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A comparative clinical study to evaluate the efficacy of *Ashwagandha Ghrita* on Growth and Development of Infants

Dr. Koushik Baishya¹, Prof. Rakesh Sharma², Dr. Vinod Kumar³

¹Post Graduate Scholar, ²Professor & HOD, ³Reader, P.G. Department of Kaumarbhritya, Rajiv Gandhi Govt. P.G. Ayurvedic Medical College & Hospital Paprola, Distt.Kangra, Himachal Pradesh, INDIA.

ABSTRACT

Introduction: Growth and development are unique characteristics of children. Growth is defined as an increase in the size of an individual due to increase in number and size of the cells, where development refers to qualitative and quantitative changes and acquisition of a variety of competencies for functioning optimally in a social milieu. The present study has been planned to evaluate the effect of Ashwagandhaghrita on physical growth and development of infants. Aims & objectives: To study the efficacy of Ashwagandha Ghrita on Growth and development of infants, in terms of change occurred in anthropometry and milestones during the study period. Materials & methods: The study was conducted on 40 healthy infants for a period of 12 weeks and a case performa was filled with the data obtained by interrogation, physical examination and collection of details of each child. Results: Ashwagandha Ghrita showed better effect on physical growth in terms of increment in weight, head circumference, chest circumference, mid arm circumference, crown to heel length as well as early significant achievement of developmental milestones compared to control group. Conclusion: Ashwagandha Ghrita has proved to be beneficial on Growth and Development of infants.

Key words: Growth, Development, Ashwagandha Ghrita, Infants.

INTRODUCTION

Growth and development are the normal biological phenomenon of all living beings. 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

Address for correspondence:

Dr. Koushik Baishya

Post Graduate Scholar, P.G. Department of Kaumarbhritya, Rajiv Gandhi Govt. P.G. Ayurvedic Medical College & Hospital Paprola, Distt.Kangra, Himachal Pradesh, INDIA.

E-mail: kb564127@gmail.com

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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 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 Garbhapoorvaavastha (prior to conception), Garbhakaleenaavastha (during pregnancy) Prasavaottaraavastha (after birth). In our classical texts Lehan karma is advised to enhance energy, intellect and to protect the child from infections.For lehan karma many compounds have been prescribed in Ayurvedic texts. Ashwagandha ghrita is one of them. Therefore, this study is planned to evaluate the effect of Ashwagandha ghrita on physical growth and development of infants, in terms of change occur in anthropometry and milestones during the study period.

AIMS AND OBJECTIVES

- To study the efficacy of Ashwagandha Ghrita on Growth and development of infants, in terms of change occurred in anthropometry and milestones during the study period.
- 2. To evaluate the safety of the trial drug in infants.

MATERIALS AND **M**ETHODS

For the present study, infants were selected from IPD/OPD of Department of *Kaumarabhritya*, R. G. G. P. G. Ayu. College & Hospital, Paprola-Baijnath, Distt.-Kangra, Himachal Pradesh. Total 40 healthy infants were registered and divided into two groups. Out of them, 6 were dropped out from the study because they never turn up on subsequent follow ups. A case proforma was filled with the data obtained by interrogation, physical examination and collection of details of each child.

Inc	lusion criteria	Exc	lusion criteria
1.	Age eligibility - upto 1 year	1.	Infant suffering from any congenital, hereditary or acute systemic illness
2.	Gender eligibility - Both	2.	Infants not fulfilling the

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	male and female		criteria of inclusion
3.	Infants whose parents will give their written informed consent	3.	Infant who has been dropped on subsequent follow up
		4.	Whose parents have refused to participate in the study

Grouping of patients

Study was conducted on 40 selected infants in two groups:

- Group A In this group 20 infants were given the trial drug Ashwagandha Ghrita. 18 infants completed the trial and 2 were dropped out.
- Group B No medication were given to the infants of this group. Out of 20 infants 16 infants completed the trial and 4 were dropped out.

Treatment schedule

Particulars	Group A	Group B
Drug	Ashwagandha Ghrita	No medication
Dosage	0.5 ml/kg/day	-
Anupana	Milk	-
Duration	4 weeks	4 weeks

^{*}Follow ups: 4 follow ups at 1, 4, 8 & 12 weeks

RESULTS

Assessment of drug response

In each group, growth and development were assessed at four weeks i.e. 4, 8 & 12 weeks interval by anthropometrical evaluation and changes occurred in achievement of age specific developmental milestones. Scoring system was adopted for assessment of different developmental milestones at different ages with grades from zero to two, according to the appearance of different developmental milestones at different ages. ('0'= early; '1'= timely; '2'= late)

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(First week follow up is to see any adverse effect of the trial drugs in infants.)

Statistical analysis

The obtained data was analyzed statistically and expressed in terms of mean, standard deviation (SD), t value and p values in paired & unpaired 't' test.

Assessment of various Anthropometrical Parameters at subsequent follow ups

Table 1: Comparison between groups R-FU2

Anthropometric parameters	Mean increment (R-FU2)		't' value	P value	Result
	Gr. A	Gr. B			
Weight (Kg)	0.861 (±0.252)	0.670 (±0.185)	2.492	0.018	S
Crown to heel length (cm)	3.250 (±0.773)	2.688 (±0.797)	2.087	0.045	S
Head Circumference (cm)	1.667 (±0.536)	1.456 (±0.560)	1.119	0.271	IS
Chest Circumference (cm)	2.008 (±0.652)	1.700 (±0.610)	1.418	0.166	IS
Mid Upper Arm Circumference (cm)	0.736 (±0.217)	0.634 (±0.196)	1.427	0.163	IS

[R= At the time of registration; FU2= Follow up 2; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 2: Comparison between groups R-FU3

Anthropometric parameters	Mean increment (R-FU3)		't' value	P value	Result
	Gr. A	Gr. B			
Weight (Kg)	1.622 (±0.462)	1.247 (±0.389)	2.544	0.016	S
Crown to heel length(cm)	6.461 (±1.622)	5.094 (±1.573)	2.488	0.018	S

Head Circumference (cm)	2.844 (±0.953)	2.506 (±1.011)	1.004	0.323	IS
Chest Circumference (cm)	3.806 (±1.110)	3.206 (±1.213)	1.504	0.142	IS
Mid Upper Arm Circumference (cm)	1.444 (±0.433)	1.222 (±0.429)	1.502	0.143	IS

[R= At the time of registration; FU3= Follow up 3; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 3: Comparison between groups R-FU4

Anthropometric parameters	Mean increment (R-FU4)		't' value	P value	Result
	Gr. A	Gr. B			
Weight (Kg)	2.272 (±0.672)	1.753 (±0.548)	2.449	0.020	S
Crown to heel length (cm)	9.194 (±2.291)	7.156 (±2.174)	2.652	0.012	S
Head Circumference (cm)	4.256 (±1.474)	3.744 (±1.528)	0.993	0.328	IS
Chest Circumference (cm)	5.483 (±1.542)	4.550 (±1.756)	1.651	0.109	IS
Mid Upper Arm Circumference (cm)	2.056 (±0.637)	1.756 (±0.641)	1.364	0.182	IS

[R= At the time of registration; FU4= Follow up 4; S= Significant; HS= Highly Significant; IS= Insignificant]

Assessment of various Developmental Domains after each subsequent follow ups

Scoring system was adopted for assessment of different developmental milestones at different ages with grades from zero to two, according to the appearance of different developmental milestones at different ages. ('0'= early; '1'= timely; '2'= late)

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Table 4: Assessment of development after 2nd follow up

Gro	Mear	1	%	S.D	S.E	't'	P valu	Res ult
ups	R	FU 2	Improve ment	±	±	val ue	e	uit
Gross motor development								
Gr A	1.7 22	1.0 00	41.9	0.4 61	0.1 09	6.6 48	<0.0 01	HS
Gr B	1.4 38	1.3 75	4.3	0.7 72	0.1 93	0.3 24	0.75 1	IS
Fine m	otor d	evelop	ment					
Gr A	1.6 67	0.9 44	43.31	0.5 75	0.1 35	5.3 33	<0.0 01	HS
Gr B	1.3 75	1.4 38	-4.5	0.6 80	0.1 70	- 0.3 68	0.71 8	IS
Langua	age de	velopm	ient					
Gr A	1.6 11	1.0 00	37.93	0.5 02	0.1 18	5.1 69	<0.0 01	HS
Gr B	1.5 00	1.4 38	4.13	0.6 80	0.1 70	0.3 68	0.71 8	IS
Social & Adaptive development								
Gr A	1.6 67	1.0 56	36.65	0.5 02	0.1 18	5.1 69	<0.0 01	HS
Gr B	1.5 00	1.5 00	0.00	0.6 32	0.1 58	0.0 00	1.00 0	IS

[R= At the time of registration; FU2= Follow up 2; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 5: Intergroup comparison after 2nd follow up

Mean difference (R-FU2)		t value	P value	Result
Group A	Group B			
Gross motor dev	velopment			
0.722			0.004	S

Fine motor development							
0.722	0.063	3.647	<0.001	HS			
Language development							
0.611	0.063	2.697	0.011	HS			
Social & adaptive development							
0.611	0.000	3.138	0.004	S			

[R= At the time of registration; FU2= Follow up 2; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 6: Assessment of development after 3rd follow up

Gro ups	Mear		% Improve	S.D ±	S.E ±	't' val	P valu	Res ult
	R	FU 3	ment			ue	е	
Gross	motor	develo	pment					
Gr A	1.7 22	0.6 67	61.26	0.5 39	0.1 27	8.3 04	<0.0 01	HS
Gr B	1.4 38	1.2 50	13.07	0.6 55	0.1 64	1.1 45	0.27 0	IS
Fine m	otor d	evelop	ment					
Gr A	1.6 67	0.7 22	56.69	0.5 39	0.1 27	7.4 30	<0.0 01	HS
Gr B	1.3 75	1.1 88	13.6	0.5 44	0.1 36	1.3 79	0.18 8	IS
Langua	age de	velopm	ent					
Gr A	1.6 11	0.5 56	65.5	0.5 39	0.1 27	8.3 04	<0.0 01	HS
Gr B	1.5 00	1.3 13	12.5	0.7 50	0.1 88	1.0 00	0.33 3	IS
Social	& Ada _l	ptive d	evelopment					
Gr A	1.6 67	0.5 56	66.65	0.5 83	0.1 37	8.0 86	<0.0 01	HS
Gr B	1.5	1.3	12.5	0.7	0.1	1.0	0.33	IS

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	00	13	50	88	00	3	

[R= At the time of registration; FU3= Follow up 3; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 7: Intergroup comparison after 3rd follow up

Mean difference (R-FU3)		t value	P value	Result	
Group A	Group B				
Gross motor development					
1.056	0.188	4.236	<0.001	HS	
Fine motor development					
0.944	0.188	4.069	<0.001	HS	
Language development					
1.056	0.188	3.907	<0.001	HS	
Social & adaptive development					
1.111	0.188	4.033	<0.001	HS	

[R= At the time of registration; FU3= Follow up 3; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 8: Assessment of development after 4th follow up

Gro	Mear	1	% Improve ment	S.D S.E		't'	P	Res
ups	R	FU 4		±	±	val ue	valu e	ult
Gross	motor	develo	pment					
Gr A	1.7 22	0.2 78	83.8	0.5 11	0.1 21	11. 99	<0.0 01	HS
Gr B	1.4 38	1.2 50	13.07	0.7 50	0.1 88	1.0 00	0.33 3	IS
Fine m	Fine motor development							
Gr A	1.6 67	0.3 33	80.0	0.5 94	0.1 40	9.5 22	<0.0 01	HS
Gr B	1.3 75	1.1 88	13.6	0.7 50	0.1 88	1.0 00	0.33 3	IS
Language development								
Gr A	1.6 11	0.3 89	75.8	0.5 48	0.1 29	9.4 57	<0.0 01	HS
Gr B	1.5 00	1.2 50	16.7	0.8 56	0.2 14	1.1 68	0.26 1	IS

Social & Adaptive development								
Gr A	1.6 67	0.3 33	80.0	0.5 94	0.1 40	9.5 22	<0.0 01	HS
Gr B	1.5 00	1.3 13	12.5	0.8 34	0.2 09	0.8 99	0.38 3	IS

[R= At the time of registration; FU4= Follow up 4; S= Significant; HS= Highly Significant; IS= Insignificant]

Table 9: Intergroup comparison after 4th follow up

Mean difference (R-FU4)		t value	P value	Result		
Group A	Group B					
Gross motor dev	Gross motor development					
1.444	0.301	5.766	<0.001	HS		
Fine motor development						
1.333	0.188	4.965	<0.001	HS		
Language development						
1.222	0.250	3.988	<0.001	HS		
Social & adaptive development						
1.333	0.188	4.653	<0.001	HS		

[R= At the time of registration; FU4= Follow up 4; S= Significant; HS= Highly Significant; IS= Insignificant]

DISCUSSION

After the completion of trial, *Ashwagandha Ghrita* is found to be beneficial in growth parameters like weight & crown heel length and also shows significant results on Development of infants compared to control group.

Ashwagandha Ghrita possesses Pushtikrit and Balavardhan properties. The table below shows the contents of Ashwagandhaghrita along with their Karma and pharmacological actions:

Ingredients	Karma	Action based on pharmacological studies
Ashwagandha	Balya , Rasayan	Antibiotic activity (Withaferin A), immunomodulator, cognition enhancing & memory improving effect, anti-oxidant (sitoindosides

		VII-X, Withaferin A,
		glycowithanolides),
Go-dugdha	Jivaniya, Rasayana, Budhhipravodhaka	Energy, micronutrients (calcium, phosphorus, iron), vitamins (Vit. A, Thiamine, Riboflavin, Niacin, Vit. C)
Go-ghrita	Deepana, Rochaka, Rasayana, Balya, Brimhana, Yogavahi, Medhya, Vayasthapaka, Rasa-Shukra- Ojovardhaka	Anti-oxidant (Vit. E, beta- carotene), 8% lower saturated fatty acid which makes it easily digestible

CONCLUSION

The growth rate of an infant is perhaps a better indicator of general health and nutritional status. From the above study we can conclude that *Ashwagandha Ghrita* enhances growth and development in the infant. Though, breast milk is best for optimal growth and development during infancy, this formulation may be used as an adjuvant to get timely development of milestones with better growth. No adverse effect of the trial drug was observed during the study.

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