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A study evaluating the effect of Punarnava Mool Churna in physiological jaundice

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Abstract
Neonatal jaundice is one of the most common problems found in infants. The present study reports the intervention of Punarnava (*Boerhavia diffusa)* for managing physiological jaundice. It can be correlated with Koshtha-ashrita Kamala of Ayurvedic texts. In this study, 60 healthy new borns with yellowish tinge and increased TSB were selected & randomly divided into 2 groups (30 patients in each group), out of which 4 patients from group B were dropped out. Group A was treated with Punarnava mool churna 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. Assessment of the effect of the therapy has been done on the basis of the subjective criteria (according to Kramer's rule) & objective criteria (according to lab investigation). Statistical analysis of the groups show the highly significant results (P<0.001) but group A shows more significant results than group B.

Keywords: Koshtha-ashrita kamala, Kramer's rule, Physiological jaundice, Total serum bilirubin.

1. Introduction
Neonatal jaundice is one of the many entities which may lead to severe morbidity or mortality. Physiological jaundice, although is 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].
Ayurvedic texts did not mention Navajata Shishu Kamala separately as a chapter. However, scattered references are available in the literature. Ayuvedic texts, especially Kashyapa Samhita have 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].

2. Aims and Objectives
1. To have a conceptual study of "Physiological jaundice" based on both Ayurvedic and Modern literatures.
2. To assess the effects of Punarnava mool churna in the management of Physiological jaundice.
3. To assess the clinical safety of the drug in the patients of Physiological jaundice.
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.

3. Materials and Methods
3.1 Selection of the patients
After obtaining permission from the 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.

3.2 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.

3.3 Inclusion criteria
I. Newborn of either sex aged between 2-5 days having yellowish tinge.
II. Newborn who developed Jaundice more than 24 hrs and less than 6 days.
III. Newborn with total serum bilirubin > 5 mg/dl but < 12 mg/dl in preterm & <15 mg/dl in term babies.
IV. Willing parents of newborn babies to participate in the trial.\

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

3.5 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.

3.6 Grouping of patients
Patients were randomly divided in to 2 groups-

i. Group - A **ii.** Group – B

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

3.7 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.

4. Assessment Criteria
4.1 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.

4.2 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

4.3 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.

4.4 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.

5. Observations and Results
Clinical observations are related to 30 patients in group A and 26 patients in Group B who completed the treatment for entire duration.

Table 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	30	2.80	0.57	2.23	79.76	1.17	0.21	10.50	0.000	<0.001
FU_1 vs FU_2	30	0.57	0.00	0.57	100	0.63	0.11	4.96	0.000	<0.001
FU_0 vs FU_2	30	2.80	0.00	2.80	100	1.19	0.22	12.93	0.000	<0.001

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

Table 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 3: Effect on TSB level

Groups	n	Mean Score		D	% relief	SD ±	SE ±	't'	P	Remarks
		BT	AT							
Group A	30	10.81	2.69	8.12	75.08	2.87	0.52	15.52	0.00	<0.001
Group B	26	10.65	5.28	5.37	50.43	2.12	0.42	12.94	0.00	<0.001

Table 4: Effect on Haematological Values in Group A

Values	N	Mean Score		D	% Relief	SD ±	SE ±	't'	P	Remark
		BT	AT							
Hb	30	15.51	15.59	0.07	0.47	0.28	0.05	1.44	0.16	>0.05
SGOT	30	32.40	32.07	0.33	1.03	0.99	0.18	1.84	0.08	>0.05
SGPT	30	27.00	26.67	0.33	1.23	0.96	0.18	1.90	0.07	>0.05
S.Creatinine	30	0.62	0.59	0.03	4.86	0.11	0.02	1.56	0.13	>0.05
BloodUrea	30	21.63	21.50	0.13	0.62	0.78	0.14	0.94	0.35	>0.05

Table 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 79.76% in group A and 24.68% in group B which are statistically highly significant ($p<0.001$), While in FU_2 from FU_1 it were 100% in group A and 51.72% in group B which are also statistically highly significant ($p<0.001$). After trail, the percentage relief were 100% in group A and 63.64% in group B which are statistically highly significant ($p<0.001$). The percentage improvements in TSB level were 75.08% in group A and 50.43% in group B, these results are statistically highly significant ($p<0.001$).

All the haematological and biochemical parameters in group A and 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 6: Intergroup comparison over yellowish tinge

N		Visits	% age Relief		% age relief Difference		't'	p		Remarks
Gr. A	Gr. B		Gr. A	Gr. B						
30	26	FU_0vs FU_1	79.76	24.68	55.08	BT	0.53	0.61	>0.05	NS
						AT	7.37	0.00	<0.001	HS
30	26	FU_1 vs FU_2	100	51.72	48.28	BT	7.37	0.00	<0.001	HS
						AT	7.98	0.00	<0.001	HS
30	26	FU_0vs FU_2	100	63.64	36.36	BT	0.53	0.61	>0.05	NS
						AT	7.98	0.00	<0.001	HS

Table 7: Intergroup comparison over TSB

N		Based on	% age Relief		% age relief Difference		't'			Remarks
Gr. A	Gr. B		Gr. A	Gr. B						
30	26	TSB	75.08	50.43	24.65	BT	0.22	0.83	>0.05	NS
						AT	8.02	0.00	<0.001	HS

According to yellowish tinge, in FU_1 the relief difference between group A & group B was 55.08%, which is statistically highly significant ($p<0.001$). In FU_2 the relief difference between group A & group B was 48.28% which is also highly significant statistically ($p<0.001$). In FU_2 from the starting of the trial, the relief difference between group A & group B was 36.36%, which is highly significant statistically ($p<0.001$).
According to TSB level, after trial the relief difference between group A & group B was 24.65% which is also highly significant statistically ($p<0.001$).

Overall effect of therapy

Table 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	25	83.33	02	7.70
Markedly Improved	05	16.67	07	26.92
Moderately improved	0	0	12	46.15
Mildly Improved	0	0	05	19.23
No improvement	0	0	0	0

About 25 patients in group A (83.33%) and 2 (7.70%) in group B were completely improved. Though, in group A 75.63% more patients got complete improvement than group B. Only 5 patients (16.67%) were markedly improved in group A while 7 (26.92%) patients were markedly improved in group B. This shows 10.25% more patients in group B were markedly improved than group A. 12 (46.15%) patients were moderately improved and 5 (19.23%) patients were mildly improved in group B.

6. Discussion: Mode of Action of the Drug

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. Punarnava 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]:

6.1 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. Drug, 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.

6.2 Action by Rasa –

Punarnava has madhura, tikta and kashaya rasa which belong to Saumyavarga, provide Sheetata which is antagonistic to pitta and causes pitta-shamana.
By Madhura rasa (Jala + Prithivi) – Causes Snehana, Tarpana (mainly Rakta dhatu cause Rakta vardhana), Vatanulomana, Pitta-shamana, Varnaya, Mriduta in the body. It also removes toxic bilirubin (Vishghna) from the body by their mutrala effect.
By Tikta Rasa (Vayu + Akasha) – 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) – Helps to recover the colour of the body from alteration, Kapha-Pitta-Rakta Prashamana, Raktasandhana and Mutrasangrahana, Srava – shoshana, Kledo-shoshana and removal of toxins from the body.

6.3 Action by Guna – Punarnava 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 causes decrease in toxins and reabsorption of secretions in the body.

6.4 Action by Veerya –

Ushna veerya – Punarnava has Ushna veerya (Agni) and by which punarnava causes Kapha-Vata shaman. Rakta has predominance of Agni and Jala so it is considered as Anushna-sheeta, Punarnava by its Ushna veerya (Agneya property) causes increase in Rakta-Karna (Haematinic action).

6.5 Action by Vipaka –

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

6.6 Doshaghnata – Punarnava is tridosha-shamaka.

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

Punarnava has main chemicals like Punarnavine-1,2, Punarnavoside, Sitosterol etc., may produce Diuresis and Choleretic activity. By choleretic action, drug stimulates liver and gallbladder to remove toxins (bilirubin which can be considered as mala of rakta i.e. Pitta), so promote the clearance of liver and gallbladder. These toxins are further remove from the body by its diuretic activity. So the drug acts by increasing the reabsorption of the unconjugated bilirubin in gut and from circulation. Punarnavine also enhances RBCs and WBCs count. It also protects and regenerates the hepatocytes thus improve the liver functions. Rotenoid, steroids and flavones etc. isolated from plant, have antioxidant activity and promote the balance of Globulin and Albumin. These chemicals also exhibit the lowering of serum bilirubin in the body.

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.

7. Conclusions

In the present research work on the basis of facts, observations and results of 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 the 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. Breastfed infants have predominance of physiological jaundice. Less as well as high, both amounts 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 Punarnava is potent enough to reduce serum bilirubin level in neonates without any side effect.

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