

Clinical study of the Immunoglobulin Enhancing Effect of “Bala compound” on Infants

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Abstract: *Kaumarbhritya* a branch of *Astbanga Ayurveda* deals with neonatal, infant and child health care. Multicentric studies conducted in various developed and developing countries have indicated that Infant Mortality Rate (I.M.R.) is very high in developing countries, and infection has been observed as the major cause. Immune system in neonates is not yet fully functional. Bala compound having the ingredients of **Atibala** (*Abutilon indicum* Linn), **Amalaki** (*Embllica officinalis* Linn), **Vidanga** (*Embllica ribes burn*), **Guduchi** (*Tinospora cordifolia* Welld Miers), **Pippali** (*Piper longum* linn), **Yashtimadhu** (*Glycyrrhiza glabra* Linn), **Shankhapuspi** (*Convolvulus pluricaulis* Chois), **Vacha** (*Acorus calamus* Linn), **Musta** (*Cyperus rotundus* Linn) and **Ativisha** (*Aconitum heterophyllum* wall) are *Medhya* as well as *Rasayana* drugs mention in *Ayurvedic* classics. 'Bala compound' was tried in infants in the form of oral drops for a period of six months and result was assessed for serum immunoglobulins IgG, IgM, IgA for three months of interval of two follow ups (i.e., third and sixth month of infant). There is significant increase of immunoglobulins observed after six months administration of 'Bala compound'

Introduction

“Baala” refers to synonym of infant, neonate and child; coined as they lack strength (Bala) and are prone to adverse environmental changes and infections. *Ojas* has been mentioned as a synonym of bala in various ayurvedic texts (Su.S.Su.2/31). Decrease in *ojas* will lead to imbalance of doshas, which are the basic factors for *vyadhi* (Disorder). *Ojas* can be termed as the inherent body constituent and Bala being its functional aspect.

Charaka has put forth the *vyadhikshamatva* in the aspect of resistance against diseases. For the purpose of enhancement of *Ojas* many medicaments have been recommended which also have capacity to increase 'Bala'. Thus the concept of *vyadhi kshamatva* seems to be close to the immunology of modern medicine.

Infant Mortality Rate is very high in developing countries. Death claims 60-250 of every 1000 live births. Within the 1st year of life and life expectancy is 30 % lower than in the developed country (Morley et al) as assessed by W.H.O. forum (1988) of about 34% which indicates that infections are the major cause of morbidity as well as mortality during infancy. The neonates particularly premature are at higher risk of developing immune defenses and responses (Rem and Puri, 1983). Immune system in neonate is functional at birth (Miller, 1977) yet not reached sufficient maturity particularly in relation to antibody production (Boxer, 1978). Immune system in man is composed of four major components.

1. Anti body mediated (Humoral immunity).
2. Cell mediated.
3. Phagocytic system.
4. Compliment system

Immunoglobulins IgG, IgM and IgA play an important role in immunity of infant.

Immunoglobulins Umbilical cord blood

Maternal IgG molecules will actively transport across the placenta and cord blood shows equal amount of maternal range. The normal values of IgG range of new born, 6 months, and 12 months are 1031± 200 mg /dl, 147 ± 86 mg/dl and 66 ± 219 mg /dl respectively. Normal value of IgM range of newborn, 6 months and 12 months is 11 ± 5 mg/dl, 43 ± 17 mg, 54 ± 23 respectively. Little IgA is found in cord blood. The concentrate in different age group of new born, 6 months and 12 months is 2 ± 3, 28 ± 18, 37 ± 18 respectively. IgE antibodies don't cross in significant amounts. IgD immunoglobulins have no known biological activity. Little IgD is found in Cord blood.

Materials and methods

Aim of the study

To evaluate the efficacy of Ayurvedic recipe 'Bala compound' in protecting against various common ailments during early infancy period especially by way of enhancing immunoglobulins which was assessed through estimation of

1. Cord blood immunological status (Baseline).
2. Changes in immunoglobulins with administrations of 'Bala compound' in comparison of conventional multivitamin drops.

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Plan of study:

24 Neonates were selected on random basis and divided in to two groups, A and B with 12 cases in each group, who delivered at prasooti tantra labour room of S.S. Hospital, B.H.U. Varanasi.

Group A was administered orally with 5 drops of 'Bala compound' twice daily and group B with 5 drops of conventional vitamin drops twice daily irrespective of neonatal age and weight.

Inclusion criteria

1. Age of the mother not to exceed 30 years.
2. Normal obstetrical history.
3. No history of maternal illness or drug intake during antenatal care except those required for essential ANC.
4. Mother undergone full immunization.
5. Neonates born by spontaneous vaginal delivery.
6. Full term neonates with gestational age between 37-41 weeks.
7. Neonates birth weight between 2500-3000gms.

Exclusion criteria:

1. Neonates not turned up for immunization schedule.

2. Neonates having history of birth anoxia, birth trauma etc.
3. Congenital anomalies in the neonate.
4. Maternal antepartum or postpartum hemorrhage.

Preparation and mode of drug administration

Equal parts of Atibala (*Abutilon indicum Linn*), **Amalaki** (*Embllica officinalis Linn*), **Vidanga** (*Embelia ribes Burn*), **Guduchi** (*Tinospora cordifolia Welld Miers*), **Pippali** (*Piper longum Linn*), **Yahstimadhu** (*Glycyrrhiza glabra Linn*), **Shankhapushpi** (*Convolvulus pluricaulis Chois*), **Vacha** (*Acorus calamus Linn*), **Musta** (*Cyperus rotundus Linn*) and **Ativisha** (*Aconitum heterophyllum wall*) are taken in the form of oral drops and administered in the dose of 5 drops twice daily irrespective of neonates age and weight on 11th day of the life onward as colonization in intestine is said to be impaired (Meharban Singh).

Parameters for Assessment of the response of the trial drug:

Purely depend up on the laboratory investigations. Changes in the immunological levels of IgG, IgM, and IgA.

Clinical profile of the study subject (n=24)

Table 1: Sex incidence in groups A & B

Sex	Group A(12)		Group B(12)		Total no of cases (12+12)	%
	No.of cases	%	No.of cases	%		
Male	7	58.3	8	66.7	15	62.50
Female	5	41.70	4	33.30	9	37.50

Table 2: Gestational age incidence on Group A & Group B

Gestational age (in weeks)	Group A(12)		Group B(12)		Total no of cases (12+12)	%
	No.of cases	%	No.of cases	%		
37-38	2	16.70	2	16.70	4	16.60
38-39	7	58.30	6	50.00	13	54.17
39-40	2	16.70	3	25.00	5	20.84
40-41	1	8.30	1	8.30	2	8.33

Table 3: Feeding status of infants on Group A & B

Feeding pattern	Group A(12)		Group B(12)		Total no of cases (12+12)	%
	No.of cases	%	No.of cases	%		
Breast fed	6	50.00	7	58.30	13	54.16
Partially Breast fed	6	50.00	5	41.70	11	45.84
Bottle feed	-	-	-	-	-	-

Table 4: Socio economic status of infants on Group A & B

Socio economic status	Group A(12)		Group B(12)		Total no of cases (12+12)	%
	No.of cases	%	No.of cases	%		
L.I.G.	3	25.00	2	16.70	5	20.80
M.I.G.	8	67.70	8	66.70	16	66.70
H.I.G.	1	8.30	2	16.70	3	12.50

Observations:

Table 5: Umbilical Cord blood serum Immunoglobulins level in groups A & B

Type of Immunoglobulin	Range	Group A (12) No. Neonate	Mean	S.E.	Group B (12) No. Neonate	Mean	S.E.
IgG	600-800	1	905.83	41.01	7	813.33	32.68
	800-1000	7			12		
	1000-1200	3			4		
	1200-1400	1			1		
IgM	10-15	7	13.66	0.44	6	13.83	0.386
	15-20	5			6		
IgA	0-1	6	1.00	0.3	7	0.833	0.297
	1-2	6			5		

Results:

Table 6: Response of the Bala compound on immunoglobulins of Group A

Parameter	Initial		I Follow up			II Follow up		
	Mean	S.E.	Mean	S.E.	t(p)	Mean	S.E.	t(p)
IgG	905.83	41-01	1031	47.26	2.004(>0.05)	1231.25	36.29	6.02(<0.001)
IgM	13.66	0.44	32.25	3.41	5.4(<0.001)	212.16	11.67	16.95(<0.0001)
IgA	1.00	0.3	20.08	2.73	8.1(<0.001)	50.50	6.09	6.78(<0.001)

Table 7: Response of the Multi vitamins on immunoglobulins of Group B

Parameter	Initial		I Follow up			II Follow up		
	Mean	S.E.	Mean	S.E.	t(p)	Mean	S.E.	t(p)
IgG	813.3	32.68	900.83	37.74	1.75(>0.05)	977.91	37.25	3.3(<0.01)
IgM	13.83	0.386	23.75	1.85	5.2(<0.001)	169.95	12.13	12.56(<0.0001)
IgA	0.833	0.297	24.50	1.43	6.78(<0.001)	37.66	1.55	6.78(<0.001)

Table 8: Showing inter group statistical analysis (unpaired t) of Groups A&B (II Fu Vs II Fu) in respect to immunoglobulins

	Serum IgG		Serum IgM		Serum IgA	
	A	B	A	B	A	B
Mean	1231,25	977.91	212.16	169.95	50.5	37.66
SE	36.29	37.25	11.67	12.13	6.09	1.55
T	6.02	4.86	16.95	2.507	6.78	5.584
P	<0.001	<0.001	<0.0001	<0.05	<0.001	<0.001

Discussion:

The results of the clinical study confirm the Immunoglobulin enhancing effect of the 'Bala compound' in Group A. There was significant increase of mean serum levels of Immunoglobulins IgG, IgM, and IgA in both Groups after three months of administered of the trial drug 'Bala compound' and conventional multi vitamin drops (i.e., I follow up), but better increase observed in Group A. And also there was a highly significant increase of mean serum immunoglobulins IgG, IgM and IgA after six months of trial (i.e., II follow up) in both groups.

Immunological factor plays an import role in neonates who're easily prone to the infections. Infant Mortality rate is very high in infants due to infectious factor which has been confirmed on the multicentric survey conducted by the W.H.O.'Bala compound' can improve and increase the immunity of neonates to combat the infections and to decline Infant Mortality Rate (I.M.R.). Since it was a time bound study a clinical trial can conducted in a large number of subjects to establish the safety and efficacy of the trial drug.

Acknowledgment

The authors are thankful to the Director, Institute of Medical Sciences, BHU, Head of the Department Prasooti and superintendent of S.S.Hospital, Varanasi for providing the facilities to conduct the trial.

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