Nephritis, Multiple pregnancy etc
- Multiple pregnancy & pregnancy with complications like Pre-eclampsia, Toxaemia, and Gestational diabetes.
- Systemic diseases such as Hypertension, Diabetes, Thalassemia, Sickle cell anaemia etc.

Follow up period

2 follow ups at an interval of one month from 6th month of gestation till the completion of 7th month.

METHOD OF PREPARATION OF DRUG⁸:

Drug was prepared in Shri Dharmastala Manjunatheshwara College of Ayurveda and Hospital Pharmacy. (Batch no-160030, Manufacture date-24.02.2016)

There are generally three essential components are required

1. *Kalka (Draksha)* -1 part
2. *Snehadravya (Go Ghrita)*- 2 parts
3. *Drava dravya (water)* - 4parts.

Draksha (*Vitisvinifera*) was collected; washed and dried it was weighed and made into *kalka* (paste) form. *MurchitaGhrita* (triturated ghee) was collected in specified amount and was heated in a copper vessel and then it was allowed to cool. After cooling, *kalka* (paste) was added along with the water in the specified ratio. Heating was done on *mandagni* (mild heat) till all the *snehasiddhilakshanas* are observed. It was then filtered and stored in air tight container.

Dose⁹

There is a reference in *Sharangadhara* for the dosage, as said below.

1 *pala-uttama*

3 *karsha –madhyama*

2 *karsha-avara*

As *garbhini* is considered to be very precious event in women life, trial has been started from *avara* dose. (Two *karsha* =24grams, when 24 grams of *Drakshaghrita* is liquefied, it was 18ml)

Assessment criteria:

Assessment of Subjective Parameters:

Table 1: Grading of *Shrama* (Fatigue)

Grade	Symptoms
0	No fatigue
1	Fatigue after exertion
2	Fatigue after routine work
3	Fatigue even after rest

Table 2: Grading of *Balahani* (General weakness)

Grade	Symptoms
0	No weakness
1	Not affecting her daily work
2	Affecting her daily work
3	Decreasing her activities

Table 3: Grading of *Gurugatrata* (heaviness of body)

Grade	Symptoms
0	No heaviness
1	Not affecting her daily work
2	Affecting her daily work
3	Decreasing her activities

Table 4: Grading of *Paadashopha* (Pedal oedema)

Grade	Symptoms
0	No Edema
1	Edema relieved on rest

2	Edema persists even after rest
3	Severe Edema even after rest

Table 5: Grading of Appetite

Grade	Symptoms
0	Good
1	Moderate
2	Reduced

Table 6: Grading of Giddiness

Grade	Symptoms
0	No giddiness
1	Giddiness occasionally
2	Giddiness increases on walking/getting up
3	Persists even during rest

Table 7: Grading of *Varnahaani* (Pallor)

Grade	Symptoms
0	None
1	Mild (conjunctiva slightly pale)
2	Moderate (conjunctiva, nail, mucous slightly)
3	Severe

Table 8: Grading of Palpitation

Grade	Symptoms
0	No palpitation
1	Only during activity
2	Severe during routine work
3	Even during rest

Table 9: Grading of Pain in the lowerlimbs:

Grade	Symptoms
0	No pain
1	Pain not affecting routine work
2	Pain during activity only
3	Pain even during rest

Table 10: Objective parameters-

Sl.No	Investigation
1	Haemogram
2	PCV
3	MCV
4	MCH
5	MCHC

Observations and Results

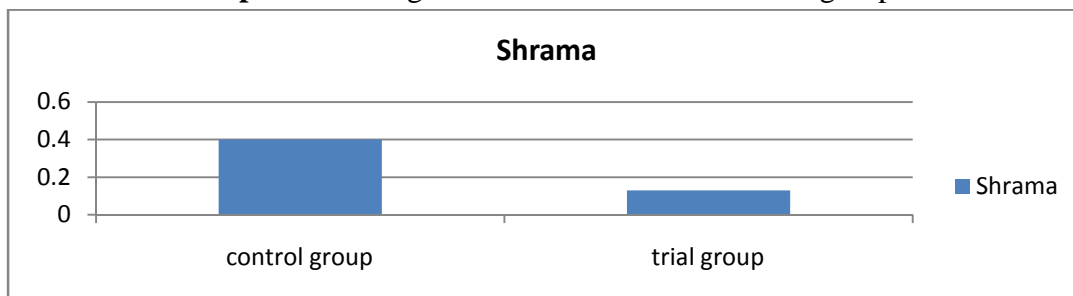
Table 11: Observations:

Parameters	Percentage	Maximum
Age	30	27-29years
Religion	60	Hindu
Education	43.3	Intermediate
Occupation	66.7	Housewife
Socioeconomic status	66	Middleclass
Domicile	53.3	Rural
<i>Gravida</i>	63.3	Primi
Sleep	53.3	Disturbed
<i>Prakruti</i>	33.3	<i>Pitta kaphaja</i>
<i>Sara</i>	100	<i>Madhyama</i>
<i>Samhanana</i>	100	<i>Madhyama</i>
<i>Satwa</i>	83.3	<i>Madhyama</i>
<i>Satmya</i>	100	<i>Madhyama</i>
<i>Aharashakti</i>	53.3	<i>Avara</i>
<i>Vyayamashakti</i>	56.7	<i>Avara</i>
<i>Pramana</i>	76.7	<i>Madhyama</i>
<i>Dosha</i>	53.3	<i>Vataja</i>

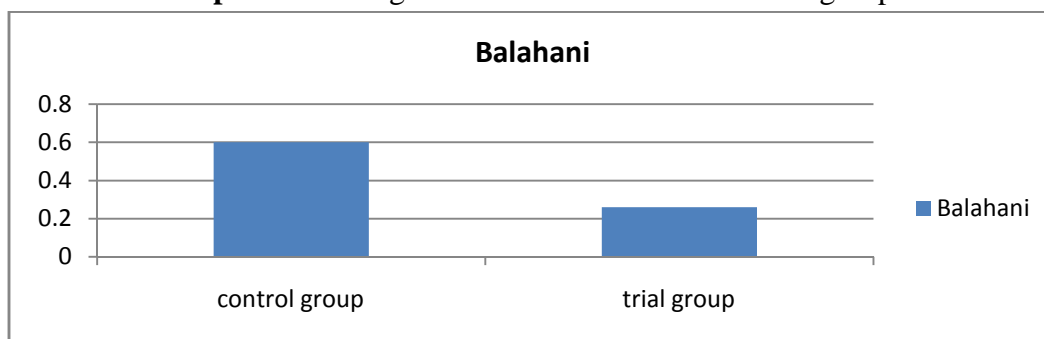
Results:

Comparison between the groups:

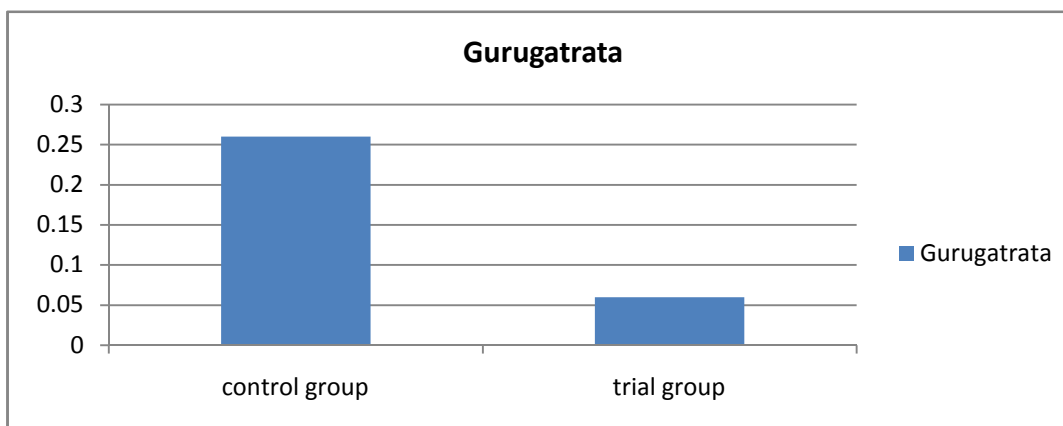
Graph 1: Showing result on *Shrama* between the groups



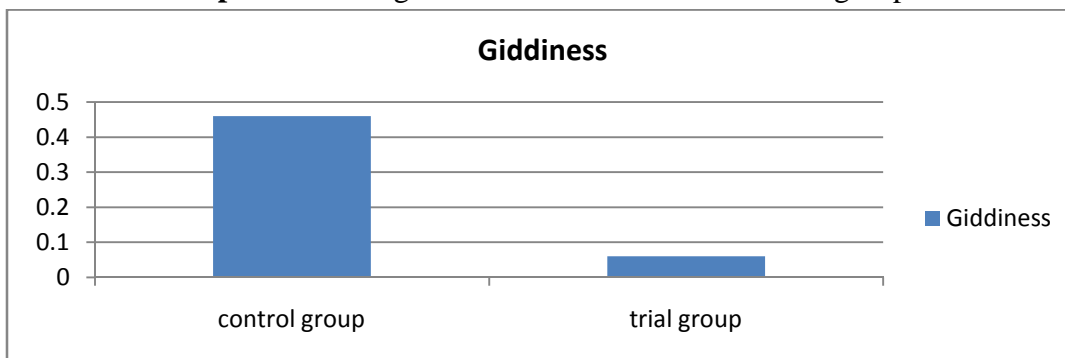
Graph 2: Showing result on *Balahani* between the groups



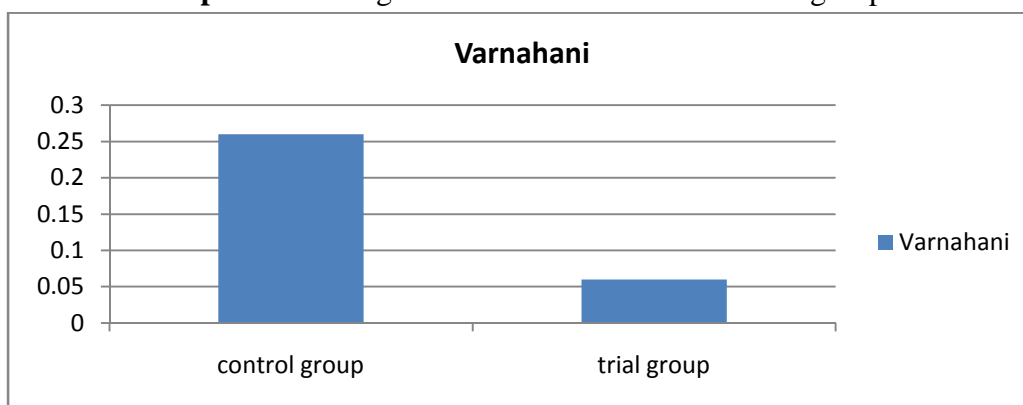
Graph 3: Showing result on *Gurugatrata* between the groups



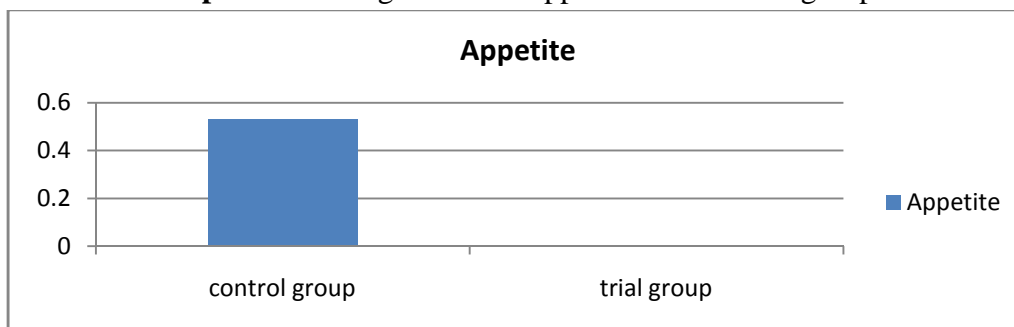
Graph 4: Showing result on Giddiness between the groups



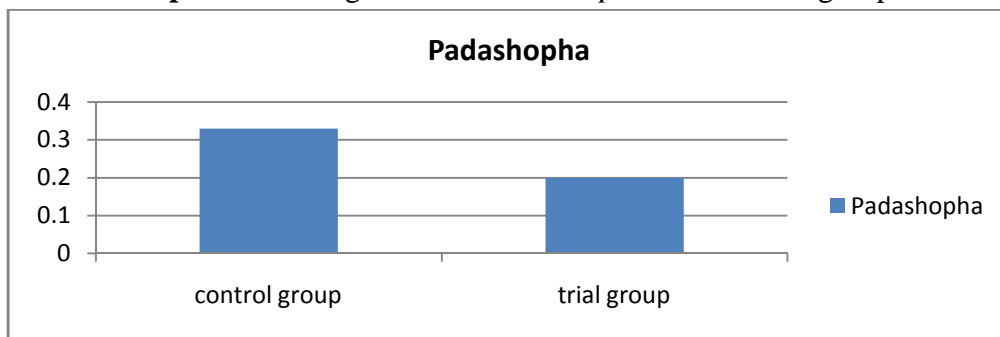
Graph 5: Showing result on Vrnahani between the groups



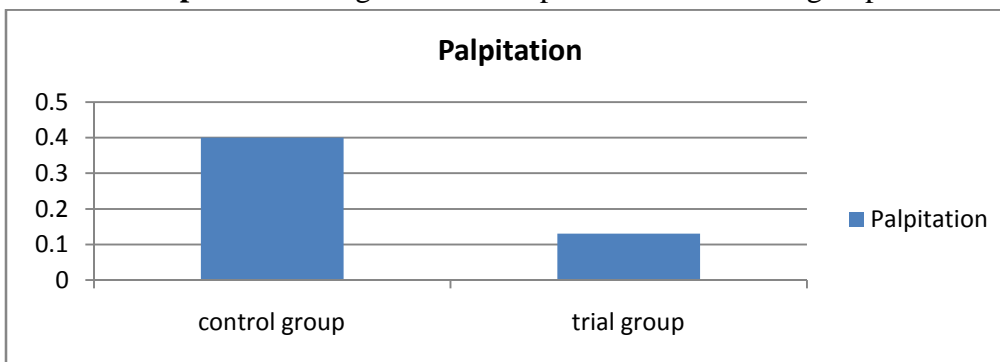
Graph 6: Showing result on Appetite between the groups



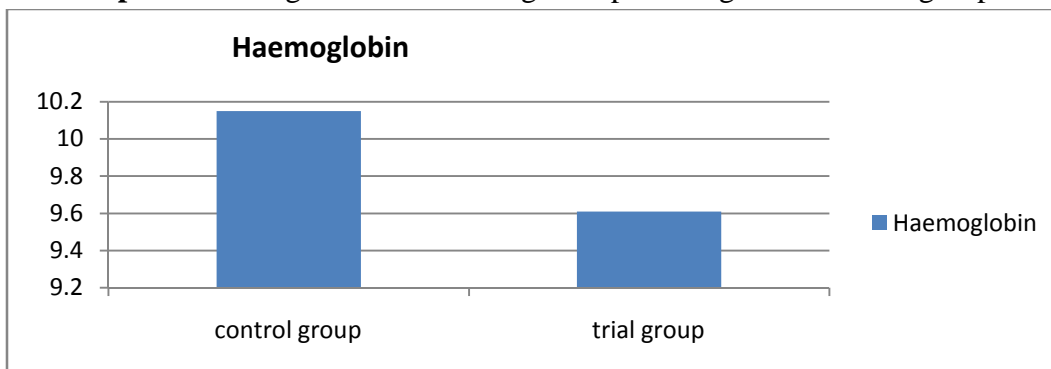
Graph 7: Showing result on *Padashopha* between the groups



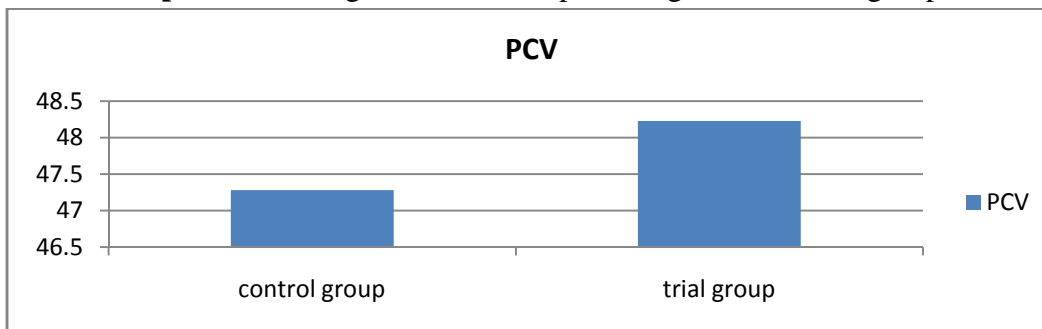
Graph 8: Showing result on Palpitation between the groups



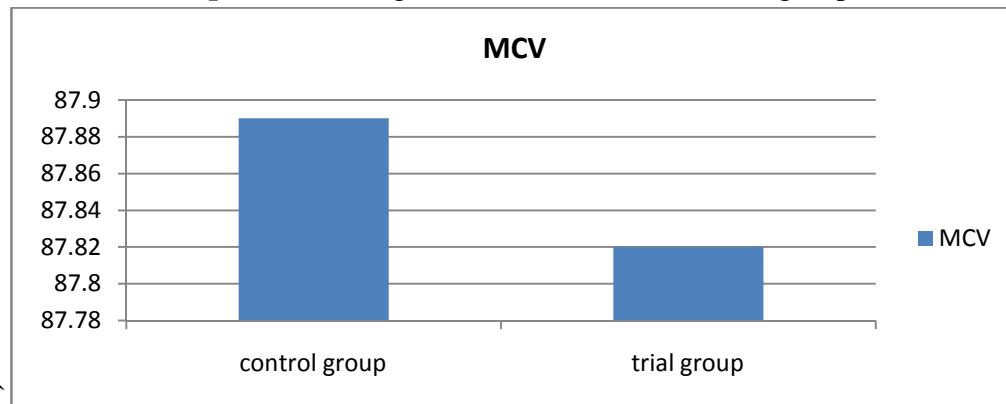
Graph 9: Showing result on Haemoglobin percentage between the groups



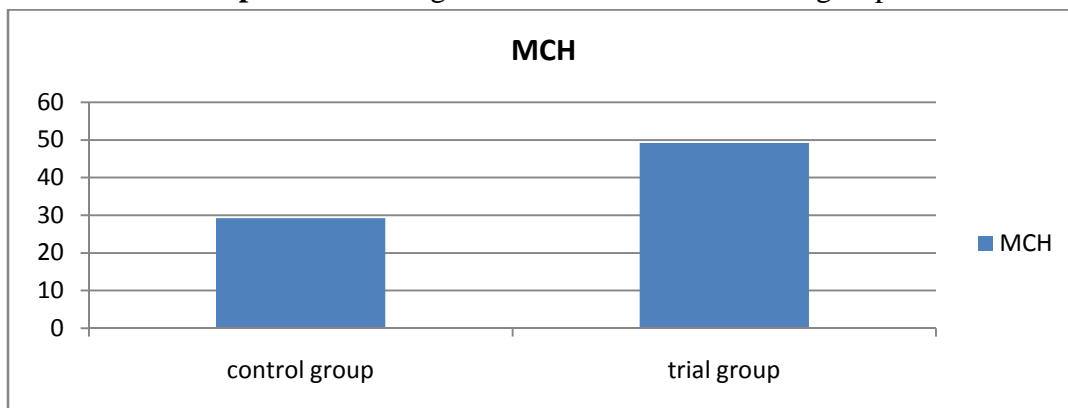
Graph 10: Showing result on PCV percentage between the groups



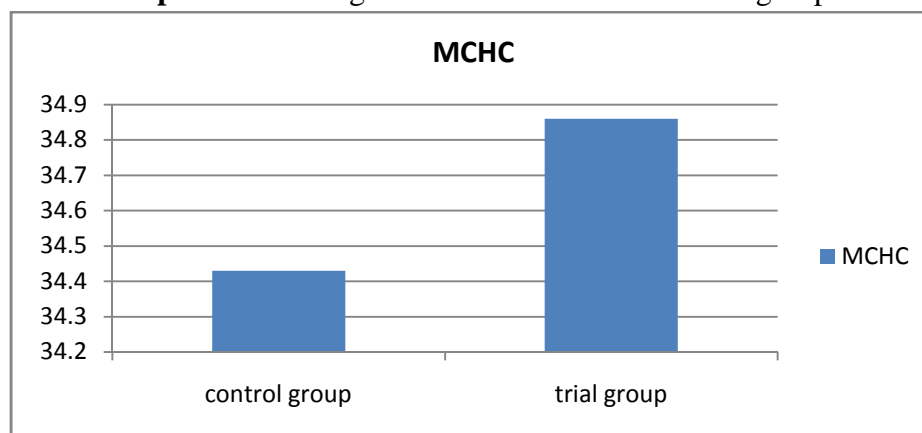
Graph11: Showing result on MCV between the groups



Graph 12: Showing result on MCH between the groups



Graph 13: Showing result on MCHC between the groups



DISCUSSION

The drug *Draksha* is *Madhura* (sweet) in *rasa* (taste), *Snigdha* (soft), *Guru* (heavy), *Mrudu* (smooth) *guna* (property), *sheeta* (cold) *veerya*

(potency), and *Madhuravipaka* (final stage of drug is sweet). It is *Vatapittashamaka*. The disease *Pandu* (anaemia) is mainly *Pittapra-kopajanyavyadhi* (disease of *pitta* vitiation)

and the drug acts as *Pittashamaka* (reduces *pitta*). The drug acts on *Dushita pitta* (vitiated *pitta*) and is effectively capable of bringing back *Pitta* to its normalcy¹⁰.

The chemical composition of the drug *Draksha* (*Vitisvinifera*) fruit contains 70 to 80% water and numerous organic and inorganic compounds. These are sugars, organic acids, phenolic compounds, nitrogenous compounds, aroma compounds, minerals, pectin substances. It also contains arginine and alanine. They are also good source of bioflavonoids. catechin, epicatechin, beta-sitosterol, ergosterol, jasmonic acid, glucose, fructose, galactose, it also contains tannic, malic, tartaric and racemic acid along with 0.05% of ash. Raisins contain calcium, magnesium, potassium, phosphorous and dehydro ascorbic acid i.e., oxidised form of ascorbic acid, which helps in the absorption of the available iron¹¹.

The Trial drug might have improved the absorption rate of nutrients, which is having *Madhurarasa* (sweet in taste) and *Madhura vipaka* (final stage of drug is sweet) could have contributed to highly significant cure rate for *Balahani* (weakness) by promoting the strength of *Dhatus* (tissues) and increasing the *Bala* (strength) of the patient.

As the drug is having *Balya* (that gives strength), *Jeevaniya* (supporting life), *Brmhana* (nutritive) property, *Shrama* (weakness) has got extremely significant result.

Though *Gurugatrata* (heaviness) has decreased during the study, the symptom again appeared due to advancing gestational age. 94% of the patients were relieved from Giddiness this might be due to *Pitta Shamaka* property of *Draksha*. As it is having *Mutrala* (diuretic) property, 80% of result is seen in

Padashopha (oedema in the lower extremities).

The drug contains Arginine¹² which improves the circulation and oxygen supply of the coronary and peripheral vessels through the release of nitric oxide. This Nitric oxide relaxes the walls of the blood vessels and thereby improves the circulation in the whole body. Hence marked result is seen in Palpitation. Though vitamin C, B present in *Draksha* enhances iron absorption from the food, haemoglobin percentage is found to be maintained throughout the study. This might be due to unable to meet the extra demand of iron during pregnancy.

CONCLUSION

Anaemia in pregnancy is the most common haematological disorder. So, considering the necessity to have a drug which is beneficial in *Panduroga*, safe and cost effective *Drakshaghrita* has been selected for study.

The study has revealed its vital role in *lakshanicachikitsa* (symptomatic treatment). Normally a fall in about 2g% of Haemoglobin concentration is seen in pregnancy, if not treated, but in this study, haemoglobin concentration has been maintained throughout the pregnancy. And also got contributory effects like relief in gastritis and itching all over the body. For further scope study can be conducted in large sample size with increased dose.

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