

# An Open label retrospective, controlled study to evaluate efficacy of Sinhyadi ghrta in the management of Balsosha with special reference to undernutrition

## Research Article

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### Abstract

*Balshosha* which can be correlated with undernutrition (P.E.M.) is one of such disease occurring in children due to hampered nutrition or *dhatuposhana*. Nutrition is necessary for maintaining growth, the effect of nutrition reflects on development. Today nutrition deficiency constitutes a major public health problem in India. The goal of treatment is to be provided adequate calories for dual purpose, to replace losses and build up nutrition to promote growth. HPERM is indicated for home remedial treatment for mild to moderate PEM (Undernutrition / Malnutrition) however condition needs to be medically intervened to prevent the worsening of the situation and to provide adequate correction. *Sinhyadi Ghrta* mentioned in *Ashtanghritya* by *Vagbhata* is best in *balshosha*. Hence an attempt was made to study the effect of *sinhyadi ghrta* in the management of *Balshosha*(undernutrition). In present study two groups containing 30 patients each suffering from undernutrition were selected randomly irrespective to sex, gestational age. *Sinhyadi ghrta* and HPERM combination was used as a trial group. Parameters such as weight, height, MUAC, skin elasticity, BMI, *dehabla*, *agnibala* were taken in to consideration for assessing results. At the end of study it was found that trial drug was very effective in the management of undernutrition.

**Keywords:** Balasosha, Sinhyadi Ghrta, undernutrition, HPERM, PEM, Dehabala, Agnibala

### Introduction

Equilibrium of doshas and freedom from all the disease is health for this purpose the sages studied the sacred Ayurveda. *Kaumarabhritya* is a branch of *Ashtang Ayurveda* deals with the management of children beginning from procreation; *Ayurveda* lays utmost importance to *Kaumarabhritya* because this age is determining how the person should become later on in his life(1),(2),(3). *Balshosha* which can be correlated with undernutrition is one of such disease occurring in children due to hampered nutrition or *dhatuposhana*. Nutrition is necessary for maintaining growth, the effect of nutrition reflects on development. Today nutrition deficiency constitutes a major public health problem in India.

India is one of the fastest growing countries in terms of population and economics, sitting at a population of 1,139.96 million (2009) and growing at 10-14% annually (from 2001–2007). Since Independence in 1947, its economic status has been classified as a low-income country with majority of the population at or below the poverty line. The combination of people living in poverty and the recent economic growth of India has led to the co-emergence of undernutrition.

According to recently released National Family Health Survey NFHS-3 carried out in 2005-2006, 40% of India's children under the age of three year are underweight, 45% are stunted and 23% are wasted. Proportion of children who are stunted or underweight increases rapidly with child age(4).

Undernutrition includes both protein-energy malnutrition and micronutrient deficiencies. Undernourishment not only affects physical appearance and energy levels, but also directly affects many aspects of the children's mental functions, growth and development which have adverse effects on their ability to learn and process information thereby leading to non-productive and non-contributing members of society. Child malnutrition is responsible for 22 percent of India's burden of disease. The prevalence of underweight children in India is among the highest in the world. The World Bank estimates that India ranks 2<sup>nd</sup> in the world for the number of children suffering from malnutrition after Bangladesh (in 1998), where 47% of the children exhibit a degree of malnutrition.<sup>[5]</sup>

Malnutrition increases the risk of infections and infectious disease; for example, it is a major risk factor in the onset of active tuberculosis. In communities or areas that lack access to safe drinking water, these additional health risks present a critical problem. Lower energy and impaired functions of the brain also represent the downward spiral of malnutrition as victims are less able to perform the tasks they need to in order to acquire food, earn an income, or gain an education.

The goal of treatment is to be provided adequate calories for dual purpose, to replace losses and

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build up nutrition to promote growth. Hyderabad Protein Energy Rich Mixture (HPERM) is indicated for home remedial treatment for mild to moderate PEM (Undernutrition / Malnutrition) however condition needs to be medically intervened to prevent the worsening of the situation and to provide adequate correction(6),(7),(8).

Due excessive sleeping during day time, excess consumption of cold water and breast milk *vitiated by kapha, etc. Cause the dushti of kapha and vata, dushit kapha* along with *vata* blocks the entire channel nourishing the *rasa, raktadi dhatus*. Due to obstruction of *strotasas, dhatvarhayas* which is needed nourishment of *dhatus* is unable to reach them which leads to their *kshayas*.

As food is not properly digested it fails to nourish all the body results in emaciation.

As the disease is *strotorodhjanya* with predominance of *kapha*, the treatment should be *strotoshodhan*. *Balshosha* is disease related with *dhatu* and its nourishment. Hence the treatment should be aimed at agitation of *jatharagni* i.e. *deepan pachan* along with proper nourishment i.e. *brimhana*.

*Sinhyadi Ghrita* mentioned in *Ashtanghridya* by *Vagbhata* is best in *balshosha*. Hence an attempt was made to study the effect of *sinhyadi ghrita* in the management of *Balshosha* (undernutrition). *Kantkari, ashwagandha, tulsi, pippali* these drug mentioned by *ashtang hridya* in *sinhyadi ghrita* is the best in the management of *balshosha*. It relieves *strotorodh* and helps in *dhatu poshan* and its *deepan pachan* properties it ignite *jatharagni*.(9)

### Materials and Methods

For the clinical study of *sinhyadi ghrita*, patient suffering from undernutrition were selected from O.P.D. and I.P.D. of *kaumarbhritya* Department.

### Materials of Study:

Patients.  
*Sinhyadi Ghrita*  
HPERM.

The materials of *Sinhyadi Ghrita* and HPERM were purchased from local market.

### Clinical Study:

Before initiation of the study, study protocol and related documents were reviewed and approved by institutional ethics committee at Government Ayurved College, Nanded, Maharashtra, India. Ethical clearance no- GACN/IEC/124/2014/ dated-15/04/2014

### Study Designs:

Randomized perspective controlled clinical study.

60 patients was selected and randomly grouped into two for trial and control group.

### Procedure for administration of drug:

#### Trial Group:

*Sinhyadi Ghrita* was given with HPERM. *Sinhyadi Ghrita* was given as per young's formula.<sup>[10]</sup>

Young's formula as follow:

$$\text{Child dose} = \frac{\text{Age in yrs} \times \text{adult dose}}{\text{Age}+12}$$

HPERM was given as per energy and protein requirements of children(11) according to their age. Both were given for duration of 12 weeks in divided doses.

#### Control Group:

Only HPERM was given as per energy and protein requirement of children according to their age for duration of 12 weeks in divided doses.

### Energy and Protein Requirement:(11) (According to National Institute of Nutrition, Hyderabad)

Particulars	Body weight (kg)	Energy (Kcal/day)	Protein (gm/day)
1-3 Years	12.2	1240	22
3-6 Years	19	1690	30

### Preparation of *Sinhyadi Ghrita*(12):

First *Ghrita Murchhana* is carried out. So the 1kg *Bharada Churna*(not fine powder) of *kantkari, ashwagandha, pippali, tulsi* and 4 litre *Goghrita* and 16 litre drinking water are taken. The ingredients are mixed, then mixture was kept for boiling with continuous stirring. *Mandagni* is given to mixture. The mixture boiled until the appearance of *sneha siddhi laksana*. When water gets evaporated completely, the heating was stopped. Then it is allowed to cool room temperature, then it was filtered to get *sinhyadi ghrita*.

### Standardization of Drugs:

Standardization of the drugs under trial was done at central Govt. certified Laboratory. The physio-chemical values of *sinhyadi ghrita* are as follows

Sr.No	Parameter	Result
1	Moisture	0.19%
2	Ph	6.50
3	Total Mineral	0.45%
4	Fat	92.94%
5	Protein	0.02%
6	Carbohydrate	3.76%
7	Energy	851Kcal

**Dose:**

In Sharangadhara Samhita (*Madhyama Khanda, Sneha Kalpana Adhyaya*) various *sneha kalpa* are mentioned. Its dose is given as *1 pala* (40ml) per day in adults.

So, according to age average value dose was decided and given in two divided doses.

AGE (year)	DOSE (ml)/day
1	4
2	6
3	8
4	10
5	12

**Aushadha Sevana Kala:**

The time of Drug taken was *Adhobhakta (Bhojanottara)* According to *Ashtanga Sangraha* the drug should be taken immediately after meals for for *Brimhana Karma*. So, in this present study according to the above reference the time was taken *bhojanottara* for *brimhana* effect.(13)

**Hyderabad Protein Energy Rich Mixture(HPERM):**

National institute of Hyderabad has given protein – energy rich mixture formula for home treatment of undernutrition which was taken in this present study to see its *brimhana* effect in *balshosha* – Mild to Moderate Malnourished 1 – 6 years aged children.

**The formula is :**

Roasted whole wheat	40 g
Roasted Bengal gram	16 g
Roasted groundnut	10 g
Jaggery	20 g
Total	86 g , providing 330 kcal and 11.3 g proteins

HPERM was given in a accordance to WHO and National Institute of Nutrition, Hyderabad recommendation of energy and protein requirement of children according to their age for a duration of 12 weeks in divided doses.(14)

**Observation Period:**

**Study period:** 12 weeks (90 days)

**Follow ups:** Assessment on 0 – 30<sup>th</sup> – 60<sup>th</sup> and 90<sup>th</sup> days.

**Inclusion Criteria:**

- Children age between 1- 5 Yrs.
- Children evaluated with grade I & II Protein Energy Malnutrition(PEM) according to Indian Academy of Pediatrics(IAP) Classification(15)
- Children should be free from any systemic or surgical illness.

**Exclusion Criteria:**

- Children of age below 1 yr and above 5 years.
- Severely malnourished children (Grade III and IV PEM according to I.A.P. classification)

Any medical emergency or condition requiring surgical intervention.

**Dropout:**

If children having complications during treatment and who were not co-operative, lack of regular follow ups were dropped out.

**Diagnostic Criteria:**

- Weight for age
- Body mass Index (B.M.I.)
- Mid upper arm circumference
- Skin fold thickness

**Criteria for Assessment and Result:**

**Objective**

- Weight
- Height
- Mid arm circumference
- Skin fold thickness
- B.M.I.

**Subjective**

- Hair pigmentation
- Skin elasticity
- Agnibala*
- Dehabala*

**Overall Assessment:** Deficient weight for age before treatment was considered as 100% and weight was assessed accordingly,

- Less than 25% - low
- 26% to 50% - mild
- 51% to 75% - moderate
- More than 75% - good

**Hair Pigmentation:**

Particulars	Score
Normal hairs	0
Hypopigmentation at the tip of hairs	1
Hypopigmented hairs involving 2/3 <sup>rd</sup> length of hairs	2
Small areas of scalp showing hypopigmented hairs	3
Alternate bands of normal and small hypopigmented hairs (flag sign)	4

**Skin Elasticity:**

Particulars	Score
Normal skin turgor	0
Loose skin with some fat when pinched and released return to normal slowly taking 2-3 seconds	1
Loose skin when pinched and released returned to normal very slowly taking few seconds	2
Thin, loose, wrinkled skin	3

**Agnibala (Abhyavaran Shakti):**

Particulars	Score
Taking food in good quantity twice / thrice a day	0
Taking food moderate quantity twice a day	1
Taking food in less quantity twice a day	2
Child not taking food at all	3

**Dehabala- Swar(Texture) Varna(Lusture) and Yoga (voice):**

Particulars	Score
Patient look cheerful	0
Lethargic and tired	1
Patient looks gloomy	2

**Discussion:**

*Balshosha* (Child malnutrition) is responsible for 22 percent of India's burden of disease. The prevalence of underweight children in India is one of the highest among the world. *Balshosha* which can be correlated to undernutrition (PEM) of modern science is one of such disease i.e. occurring in children due to hampered nutrition or *dhatuposhana*. This disease has been described in detail by *Acharya Vagbhata* only, but other conditions that are similar with the signs and symptoms of *phakka*, *karshya*, *gatrashosha*, etc., are described in almost all *samhitas*. Regarding to *samprapti* of *balshosha*, there are two main entities i.e. *vata-kapha prakopa* and *strotorodha*, which ultimately leads to improper nutrition and emaciation of *dhatu*.

WHO has described malnutrition as a "global problem", having adverse effects on the survival, health, performance and progress of populating groups. The most significant preventive measures for this disease is "nutritional education" which includes good antenatal care, encouraging mothers for regular breast feeding, complementary feeding, supplements should be the combination of cereals, protein-rich foods and fruits, National Nutrition Programs, etc.

The goal of treatment is to provide adequate calories for dual purpose to replace the losses and build up nutrition to promote growth. HPERM is indicated for home remedial treatment for mild to moderate PEM (Undernutrition / Malnutrition), however condition needs to be medically intervened to prevent the worsening of the situation and to provide adequate correction.

*Sinhyadi Ghrita* mentioned in *Ashtanghriddya* by *Vagbhata* is the best in *balshosha*. *Sinhyadi ghrita* contains *kantakari*, *ashwagandha*, *tulsi*, *pippali* and *ghrita*. All these drugs are well known for their *srotoshodhana* and *brimhana karma*. These drugs help in improving digestion and increase the appetite by agitating the *jathragni* and help to maintain nutrition of the body and weight gain. (17)(18)(19)

For this present study, children from the age of

1 year to 5 year of either sex with the problem of poor growth & under development and without any chronic diseases, systemic disorders, congenital anomalies, neurological disorders, endocrine disorders, anatomical defects were included. Simple Random Multiphase Sampling Method was adopted for this present study. According to IAP classification of PEM, children of body weight 61-80% of expected weight for age i.e. grade – I & II were selected for this study. For Average weight the chart of I.C.M.R. - Average weight of boys and girls at different ages for Indian children was used. (20)

In religion wise distribution, patients were selected from the Hindu and Muslim religions of the society. Maximum number of patients was Hindu i.e. 96.66% in experimental group and 93.33% in control group. As in Muslim community there is more intake of non-vegetarian diet so there is less percentage of *balshosha*.

In socio-economic status wise distribution patients were selected randomly from poor and middle classes, maximum number of patients were from poor class i.e 63.33% in experimental group and 53.33% in control group. Children from Poor class are more prone to undernutrition.

Grade wise distribution of patients of malnutrition, it was found that maximum number of patients of grade –II i.e. 60%, and patients of grade –i.e. 40%.

The assessment of nutritional status was done on the basis of anthropometric measurements with the help of weighing machine, measuring tape and skin fold callipers and subjective parameters as mentioned earlier.

As far as *Agni* is concerned, it is very difficult to assess the status of *Agni* in patient of paediatric age group. It is assessed by *abhyavarana* and *jarana Shakti* of patients.

Patients were advised to give regular follow up. In successive follow up they were observed every 30 days. Nine patients were dropped out during the study due to irregular follow up. After complete follow up, results in objective and subjective parameter were recorded and analyzed statistically. This is explained in detail in chapter observation and results.

This study requires further research in order to study for its better effects of *ayurvedic* remedies on *balsosha*. Further research can be carried out by the increasing duration of treatment and remodelling the dose, according to the age and weight of the patients.

Statistical analysis showed there was a significant improvement in weight, height, mid arm circumference, skin fold thickness, body mass index, hair pigmentation, skin elasticity, agnibala, dehabala in both the groups. But trial group showed overall better results as compared to control group.

**Conclusion:**

*Balshosha* (undernutrition) is more common in India and it is the most common cause of morbidity and mortality.

Most of the patients of *balshosha* are between the ages of 1-3 years and male and female are equally affected by *balshosha*.

Patients suffering from Grade II malnutrition are more as compared to patients suffering from grade I malnutrition.

It is a scenario of our India that due to poverty, population and unemployment many people do not get food properly in quantity as well as quality. So, due to lack of proper nourishment, most of the poor children are more affected to *balsosha*.

In developing country like India, many children are suffering with *balsosha*. So, this study will be the largest research topic in future. Large sample will make better conclusion and less bias.

Statistical analysis showed that there is significant improvement in weight, height, mid upper arm circumference, skin fold thickness, body mass index, hair pigmentation, skin elasticity, *agnibala*, *dehabala* in both groups. But trial group shows overall better results as compare to control group.

It concluded that comparison between trial and control groups, showed insignificant results on most of the parameters. This may be due to around same, mean score found in both groups. It means that the result of control group was as good as the results of trial group. Trial Group shows better results individually.

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**Table No.1 Effect of Therapy on Weight**

Gr.	T.Gr.		C.Gr.		t calc.	t table	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	9.97	2.03	10.51	2.08	16.26	2.05	<0.05
A.T.	11.32	1.91	11.70	2.11	16.18	2.05	<0.05

**Table No.2 Effect of Therapy on Height**

GROUP	T.Gr.		C.Gr.		t calc.	t table	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	84.83	12.23	85.30	11.47	16.00	2.05	<0.05
A.T.	85.90	12.10	86.23	11.20	9.81	2.05	<0.05

**Table No.3 Effect of Therapy on M.U.A.C**

GROUP	T.Gr.		C.Gr.		t calc.	t table	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	13.23	0.81	13.33	0.95	5.76	2.05	<0.05
A.T.	13.62	0.71	13.55	0.82	4.17	2.05	<0.05

**Table No.4 Effect of Therapy on S.F.T.**

GROUP	T.Gr.		C.Gr.		t calc.	t	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	8.85	1.14	9.15	1.05	8.36	2.05	<0.05
A.T.	9.21	1.08	9.45	0.91	4.44	2.05	<0.05

**Table No.5 Effect of Therapy on H.C.**

GROUP	T.Gr.		C.Gr.		t calc.	t table	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	45.80	2.63	45.33	1.74	2.02	2.05	<0.05
A.T.	45.90	2.42	45.40	1.73	1.68	2.05	<0.05

**Table No.6 Effect of Therapy on C.C.**

GROUP	T.Gr.		C.Gr.		t calc.	t table	P
	MEAN	S.D.	MEAN	S.D.			
B.T.	47.50	4.16	46.83	2.42	2.79	2.05	<0.05
A.T.	47.68	4.00	47.17	2.46	3.80	2.05	<0.05

**Table No.7 Effect of Therapy on Hair Pigmentation**

GROUP	T.Gr.		C.Gr.		Z Value	P
	MEAN	S.D.	MEAN	S.D.		
B.T.	1.20	0.71	1.03	0.80	4.1973	<0.05
A.T.	0.43	0.56	0.63	0.55	2.9341	<0.05

**Table No.8 Effect of Therapy on Skin Elasticity**

GROUP	T.Gr.		C.Gr.		Z Value	P
	MEAN	S.D.	MEAN	S.D.		
B.T.	1.40	0.56	1.03	0.55	4.4573	<0.05
A.T.	0.50	0.57	0.70	0.46	2.8031	<0.05

**Table No.9 Effect of Therapy on Agnibala**

GROUP	T Gr.		C.Gr.		Z	P
	MEAN	S.D.	MEAN	S.D.		
B.T.	1.76	0.43	1.53	0.57	4.5407	<0.05
A.T.	0.80	0.48	0.90	0.40	3.8230	<0.05

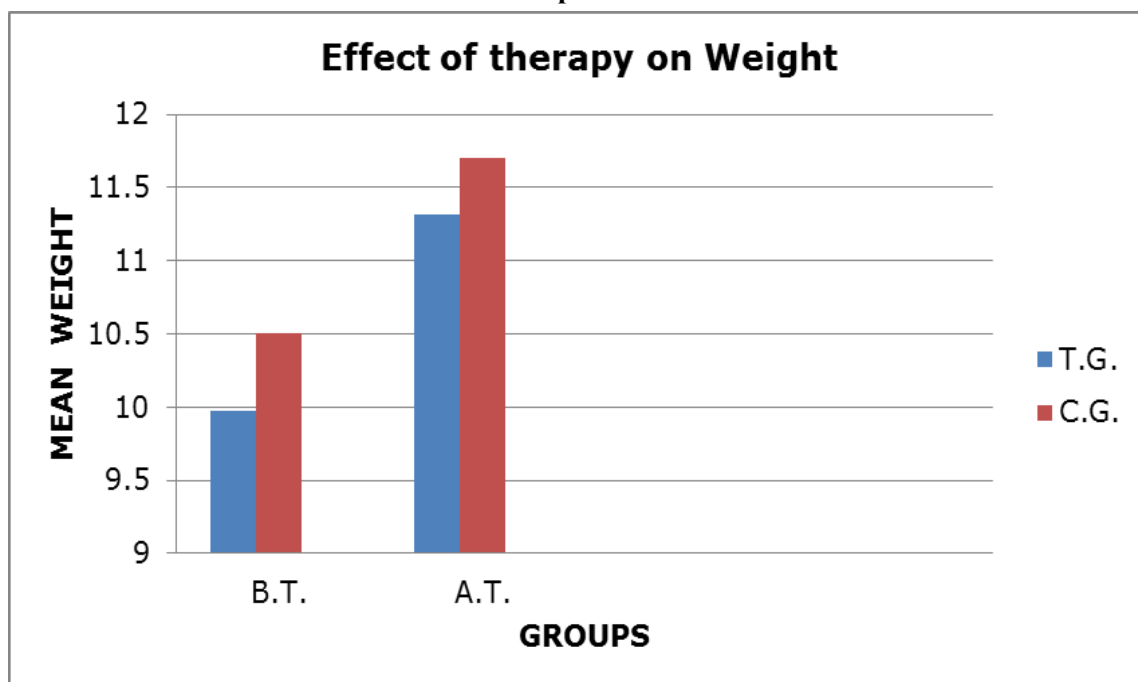
**Table No.10 Effect of Therapy on Dehabala**

GROUP	T.Gr.		C.Gr.		Z	P
	MEAN	S.D.	MEAN	S.D.		
B.T.	0.80	0.40	0.80	0.41	3.1798	<0.05
A.T.	0.36	0.49	0.63	0.49	2.0226	<0.05

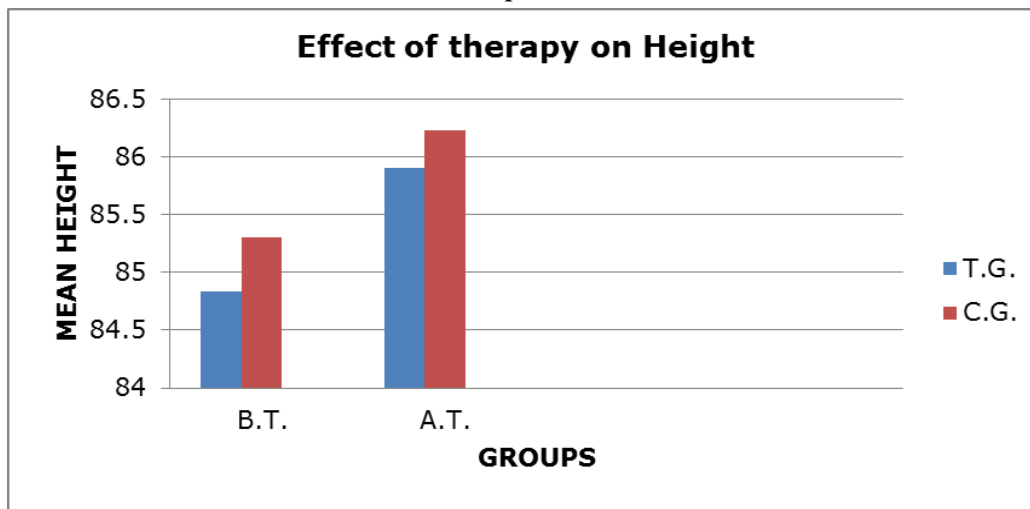
**TABLE NO.11 Overall Assessment According To Weight**

IMPROVE MENT	LOW (<25%)	MILD (25-50%)	MOD. (50-75%)	GOOD (>75%)	$\chi^2$ Calc.	P
T.Gr.	5	11	12	2	1.84	0.6
C.Gr.	6	15	8	1		

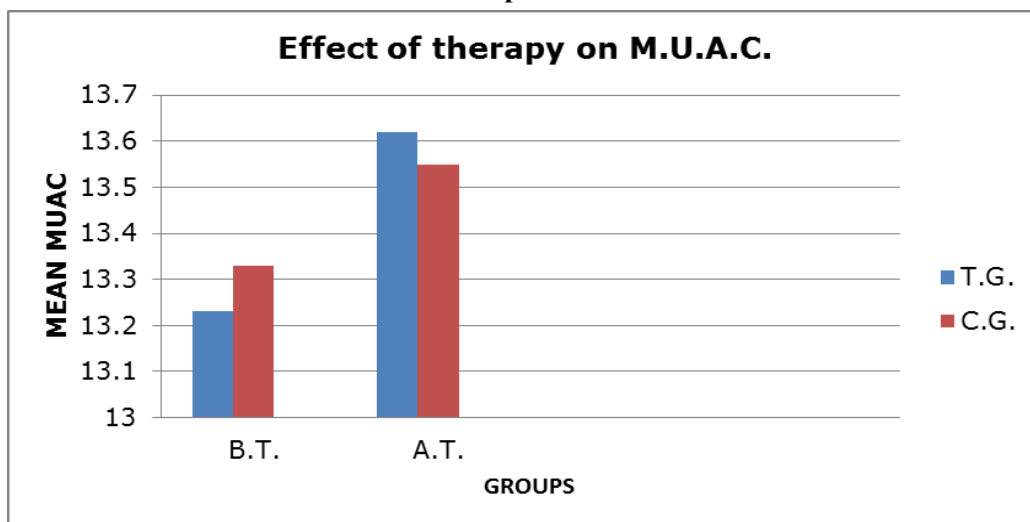
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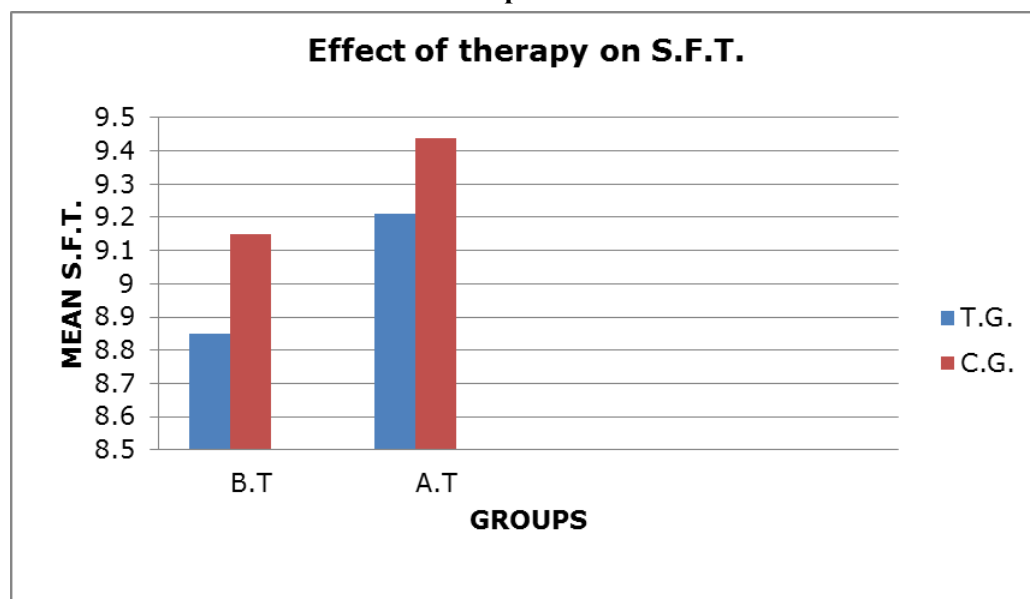
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**Graph no.3**

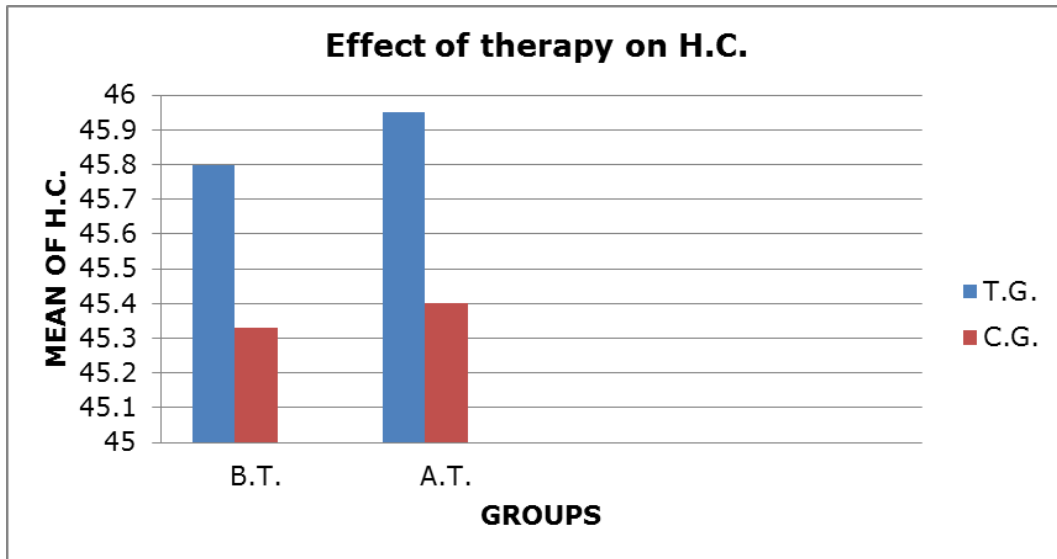


**Graph no.4**

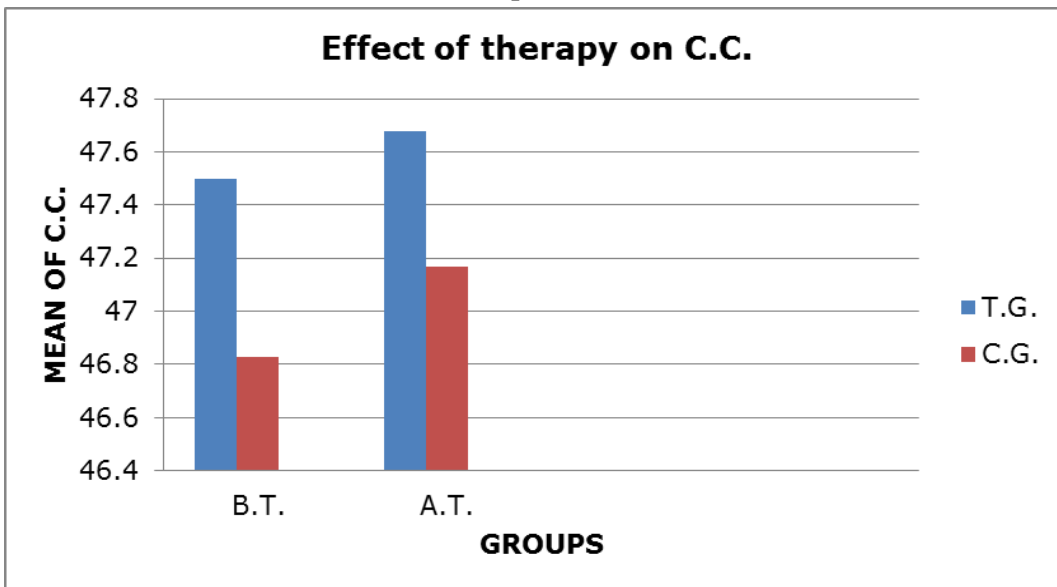




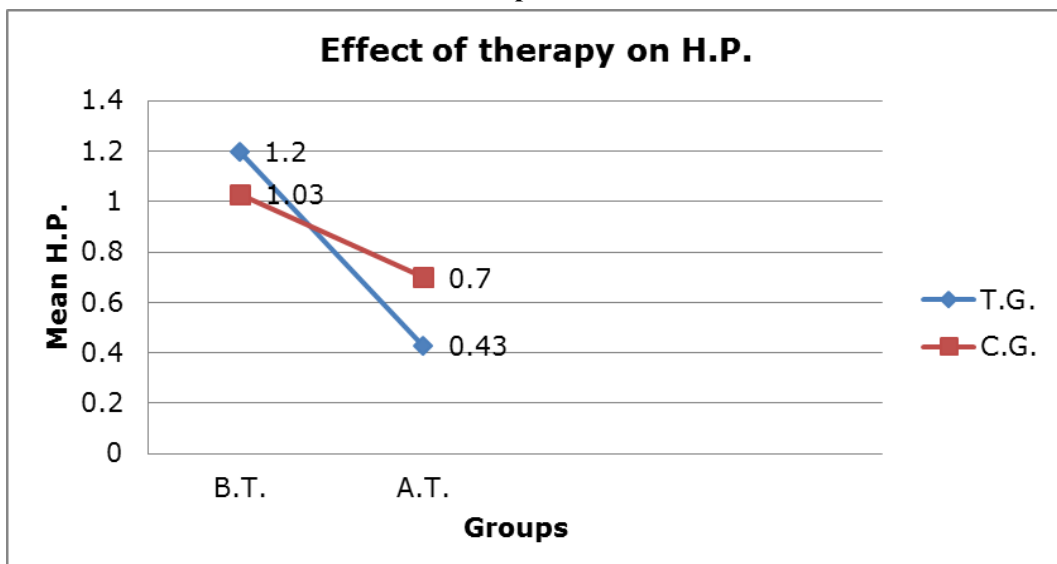
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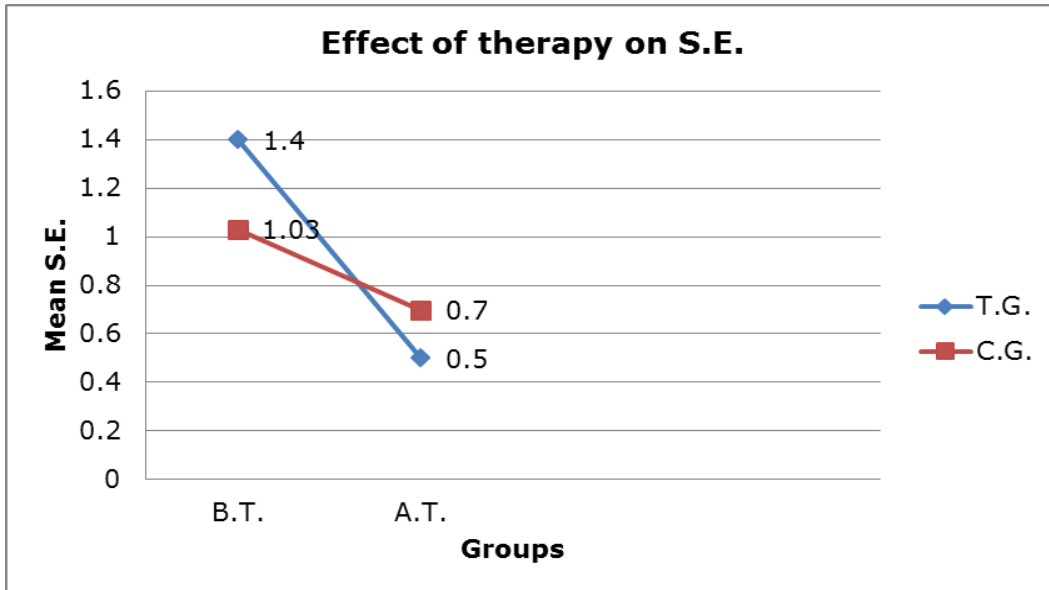
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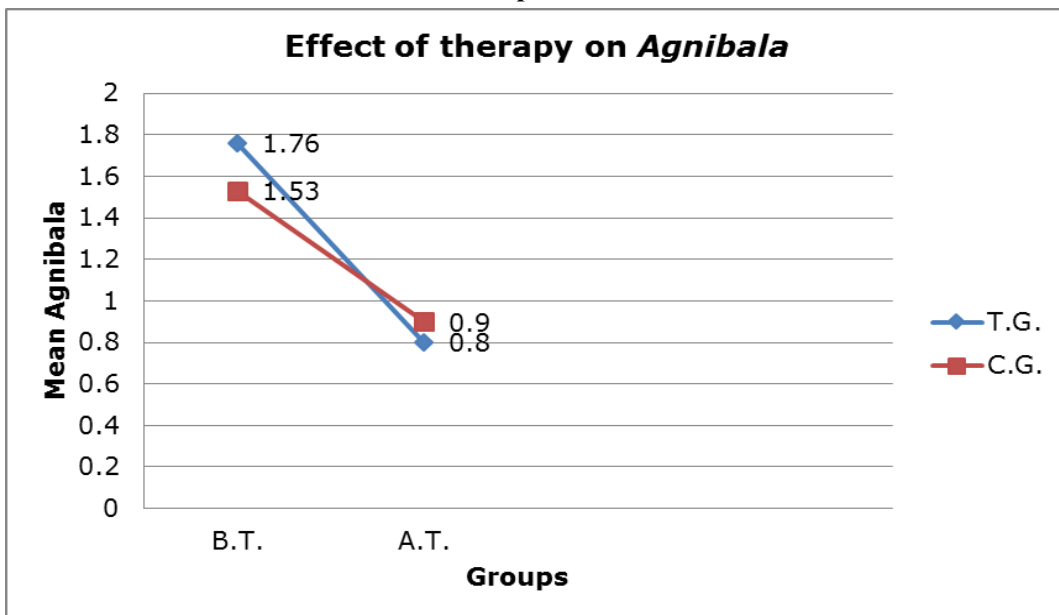
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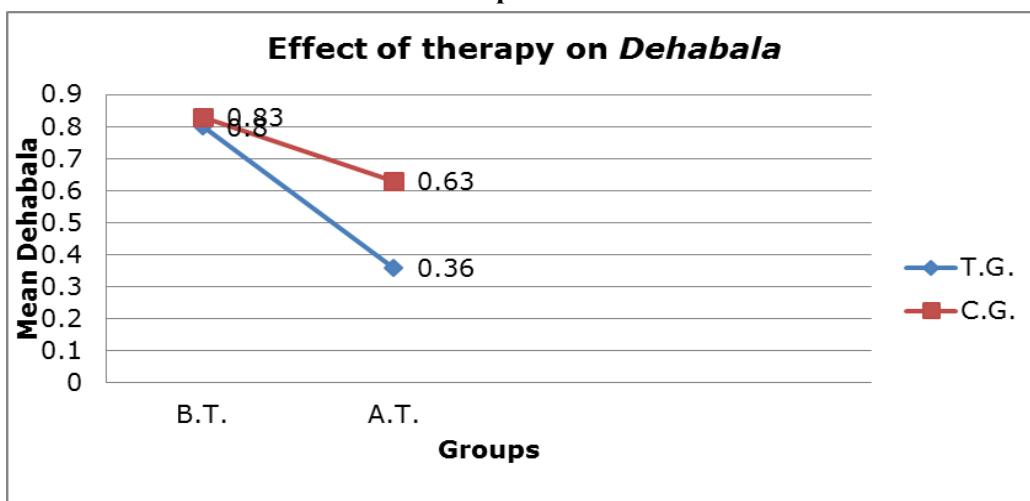
**Graph no.8**



**Graph no.9**



**Graph no.10**



Graph no.11



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