

Evaluation of Ashtamangal Ghrita and Ashwagandha Ghrita in growth and development of infants

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ABSTRACT

The growth and development of infants are periods of rapid change in the child's body, senses, and organs. Each change brings about new abilities. An infant's development in motor coordination, forming concepts, learning and using language, having positive feelings about self and others prepares them to build upon new abilities that will be needed for each change in a new stage of development. Keeping these in mind the present study "*A Comparative Clinical Study to Evaluate the Efficacy of Ashtamangal Ghrita and Ashwagandha Ghrita on Growth and Development of Infants.*" was designed in three groups. One group treated with *Ashtamangal Ghrita* and one group treated with *Ashwagandha Ghrita* and third group was left without any drug. Results shows *Ashtamangal Ghrita* and *Ashwagandha Ghrita* was effective in promoting growth and development of infant.

Keyword- *Ashtamangal Ghrita, Ashwagandha Ghrita, Growth, Development*

INTRODUCTION

Growth and development are the normal biological phenomenon of all living beings. The most dramatic events occur before birth and involve the transformation of a fertilized egg into an embryo and foetus. They are unique characteristics of children and any obstacle in this process at any stage can possibly result in aberration. Growth is an essential feature of life of a child that distinguishes him or her from an adult. The process starts from the time of conception and continues until maturity. It is defined as an increase in the size of an individual due to increase in number and size of the cells, resulting in an overall increase.

Development refers to qualitative and quantitative changes and acquisition of a variety of competencies for functioning optimally in a social milieu. It depends on maturation and myelination of brain; unless that has occurred, no amount of practice can make the child learn that skill. It may be stressed that, besides 10% prevalence of developmental delay, the early identification of such problems remains difficult. Although severe disorders can be recognized in infancy, it is unusual to diagnose speech impairment, hyperactivity or emotional disorders before the age of 3 or 4 years; learning disabilities are rarely recognized before children start their schooling. If one can diagnose developmental delay in early stages of growth, the intervention can reduce long term sequel. The child acquires different skills and talent at different periods of growth and development, when the relevant neurons spring into action.

There are different factors explained in *Ayurvedic* classics which are going for the maintenance and promotion of growth and development in children. These factors, influencing growth and

development can be classified as *Garbhapoorva avastha* (prior to conception), *Garbhakaleena avastha* (during pregnancy) and *Prasavaottara avastha* (after birth)

Now a days *Ayurveda* is on the way to regain its past glory because of its preventive and curative nature, least side effects and holistic approach. But there is need for standardization, clinical trials and evidence based medicines. So revalidation and revitalization is essential through research, in both fundamental and applied aspect.

AIMS AND OBJECTIVES:

- To study the efficacy of *Ashtamangal Ghrita* and *Ashwagandha Ghrita* on Growth and development of infants, in terms of change occurred in anthropometry and milestones during the study period.
- To compare the efficacy of both the drugs with each other.
- To evaluate the safety of both the drugs in infants.

MATERIALS AND METHODS:

1. Screening
2. Enrollment

A. Screening:

The infants attending the departmental OPD or admitted in IPD, who fulfill the inclusion and exclusion criteria, were included in the study.

B. Enrollment:

Selection of patients

Total 60 healthy infants were registered from the Kaumarbhritya/Balrog OPD/IPD, R G G P G Ayurvedic College & Hospital, Paprola, randomly fulfilling the criteria of this study. Out of 60 patients, 6 patients were dropped out from the study because they never turn up on subsequent follow ups. A case performa was filled with the data obtained by interrogation, physical examination and collection of details of each child.

Inclusion criteria:

- Age eligibility – up to 1 year.
- Gender eligibility – Both male and female.
- Infants whose parents will give their written informed consent.

Exclusion criteria:

- The infant who is suffering with any congenital, hereditary or acute systemic illness.
- Infants who do not fulfill the above mentioned criteria.
- Infant who has been dropped on subsequent follow up.
- Whose parents have refused to participate in the study.

PROTOCOL OF RESEARCH:

Grouping of the patients:

Study was conducted on 60 selected infants in three groups:

- GROUP - A – 20 Infants in this group were given *Ashtamangal Ghrita*.
- GROUP - B – In this group 20 infants were given the trial drug *Ashwagandha Ghrita*. 18 infants completed the trial and 2 were dropped out.
- GROUP - C – No medication were given to the infants of this group. Out of 20 infants 16 infants completed the trial and 4 were dropped out.

The proposed work was an open-label clinical trial.

Assessment criteria:

A. Subjective Assessment:

All the parameters like gross motor skill, fine motor skill, language at different month are graded as 0, 1 and 2 for early, timely and late development respectively.

Months	Gross motor skills	Fine motor skills	Language
1	Head up in prone position	Hands tightly fist	Alerts to sound
2	Chest up in prone position Head bobs erect if held sitting	Hands mostly closed	Social smile Coos
3	Partial head lag Rests on forearms in prone	Hands kept open more	Chuckles Echoes speaker immediately
4	Up on hands in prone No head lag	Hands mostly open	Orients to voice Laughs out loud
5	Lifts head when pulled to sit	Obtains/retains rattle Tries to reach objects but overshoots	Orients Bell – I Smiles & vocalizes to mirror
6	Sits-props on hands	Puts objects into mouth Goes for objects & gets them usually with bidextrous approach	Babbles : ‘baba’, ‘gagaga’
7	Sits without support Feet to mouth	Transfers objects hand to hand	Orients bell – II
8	Gets into sitting position	Scissors grasp of pellet held between thumb and side of curled index finger Holds one block in each hand	Enjoys peek-a-boo & other gesture games Mimics sounds

9	Pulls to stand Creeps on hand and knees	Radial digital grasp of cube held with thumb and finger tips	Waves 'bye bye'
10	Cruise around furniture Walks with 2 hands held	Isolates index finger and pokes Clumsy release of cube into box	Orients to name Dada/Mama appropriately
11	Stands alone Walks with 1 hand held	-	First word Imitates simple sounds
12	Independent steps	Fine pincer grasp of pellet between finger tips	Follows command with gesture Immature jargonizing

- Social & Adaptive Development**

Months	Social & Adaptive	Score
		0 (Early) 1 (Timely) 2 (Late)
1-3	Watches mother intently when she speaks to him Follows moving objects with eye Recognizes mother	0 1 2
3-6	Recognizes stranger Stranger anxiety	0 1 2
6-9	Waves 'bye bye' Preference for a given person	0 1 2
9-12	Comes when called Plays simple ball game	0 1 2

B. Objective criteria (anthropometric parameters):

- **Head Circumference** (in centimeter)
- **Chest Circumference** (in centimeter)
- **Mid Upper Arm Circumference** (in centimeter)
- **Crown Heel Length** (in centimeter)
- **Weight** (in kilogram)

Duration of the intervention: 4 weeks

Duration of the trial: 12 weeks

Mode of intervention: orally

Drug dosage:

- *Ashtamangal Ghrita* - 0.5 ml/kg/day in two divided dose via calibrated dropper
- *Ashwagandha Ghrita* - 0.5 ml/kg/day in two divided dose via calibrated dropper

Follow up: 4 follow ups at 1, 4, 8 & 12 weeks

OBSERVATIONS & RESULTS**A. Data regarding socio-demographic condition****1. Age Wise Distribution**

Age group	No. of Infants			Total	Percentage
	Group A	Group B	Group C		
0 – 3 mo	15 (75%)	16 (88.8%)	13 (81.2%)	44	81.5
4 – 6 mo	3 (15%)	1 (5.5)	2 (12.5%)	6	11.1
7 – 12 mo	2 (10%)	1 (5.5)	1 (6.25%)	4	7.4

2. Gender Wise Distribution

Gender	No. of Infants			Total	Percentage
	Group A	Group B	Group C		
Male	15	7	11	33	61.1
Female	5	11	5	21	38.9

3. Religion Wise Distribution

Religion Group	No. of patients			Total	Percentage
	Group A	Group B	Group C		
Hindu	19	18	16	53	98.2%
Others	1	0	0	01	1.8%

4. Parental education wise distribution

Table no. 4						
Parent	Educational qualification	Gr A	Gr B	Gr C	Total	%
Father	Illiterate	-	-	-	-	-
	School education	1	3	1	5	9.26
	Higher education	19	15	15	49	90.74
Mother	Illiterate	-	-	1	1	1.85
	School education	7	6	2	15	27.78
	Higher education	13	12	13	38	70.37

5. Socio-economic wise distribution

Socio economic Status	No. of Infants			Total	Percentage
	Group A	Group B	Group C		
Lower class	1	4	1	6	11.11
Middle class	19	14	15	48	88.89
Higher class	0	0	0	0	0.00

6. Habitat Wise Distribution

Table no. 6					
Habitat	No. of Infants			Total	Percentage
	Group A	Group B	Group C		

Rural	15	18	15	48	88.89
Urban	5	0	1	6	11.11

7. Birth order wise distribution

Birth order	No. of infants			Total	Percentage
	Group A	Group B	Group C		
First	12	10	9	31	57.41%
Second	8	7	6	21	38.89%
Third	-	1	1	2	3.7%
Fourth	-	-	-	-	-

B. Data Regarding Personal History

8. Infant feeding status (up to 6 months) wise distribution

Table no. 8						
Bowel habits	Gr. A	Gr. B	Gr. C	Total	% age	
Exclusively breastfed	18	17	16	51	94.44%	
Breastfed + formula fed	2	1	0	3	5.56%	
Never breastfed	-	-	-	-	-	

9. Bowel habit wise distribution

Bowel habits	Gr. A	Gr. B	Gr. C	Total	% age
Normal	20	17	15	52	96.3%
Loose consistency	-	-	-	-	-
Constipated	-	1	1	2	3.7%

10. Sleep wise distribution

Sleep	Gr. - A	Gr. - B	Gr. C	Total	%age
Normal	20	16	15	51	94.44%
Inadequate	0	2	1	3	5.56%

Assessment of various Anthropometrical Parameters at 4th follow up

❖ Weight

11. Comparison between groups R-FU4

Groups	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	2.425	0.885	0.198	0.594	0.556
B	2.272	0.672	0.158		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	2.425	0.885	0.198	2.653	0.012
C	1.753	0.548	0.137		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
B	2.272	0.672	0.158	2.449	0.020
C	1.753	0.548	0.137		

12. Inter group comparison R-FU4

Table no. 16						
	Mean increment	% Improvement	SST		F	P

Group A Vs Group B Vs Group C	(R-FU4)						M ST			
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	2.42 5	2.272	1.75 3	50.4	55.8	42.1	31.3 3	0.5 9	3.3 6	0.04 8

❖ Crown heel length

13. Comparison between groups R-FU 4

Table no. 21					
Groups	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	9.240	3.014	0.674	0.052	0.959
B	9.194	2.291	0.540		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	9.240	3.014	0.674	2.322	0.026
C	7.156	2.174	0.543		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
B	9.194	2.291	0.540	2.652	0.012
C	7.156	2.174	0.543		

14. Inter group comparison R-FU4

Table no. 22										
Group A Vs Group B Vs Group C	Mean increment (R-FU4)			% Improvement			SST	M ST	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	9.24 0	9.194	7.15 6	16.5	17.3	13.4	380.5 3	7.1 8	3.35 8	0.04 7

❖ Head Circumference

15. Comparison between groups R-FU4

Table no. 27					
Groups	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	5.305	1.970	0.441	1.842	0.074
B	4.256	1.474	0.347		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	5.305	1.970	0.441	2.602	0.014
C	3.744	1.528	0.382		
	Mean increment	S.D.	S.E.	't' value	P value

	R-FU4	±	±		
B	4.256	1.474	0.347	0.993	0.328
C	3.744	1.528	0.382		

16. Inter group comparison R-FU4

Table no. 28										
Group A Vs Group B Vs Group C	Mean increment (R-FU4)			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	5.30	4.256	3.74	13.7	11.5	10.0	168.9	3.18	3.3	0.04
	5		4				4	7	2	9

❖ Chest Circumference

17. Comparison between groups R-FU4

Table no. 33					
Groups	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	5.670	1.881	0.421	0.332	0.742
B	5.483	1.542	0.363		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
A	5.670	1.881	0.421	1.828	0.076
C	4.550	1.756	0.439		
	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value
B	5.483	1.542	0.363	1.651	0.109
C	4.550	1.756	0.439		

18. Inter group comparison R-FU3

Table no. 34										
Group A Vs Group B Vs Group C	Mean increment (R-FU4)			% Improvement			SST	M ST	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	5.67 0	5.483	4.55 0	15.5 3	15.7 6	12.8 6	166.1 7	3.1 4	1.6 4	0.210

❖ MUAC

19. Comparison between groups R-FU4

Table no. 39					
Groups	Mean increment R-FU4	S.D. ±	S.E. ±	't' value	P value

A	2.090	0.713	0.159	0.156	0.877
B	2.056	0.637	0.150		
	Mean increment R-FU4	S.D. ±	S.E. ±	‘t’ value	P value
A	2.090	0.713	0.159	1.459	0.154
C	1.756	0.641	0.160		
	Mean increment R-FU4	S.D. ±	S.E. ±	‘t’ value	P value
B	2.056	0.637	0.150	1.364	0.182
C	1.756	0.641	0.160		

20. Inter group comparison R-FU4

Table no. 40										
Group A Vs Group B Vs Group C	Mean increment (R-FU4)			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	2.090	2.056	1.756	18.55	18.9	16.15	23.863	0.450	0.92	0.409

Assessment of various Developmental Domains after each subsequent follow ups

❖ Gross Motor Development

21. Assessment after 4th follow up

Table no. 45							
Groups	Mean		% Improvement	S.D. ±	S.E. ±	‘t’ value	P value
	R	4 th FU					
Gr A	1.450	0.150	89.7	0.657	0.147	8.850	<0.001
Gr B	1.722	0.278	83.8	0.511	0.121	11.99	<0.001
Gr C	1.438	1.250	13.07	0.750	0.188	1.000	0.333

22. Inter group after 4th Follow up

Table no. 46										
Group A Vs Group B Vs Group C	Mean			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n = 20	n = 18	n = 16							
	1.300	1.444	0.301	89.7	83.8	13.07	30.83	0.582	22.9	<0.001

❖ Fine Motor

23. Assessment after 4th follow up

Table no. 51

Groups	Mean		% Improvement	S.D. ±	S.E. ±	't' value	P value
	R	4 th FU					
Gr A	1.450	0.150	89.65	0.657	0.147	8.850	<0.001
Gr B	1.667	0.333	80.0	0.594	0.140	9.522	<0.001
Gr C	1.375	1.188	13.6	0.750	0.188	1.000	0.333

24. Inter group comparison after 4th follow up**Table no. 52**

Group	Mean			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n =	n =	n =							
A Vs Group B Vs Group C	20	18	16	89.6 5	80.0	13.6	36.9 8	0.69 8	18. 6	<0.00 1

❖ **Language Development****25. Assessment after 4th follow up****Table no. 57**

Groups	Mean		% Improvement	S.D. ±	S.E. ±	't' value	P value
	R	4 th FU					
Gr A	1.500	0.250	83.3	0.639	0.143	8.753	<0.001
Gr B	1.611	0.389	75.8	0.548	0.129	9.457	<0.001
Gr C	1.500	1.250	16.7	0.856	0.214	1.168	0.261

26. Inter group comparison after 4th follow up**Table no. 58**

Group	Mean			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
	n =	n =	n =							
A Vs	20	18	16							
Group B Vs Group C	1.25 0	1.222	0.25 0	83.3	75.8	16.7	34.8 3	0.65 7	13. 7	<0.00 1

❖ **Social & Adaptive****27. Assessment after 4th follow up****Table no. 63**

Groups	Mean		% Improvement	S.D. ±	S.E. ±	't' value	P value
	R	4 th FU					

Gr A	1.450	0.250	82.8	0.616	0.138	8.718	<0.001
Gr B	1.667	0.333	80.0	0.594	0.140	9.522	<0.001
Gr C	1.500	1.313	12.5	0.834	0.209	0.899	0.383

28. Inter group comparison after 4th follow up

Table no. 64										
Group	Mean			% Improvement			SST	MS T	F	P
	Df _a	Df _b	Df _c	Gr. A	Gr. B	Gr. C				
A Vs Group B Vs Group C	n = 20	n = 18	n = 16							
	1.20 0	1.333	0.18 8	82.8	80.0	12.5	36.8 3	0.69 5	14. 5	<0.00 1

DISCUSSION

Most infants (81.5%) in this study were between ages 0-3 months. In this study, religion wise distribution shows that maximum number of infants i.e. 98.2 % were Hindus. This may be due to Hindu dominant population residing this area. Parents of maximum number of infants have completed higher education (Father-90.74%, Mother-70.37%). Evidence showed that, specifically related to child nutrition and physical development, higher educational attainment for parents was inversely associated with childhood stunting, underweight and wasting (**Christiaensen L, Alderman H, 2004**). It was also found that only the mother's education was a significant predictor of child height and weight (**Aslam M, Kingdon GG, 2012**). 88.89% infants in this study were from rural area. Socio economic class wise distribution also shows that large part of the sample (88.89%) belongs to middle class population. The variability in child growth across nations is due much more to social, demographic and economic factors than to genetics (**Beaton et al.1990, Frongillo and Hanson 1995, Osmani 1992**). As most infants were from rural area and belonged to middle class family, so the variability in growth can be considered unremarkable. Most infants (94.4%) were exclusively breast fed during the study or up to 6 months from birth. Breastfeeding may influence parenting by facilitating mother-child bonding, interaction and, indirectly, cognitive growth. Breast milk also contains growth factors and hormones which influence brain biochemistry and functional development, and are not found in formula milk. In relation to intelligence, the breastfed infant has been shown to have an advantage over the non-breastfed infant. 94.4% infants had normal sleep pattern. Sleep plays a key role in all the developmental domains with its maturation paralleling, preceding, as well as resulting from interactions with cognitive and physical maturation (**Elaine KH Tham, Nora Schneider, Birit FP Broekman, 2017**).

Overall effect of therapy on Physical growth

Comparing the three groups, group A (*Ashtamangal Ghrita*) and group B (*Ashwagandha ghrita*) both have showed better effect on physical growth compared to group C as evident from above discussion. After the completion of trial, *Ashwagandha Ghrita* is found to be more beneficial than *Ashtamangal Ghrita* in growth parameters like weight, crown heel length and chest circumference. This may be due to its *pushtikrit* and *balavardhan* properties. On the other hand, *Ashtamangal Ghrita* has better effect on head circumference increment and this may be

due to nootropic properties *ghrita*, *brahmi*, *vacha*, *kustha* which are considered to cause the brain growth.

Discussion on effect of therapy on Developmental domains - all the developmental domains shows that both *Ashtamangal Ghrita* (group A) and *Ashwagandha Ghrita* (group B) are proved to be beneficial on Development of infants compared to group C.

Discussion on probable mode of action of the trial drugs

Ashtamangal ghrita enhances physical and mental growth in infants having *rakshoghna*, *medhya*, and *smritivardhak* properties.

Balya, *brimhaniya*, and *vrisyā* effect of *brahmi*, *vacha* and *pippali*; *agnimandyanashak* effect of *sariva*, *pippali*, *siddharthak*; *ayurvedhak* property of *vacha* & *brahmi* may be helpful in enhancing the physical growth and development.

Better mental growth is occurred due to *smritikar* (memory enhancer) and *medhya* effect of *brahmi*; neuro protective, memory enhancer effect of *vacha*.

Swarya, *swarakrit* or *vak-swaraprada* effects of *vacha* and *brahmi* initiates speech and language, enhances nerve impulse transmission that helps in early achievement of language milestones. *Sangyasthapaka* property of *vacha* can be considered for the alert state of the infants, which may help in early achievement of mile stones.

Antimicrobial and antioxidant properties of *vacha*, *kustha*, *brahmi*, *sariva*, *pippali*, *siddharthak* and immunomodulatory effect of *vacha*, *pippali*, and *siddharthak* helps in lowering down the morbidity incidence in infants.

Go ghrita also have *deepana*, *rochaka*, *rasayana*, *balya*, *brimhana*, *yogavahi*, *medhya*, anti-oxidant, anti-infective effect; promotes physical as well as mental growth and a healthy life.

Tridosh shamaka properties of *saindhava* and *srotoshodhaka* property of *vacha* and *pipali* can help in increasing drugs bioavailability at tissue level. *Saindhava* is also rich in micro-nutrients which are required for optimal growth and development.

Ashwagandha Ghrita possesses *pushtikrit* and *balavardhan* properties.

Balya, *vrisyā* and *rasayan* quality of *ashwagandha* promotes growth; as well as helps in immunomodulation and *tikta rasa* causes *deepana*.

Cow milk is considered to be *jivaniya*, *rasayana*, *budhhi pravodhaka*, thus helps in growth and development as well as has immunomodulator effect.

Go ghrita possesses *deepana*, *rochaka*, *rasayana*, *balya*, *brimhana*, *yogavahi*, *medhya*, *vayasthapaka*, *rasa-shukra-ojovardhaka* properties; promotes physical as well as mental growth of the child.

CONCLUSION

After the completion of trial on all the developmental domains shows that both *Ashtamangal Ghrita* (group A) and *Ashwagandha Ghrita* (group B) are proved to be beneficial

on Gross motor, fine motor, language and social activity Development of infants compared to group C.

The improvement rate is gradually increased in Group B in comparison with group A in each subsequent follow ups, which may suggest long term effect of *Ashwagandha Ghrita*. The drug mentioned in Ayurveda can help to promote and modify the growth and development of infant. There is requirement to establish these fact in broader sense.

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