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THE EFFECT OF BHUMYAMALAKI PANCHANGA CHURNA IN PHYSIOLOGICAL JAUNDICE.

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ABSTRACT

Physiological Jaundice may be defined as the condition characterized by yellow discoloration of sclera, skin and mucous membrane due to an increase in the bilirubin level of the circulation, usually > 5 mg %. It can be correlated with Koshtha-ashrita Kamala of Ayurvedic texts. To manage it, this study reports the intervention of Bhumyamalaki *(Phyllanthus niruri)*. In this selected 60 healthy newborns with yellowish tinge and increased TSB were randomly divided into 2 groups (30 patients in each group), out of which 8 patients were dropped out (4 from each group). In Group A, patients were treated with Bhumyamalaki panchanga churna given in dose of 60mg/kg/day, bid, orally after feed with madhu for 15 days while group B was untreated group. There were 3 follow ups, 1st after 7 days, 2nd after 15 days & 3rd after 30 days, from the starting of the trail. Then by subjective & objective criteria the effect of the therapy has been assessed. Statistical analysis of both groups show the highly significant results ($P<0.001$) but group A shows more significant results than group B.

KEYWORDS: Koshtha-ashrita kamala, Physiological jaundice, Total serum bilirubin.

INTRODUCTION

Physiological jaundice is one of the most common problems found in newborn which may lead to severe morbidity or mortality, although present in 60% of term infants and 80% of preterm infants. Usually it starts on 3rd day and subsides within a week but sometimes when exceeding the limits both quantitatively and qualitatively may cause concern as it may ensure various complications leading to morbid state needing treatment.[1,2]

Navajata Shishu Kamala has not mentioned in ayurvedic texts separately as a chapter. However, scattered references are available. Ayuvedic texts especially Kashyapa Samhita has ample description regarding Navajata Shishu Kamala.[3] Acharya Kashyapa in "Vedanadhyaya" has described signs & symptoms of Pandu & Kamala.[4] He described yellowish discolouration of eyes, nails, mukha, vita & mutra along with lethargy and refusal of feed as symptoms by which one may suspect Kamala also in neonates. Physiological jaundice is caused due to excessive destruction of RBCs & Ayurveda has considered pitta as a mala of rakta and accumulation of mala may lead to Kamala. So it can be correlated with Koshtha-ashrita Kamala of Ayurvedic texts.[5] According to Acharya Kashyapa Revati is one Graha that causes Kamala while describing clinical features of child seized with Jataharini, concept of Navajata Shishu Kamala may be inferred.[6]

AIMS AND OBJECTIVES

1. To study physiological jaundice conceptually based on Ayurvedic and Modern literatures both.
2. To assess the effects of Bhumyamalaki panchanga churna in the management of Physiological jaundice.
3. To assess the clinical safety of the drug.
4. To compare the effect of the drug with other untreated group.
5. To study the complications, if any during the course of the treatment.

MATERIALS AND METHODS

Selection of the patients

After obtaining permission from Institutional Ethics Committee, 60 Patients were selected from IPD/OPD of Department of Kaumarabhritya-Balroga, Patients fulfilling the diagnostic criteria were included in the present study.

Diagnostic criteria

Diagnosis was done on the basis of following:

a. History and Symptomatology of physiological jaundice.

b. By assessing the patients physically, according to Kramer's rule.

c. Increased Serum bilirubin according to laboratory Investigations.

Inclusion criteria

1. Newborn of either sex aged between 2-5 days having yellowish tinge.

2. Newborn who developed Jaundice more than 24hrs and less than 6 days.
3. Newborn with total serum bilirubin > 5mg/dl but < 12mg/dl in preterm & <15mg/dl in term babies.
4. Willing parents of newborn babies to participate in the trial.

Exclusion criteria

1. Newborn of either sex aged less than 1 day and greater than 5 days.
2. Newborn who developed icterus within 24 hours & more than 5 days.
3. Newborn with serum bilirubin >12 mg/dl in preterm & >15 mg/dl in term babies.
4. Newborn with any systemic congenital abnormalities (Blood group incompatibility etc. and infectious diseases).
5. Newborn who developed hypersensitivity in between the trial duration.
6. Unwilling parents of newborn babies to participate in the trial.

Protocol of the study

After obtaining the consent from the Parent/Guardian a detailed proforma has been filled to note down all the details of the patients and the disease.

Grouping of patients

Patients were randomly divided in to 2 groups-

i. Group - A **ii.** Group - B

	Group – A (treated with Bhumyamalaki panchanga churna)	**Group - B (without any type of drugs)**
Dose	60mg/kg/day	
Route of administration	Oral	
Time of administration	Twice a day after feed	
Anupana	Madhu	
Duration	15 days	

Follow up

There were three follow ups, first after 7 days, second after 15 days and third after 30 days from the starting of the trial. At first and last follow up only physical assessment was done while in second follow up laboratory investigations were also done.

ASSESSMENT CRITERIA

Subjective Criteria

It has been based on physical examination of the baby by blanching the skin for assessing the level of the yellowish tinge. By it accorded grades/scores according to the Kramer's rule.

Objective Criteria

It has been based on laboratory investigations

- Hb gm%
- Blood group with Rh factor
- S. Bilirubin – total and direct
- S.G.O.T
- S.G.P.T.
- S. Creatinine
- Blood urea

Scoring pattern adopted

S.no.	Subjective criteria	Objective criteria		Grades
		in term baby	in preterm baby	
i.	No Yellowish tinge	TSB - < 4 mg/dl	TSB - <4 mg/dl	Grade 0
ii.	Yellowish tinge in Zone 1 (upto neck)	TSB - 4 - 6 mg/dl	TSB - 4 -6 mg/dl	Grade I
iii.	Yellowish tinge in Zone 2 (upto umbilicus)	TSB – 6 - 8 mg/dl	TSB – 6 - 8 mg/dl	Grade II
iv.	Yellowish tinge in Zone 3 (upto knee)	TSB – 8 - 12 mg/dl	TSB – 8 - 10 mg/dl	Grade III
v.	Yellowish tinge in Zone 4 (upto arms & legs)	TSB -12 - 15 mg/dl	TSB - 10 - 12 mg/dl	Grade IV
vi.	Yellowish tinge in Zone 5 (upto palms & soles)	TSB - > 15 mg/dl	TSB - > 12 mg/dl	Grade V

With this registered patients have been assessed for the improvement in the subjective and objective criteria before and after the treatment.

Assessment of improvement

a. Complete relief

- Complete relief in the initial chief complaints of the patients.
- Normalization of the total S. bilirubin level.

b. Marked relief

- More than 75% relief in initial chief complaints.
- Marked decrease in total S. bilirubin level.

c. Moderate relief

- More than 50% relief in initial chief complaints.
- Moderate decrease in total S. bilirubin level.

d. Mild relief

- More than 25% relief in initial chief complaints.
- Mild decrease in total S. bilirubin level.

e. No relief

- No changes in complaints & total S. bilirubin level.

OBSERVATIONS AND RESULTS

Clinical observations are related to 26 patients in both group A and in Group B who completed the treatment for entire duration.

Table No. 1: Effect on yellowish tinge in Group A.

Visits	N	Mean Score		D	% relief	SD ±	SE ±	't'	P	Remark
		BT	AT							
FU_0 vs FU_1	26	2.58	0.65	1.92	74.63	0.74	0.15	13.18	0.000	<0.001
FU_1 vs FU_2	26	0.65	0.15	0.50	76.48	0.58	0.11	4.37	0.000	<0.001
FU_0 vs FU_2	26	2.58	0.15	2.42	94.03	0.70	0.14	17.58	0.000	<0.001

FU_0 – at registration, FU_1 – first follow up, FU_2 – second follow up.

Table No. 2: Effect on yellowish tinge in Group B.

Visits	N	Mean Score		D	% Relief	SD ±	SE ±	't'	P	Remark
		BT	AT							
FU_0 vs FU_1	26	2.96	2.23	0.73	24.68	0.78	0.15	4.79	0.00	<0.001
FU_1 vs FU_2	26	2.23	1.08	1.15	51.72	0.61	0.12	9.60	0.00	<0.001
FU_0 vs FU_2	26	2.96	1.08	1.88	63.64	0.95	0.19	10.09	0.00	<0.001

FU_0 – at registration, FU_1 – first follow up, FU_2 – second follow up.

Table No. 3: Effect on TSB level.

Groups	N	Mean Score		D	% relief	SD ±	SE ±	't'	P	Remarks
		BT	AT							
GroupA	26	10.00	2.66	7.35	73.43	2.99	0.59	12.51	0.00	<0.001
GroupB	26	10.65	5.28	5.37	50.43	2.12	0.42	12.94	0.00	<0.001

Table No. 4 : Effect on Haematological Values in Group A.

Values	N	Mean Score		d	% Relief	SD ±	SE ±	't'	P	Remark
		BT	AT							
Hb	26	15.39	15.45	0.06	0.40	0.20	0.03	1.87	0.07	>0.05
SGOT	26	32.65	32.12	0.54	1.65	1.39	0.33	1.97	0.10	>0.05
SGPT	26	27.81	27.35	0.46	1.66	1.27	0.54	1.85	0.07	>0.05
S.Creatinine	26	0.67	0.69	0.02	2.87	0.06	0.01	1.73	0.17	>0.05
BloodUrea	26	24.38	24.77	0.39	1.58	1.02	0.20	1.92	0.56	>0.05

Table No. 5: Effect on Haematological Values in Group B.

Values	N	Mean Score		D	% Relief	SD ±	SE ±	't'	P	
		BT	AT							
Hb	26	15.24	15.29	0.05	0.35	0.20	0.04	1.36	0.19	>0.05
SGOT	26	35.77	35.19	0.58	1.61	1.70	0.33	1.73	0.10	>0.05
SGPT	26	31.31	30.31	1.00	3.19	2.73	0.53	1.87	0.07	>0.05
S.Creatinine	26	0.66	0.64	0.02	2.91	0.07	0.01	1.41	0.17	>0.05
BloodUrea	26	27.88	27.77	0.12	0.41	0.99	0.19	0.59	0.56	>0.05

According to effect on yellowish tinge in FU_1, the percentage relief were 74.63% in group A and 24.68% in group B which are statistically highly significant ($p<0.001$). While in FU_2 (2^{nd} follow up) from FU_1 it were 76.48% in group A and 51.72% in group B which are also statistically highly significant ($p<0.001$). After trail, the percentage relief were 94.03% in group A and 63.64% in group B which are also statistically highly significant ($p<0.001$). The percentage improvements in TSB level were 73.43% in group A and 50.43% in group B. Both of these results are statistically highly significant ($p<0.001$).

All the haematological and biochemical parameters in group A and in group B were within normal limits in both before and after the therapy and statistically insignificant changes ($p>0.05$) are observed in these values after the completion of therapy.

Comparative evaluation

Table No. 6: Intergroup comparison over yellowish tinge.

N		Visits	%age Relief		%age relief Difference		't'	P		Remarks
Gr.A	Gr.B		Gr.A	Gr.B						
26	26	FU_ovs FU_1	74.63	24.68	49.95	BT	1.53	0.13	>0.05	NS
						AT	6.48	0.00	<0.001	HS
26	26	FU_1vs FU_2	76.48	51.72	24.76	BT	6.48	0.00	<0.001	HS
						AT	6.03	0.00	<0.001	HS
26	26	FU_ovs FU_2	94.03	63.64	30.39	BT	1.53	0.13	>0.05	NS
						AT	6.03	0.00	<0.001	HS

Table No. 7: Intergroup comparison over TSB.

N		Based on	%age Relief		%age relief Difference		't'	p		Remarks
Gr. A	Gr. B		Gr. A	Gr. B						
30	26	TSB	73.43	50.43	23.00	BT	0.93	0.36	>0.05	NS
						AT	7.73	0.00	<0.001	HS

According to yellowish tinge, in FU_1 the relief difference between group A & group B was 49.95% which is highly significant statistically ($p<0.001$). In FU_2 the relief difference between group A & group B was 24.76% which is highly significant statistically ($p<0.001$). In FU_2 from the starting of the trial, the relief difference between group A & group B was 30.39% which is highly significant statistically ($p<0.001$).

According to TSB level, after trial the relief difference between group A & group B was 23% which is highly significant statistically ($p<0.001$).

Overall effect of therapy

Table No. 8: Assessment on the basis of yellowish tinge and TSB.

Results	Group A (Trial Group)		Group B (Control Group)	
	No. of Patients	%age	No. of Patients	%age
Completely Improved	18	69.23	02	7.70
Markedly Improved	06	23.08	07	26.92
Moderately improved	02	7.70	12	46.15
Mildly Improved	0	0	05	19.23
No improvement	0	0	0	0

About 18 (69.23%) patients in group A and 2 (7.70%) in group B were completely improved. Though, in group A 61.53% more patients were completely improved than group B. Only 6 patients (23.08%) were markedly improved in group A and 7 (26.92%) patients were markedly improved in group B. This show 3.84% less patients in group A were markedly

improved than group B. 2 patients (7.70) in group A were moderately improved while 12 (46.15%) patients were moderately improved in group B. The difference between these two groups was 38.45%. Only in group B mildly improved patients were 5 (19.23%).

DISSCUSSION

Mode of Action of the Drugs

Drugs perform their action with the properties like Rasa, Guna, Veerya, Vipaka and Prabhava. Kamala is a Pittaja vyadhi with involvement of Dushyas Rakta and mamsa. Koshtha and Shakha are main Adhishthana. Raktavaha, Rasavaha, Annavaha and Purishvaha are main srotas which involved in it. Srotodushti is seen in the form of Atipravriti, Sanga and Vimargamana.

Physiological jaundice can be considered as Koshtha-ashrita Kamala in Ayurvedic texts. According to Acharya Charaka, principle of the treatment for koshtha-ashrita kamala is – **Samshodhyo MrdubhihTiktaih Kamale tu Virechanam"[7].**

It shows that treatment of Kamala is Samshodhana with Mridu virechana by the dravyas of Tikta rasa.

But in newborn, virechana is contraindicated, although, newborn already has increased no. of frequency of stool and urine naturally. Here virechana occurs in the sense of Pitta; so drugs cause pitta-rechana not purgation. Bhumyamalaki has virechana properties as well as other properties to treat Kamala. The probable mode of action of the drug may be explained as follows.[8]

Pitta-Virechana Karma

In Physiological Jaundice, Pitta is formed as mala of Rakta due to breakdown of RBCs and due to immaturity of organs and systems; this mala (pitta) causes Srotodushti by sanga, atipravriti and vimargamana. Bhumyamalaki, by the action of Yakriduttejaka karma (Liver stimulation) causes fast pitta-rechana from liver and further causes rapid reabsorption of pitta in gut & from bloodstream and then by mutra virechna karma causes excretion of pitta through urine.

Action by Rasa

Drug has tikta, kashaya and madhura rasa which belong to Saumyavarga, provide Sheetata which is antagonistic to pitta and causes pitta-shamana.

By Madhura rasa (Jala + Prithivi)

Drug causes Snehana, Tarpana (mainly Rakta dhatu cause Rakta vardhana), Vatanulomana, Pitta-shamana, Varnaya, Mriduta in the body by madhura rasa. It also removes toxic bilirubin (Vishghna) from the body by their mutrala effect.

By Tikta Rasa (Vayu + Akasha)

By Tikta rasa, drug causes Removal of Khavaigunya, Sroto-shodhana (So inhibit sanga of the srotas and increases the flow of the secretion in the body, so that it stimulate Liver and gallbladder to secrete Pitta rapidly and further remove toxins from the body), Ama-Pachana, Deepana, Rochana, Rakta shodhana, Dahaprashamana, srava-shoshana (i.e. Pitta absorbed from gut and circulation), Pitta-Kapha-shamana and removes toxins from the body (Vishghna).

By Kashaya Rasa (Vayu + Prithivi)

Drug helps to recover the colour of the body from alteration, Kapha-Pitta-Rakta Prashamana, Raktasandhana and Mutrasangrahana. Kashaya rasa also helps in Srava – shoshana, Kledo-shoshana and removal of toxins from the body.

Action by Guna

Drug has Laghu (Vayu, Agni, Akash) and Ruksha guna (Vayu, Agni) (Prithivi). Due to laghu guna, drug causes Deepan, Kapha-shamana, Vatanulomana, Srotoshodhana and decrease in mala. Laghu guna made the drug to digest easily.

Ruksha guna also causes Kapha-shamana, Vatanulomana. It also helps in Mala-shoshana (Dravansh-shoshana) which further cause decrease in toxins and reabsorption of secretions in the body.

Action by Veerya

Sheetaveerya

Bhumyamalaki has sheeta veerya (Prithivi and Jala). By which bhumyamalaki causes Pitta shaman, Vatanulomana and Dhatu poshana (mainly Rakta dhatu; due to its jaliya and parthiva properties increases rakta rasa).

Action by Vipaka

By madhura vipaka drug causes Pittashaman, Dhatu poshana (mainly Rata dhatu), easily removes vata, mutra, mala, immunomodulation and antioxidant effect. It also increases the action of drug which was done by madhura rasa.

Doshaghnata

Bhumyamalaki is kapha-Pitta shamaka.

Karma

Deepana, Pachana, Anulomana, Yakriduttejaka, Raktavardhaka, Raktashodhaka, Vishaghna and Pitta-rechaka karma.

Bhumyamalaki has various chemicals, produce choleretic activity, by which it stimulates the liver to remove the toxins which further reabsorbed in blood stream and filtered by the kidneys and then by the diuretic activity remove the toxins from the body. It has flavones, lignans, steroids, Alkaloids etc., produce antioxidant activity which improve function and protection of the liver and GIT flora.

Drug was given with honey which itself has good effects on kamala as per classics. It is one of the best suggested vehicles that have yogavahi property which does not interfere with drug property and just transports it. The studies indicate its power to enhance the drug action which is the best quality for anupana.

CONCLUSIONS

In the present research work on the basis of facts, observations and results of the drug and clinical studies, the following can be concluded.

Physiological jaundice is very common and benign problem in newborns, although, it is self-limiting. It is visible on 2^{nd} -3^{rd} day of age with peak level on 4^{th} -5^{th} day of life and disappears by 14^{th} day of life. In preterm babies, it manifest earlier but never before 24 hours of age and maximum intensity reach on 5^{th} or 6^{th} day and it may persist upto 14^{th} day. It is more common in male baby than female baby (4:1) and infants of 37-38 weeks of gestational age.

After birth, fetal Hb (with 2α & 2γ chains) convert into adult Hb (with 2α & 2β chains) which results in shorter life span (90 days) of fetal RBCs causing hemolysis and bilirubin

production but due to immaturity of organs and system in neonate, produce increase level of serum unconjugated bilirubin called as Physiological jaundice. About 1 gm Hb yield 35 mg of bilirubin. It can be correlated with Koshtha-ashrita Kamala of Ayurvedic texts. It is a pittaja disease as mala (pitta) of rakta can be equated with bilirubin.

Age group of mothers < 25 yrs shows more predominance to develop Physiological jaundice in neonates. Breast fed infants have predominance of physiological jaundice. Less as well as high, both amount of breast milk may cause neonatal jaundice. Insufficient intake of breast milk results in infrequent bowel movement causes excretion of bilirubin relatively (retained meconium has 1mg/dl bilirubin). High amount of breast milk causes presence of an unusual metabolite of progesterone (Pregnane-3-alpha-20-beta-diol) in the circulation of infant, inhibits UDPGA and produces breast milk jaundice (BMJ). There is cephalo-caudal progression of yellowish tinge in the jaundiced body whereas disappearance is in caudo-cephalic pattern. Though physiological jaundice is safe but it can be a serious condition when untreated and may produce Kernicterus.

From the study, it can be concluded that Bhumyamalaki is potent enough to reduce serum bilirubin level in neonates without any side effect.

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