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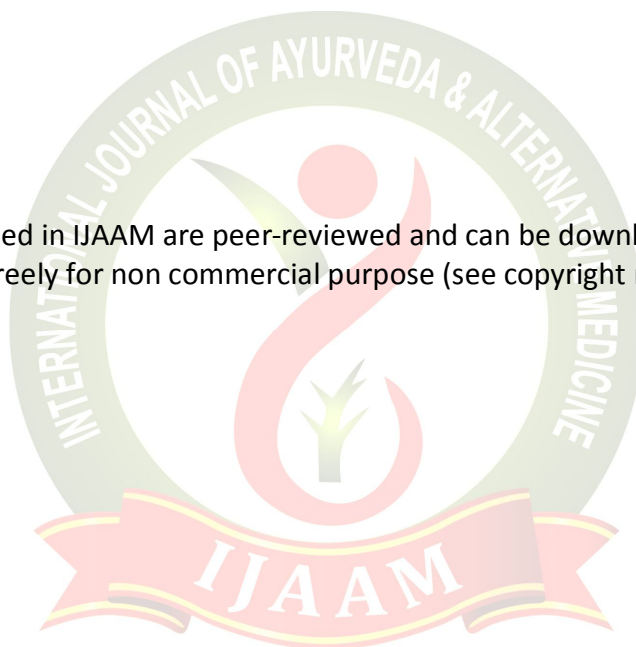
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**AN OPEN LABLE, RETROSPECTIVE, CONTROLLED STUDY TO
EVALUATE EFFICACY OF *DARUHARIDRA KASHAYA* (AN HERBAL
PREPARATION) IN MANAGEMENT OF *BAHUPITTA KAMALA* WITH
SPECIAL REFERENCE TO NEONATAL JAUNDICE****Chavan D.B.¹, Raut D.W.^{1*}, Lagad M.A.²**

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**AN OPEN LABLE, RETROSPECTIVE, CONTROLLED STUDY TO
EVALUATE EFFICACY OF DARUHARIDRA KASHAYA (AN HERBAL
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SPECIAL REFERENCE TO NEONATAL JAUNDICE****ABSTRACT**

Kaumarbhritya a branch of *Ayurveda* highlights the child rearing as the foremost feature. Hence Ayurvedic paediatrics aimed at treatment of disease and method of the bringing up the child to a healthy individual. *Rigveda* and *Atharvaveda* suggested treating *Kamala* (Neonatal Jaundice) with rays of rising sun. Based on similar symptoms *Bahupitta Kamala* mentioned in Ayurvedic classics is considered as Neonatal Jaundice in modern science. Nearly all texts mentioned use of *Daruharidra* (*Berberis aristata* DC) in management of Neonatal jaundice. In present study two groups containing 30 newborns each suffering from Neonatal jaundice were selected randomly irrespective to sex, gestational age. *Daruharidra Kashaya* and honey combination was used as a trial drug. Phototherapy was also given as supportive treatment along with trial drug. Parameters such as Serum bilirubin, alertness and activity, duration of jaundice, icterus with relative to serum bilirubin level were taken in to consideration for assessing results. At the end of study it was found that trial drug was very effective in the treatment of Neonatal Jaundice. It decreases serum bilirubin level, icterus, increases alertness & activity, decreases duration of jaundice.

KEY-WORDS- Icterus, Bilirubin, Kernicterus, Phototherapy, Hyperbilirubinemia, *Bahupitta Kamala*

INTRODUCTION:

The importance of childhood has been emphasized from the literature right up to the medical the childhood has an influence on the adult life. A healthy childhood is therefore mandatory for expecting a healthy adulthood. The importance of childhood was well recognized in *Ayurveda* as one of the eight branches of *Ayurveda* is dedicated to the *Bala Chikitsa* i.e. *Kaumarbhritya*.^[1] *Acharya Kashyapa* placed *Kaumarbhritya* above all the other eight branches in text *Kashyapa Samhita*.^[2] As the God of fire - Agni is crucial for carrying the offerings given by the worshipers to the respective gods, in the same way the branch of *Kaumarbhritya* is important for the rearing of child into a healthy adulthood.^[3] Though much of the literature dealing with *Kaumarbhritya* is mutilated even the available matter gives a glimpse of the prosperity of this branch in the older era. As the term, *Kaumarbhritya* suggests *Ayurvedic* Paediatrics highlights the child rearing i.e. *Kumara Bharana* as the main aspect of this field. Hence conceptually *Ayurvedic* paediatrics is not a mere therapeutic branch aimed at treatment of diseases but it also deals with methods of the bringing up the child to a healthy individual.^[4] The concept of health in *Ayurveda* not only means physical health but also the mental well being of a person. *Bala chikitsa* (paediatric medicine) described by *Vagbhata*. *Kaumarbhritya* is mentioned by *Sushruta* and at ancient days *Kaumarbhritya*

branch had a greater responsibility of both the Obstetrics & Paediatrics difficulties.

Kaumarbhritya emerged as an independent medical speciality right from the dawn of civilization. This revolutionary development was the result of increasing awareness among the health professionals that the problems of neonates differ considerably from those of adults and from the point of view of medical therapeutics, "a newborn cannot be considered as miniature adult".

These statistics definitely increase the responsibility of paediatric community from both *Ayurveda* as well as the modern contemporary sciences towards the society.

A Playful child is a pride of home. Many diseases cloud to deny this happiness by running the health of child. One of them is '*Kamala*'. *Rigveda* and *Atharvaveda* clearly explained this disease and supplemented to treat it with rays of rising sun.

Ayurveda, a fine solution for healthy life, treats neonatal jaundice under the heading of *Bahupitta Kamala*. For this treatment view nearly all *Acharyas* described the hepatoprotective action of *Daruharida* (*Berberis aristata*) with honey.

Around 60% of all term and 80% of all preterm are affected by neonatal jaundice.^[5] Moreover 16% of these are cut off in buds from their lives due to Kernicterus and associated acute bilirubin encephalopathy. The survivors may get penetration to brain cells under certain circumstances and result in a neurological dysfunction.^[6]

Near about all texts described *Daruharida* as hepatoprotective,^{[7],[8],[9],[10],[11],[12]} antibacterial^[13]. It is astringent in nature, in high dose it acts as laxative.

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It is assessed in adults by many researchers yet it was not assessed in newborns. Neonatal jaundice does not require any treatment.^[14] so there is a need of establishing possible treatment modalities to cure neonatal jaundice. Though phototherapy is suggested as treatment of neonatal jaundice but photochemical damages and long term side effects of phototherapy are remains underclothes.^[15] Unconjugated hyperbilirubinemia which can be reduced only by Blood Transfusion.

Exchange blood transfusion is quite risky and costly procedure. Neonatal hyperbilirubinaemia is a medical emergency and delay in management can lead to irreversible brain damage or death. Also rational management of Jaundice in newborn babies initiated by further customs.^[16]

- 1) There is lack of reliable laboratory facility for estimation of serum bilirubin level on micro sample of blood in most NICU's.
- 2) There are no uniformly acceptable guidelines initiating phototherapy or undertaking EBT in babies of different birth Weight and gestation.
- 3) As we know how to treat hyperbilirubinaemia but we don't know when to treat it because there is as yet no single test that can identify the level of bilirubin which is dangerous to the brain.
- 4) There is lack of facilities for undertaking bedside evaluation of brain stem evoked responses (BERA) with portable machine.

AIM

To study the efficacy of *Daruharidra kashaya* in *Bahupitta Kamala* (Neonatal Jaundice)

MATERIALS AND METHOD

In the treatment of neonatal jaundice *Daruharidra kashaya* was given orally to the neonates in a dose of 1ml/kg/day with phototherapy up to maximum five days.

Materials

Phototherapy unit – (single surface over head) as per level of serum bilirubin.

Drug

Daruharidra (*Barberis aristata*) & Honey

Method of preparation of kashaya

Daruharidra (coarse powder) procured from the local market and cleaned. For preparation of *Daruharidra kashaya* one part of *Daruharidra* and sixteen parts of water were mixed in wide mouth vessel.^[17] It was heated over low flame to reduce to 1/8th part.^[18] For 3ml kashaya 1/2 ml honey was used as *prakshepa dravya*.

Dose of Kashaya

Generally the dose of *kashaya* as per the *Sharagdhara* in neonatal age of 1st month is 4 *ratti*.^[19]

1 *Ratti* = 125 mg, so 4 *Ratti* = 500 mg = 1/2 ml. Adult dose of *kashaya* is 1 to 2 *pala* i.e. approximately 40 to 80 ml for 50 kg. According to Clark's formula-

Weight in pounds

Dose of a child = ----- x adult's dose.
150

For a neonate of 3 kg we accepted 3 ml as a standard dose. The dose for 1 kg is approximately 1 ml for 1 kg as suggested dose in texts has no specific weight related criteria with wide weight range from 1 kg in L.B.W. to 4 kg in post term neonate.

Clinical study

Before initiation of the study, study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Government Ayurved College, Nanded, Maharashtra, India.

Ethical clearance no - GACN/1087-91/ dated- 18/02/2010

Two groups of 30 Newborns each irrespective of sex were selected randomly.

Experimental group

Daruharidra kashaya with honey was given orally for maximum five days to the neonates suffering from *Bahupitta Kamala* with overhead phototherapy.

Control group

Only over head phototherapy is given for maximum five days to the neonates suffering from neonatal jaundice.

Criteria for the selection of patient

- Full term neonate having weight above 2.5 kg.
- Age- above 2 days and below 7 days.
- Total serum bilirubin level (TSBL) - >8 mg/dl and < 20 mg/dl
- Jaundice appearing after 36 hours of age.
- Exclusively breast fed infants.

Criteria for the rejection of patient

- Weight < 2.5 kg & > 4 kg.
- SBL- < 8 mg/dl and > 20 mg/dl
- Jaundice appearing within first 36 hours of age.
- Rh and ABO incompatibility, HDN patient.
- Age below 2 days and above 8 days.
- Any medical emergency & problem having surgical intervention.
- Patients with complications are also dropped out.

Criteria for Assessment

Objective

Serum Bilirubin Level – Indirect and total

Subjective

- Increased alertness & activities.

- Decreased durations of jaundice.
- Decreased skin colour with relative to S.B.L. by Krammer's rule.

Method of Assessment of Result

During the treatment period Serum Bilirubin level was tested on 1st, 3rd & 5th day to assess the result of *Daruharidra Kashaya*

Major criteria for assessment

Conclusion will drawn by following method

- a) Cured - If TSBL is < 5mg/dl after treatment.
- b) Relieved- If TSBL is in range 5-8 mg/dl after treatment.
- c) Not cured - If TSBL is 8-20 mg/dl after treatment.

TSBL – Total serum bilirubin level

Total fall and peak assessment:

- 1st day – 5th day = TSBL, to assess fall in jaundice.
- 3rd day – 1st day and 3rd day – 5th day = TSBL, to assess rise / fall on middle in Jaundice.
- 1st day – 5th day = Unconjugated Bilirubin level (UCBL), to assess fall in jaundice.
- 3rd day – 1st day and 3rd day – 5th day = UCBL, to assess rise (peak)/ fall on middle in jaundice.

Dietary regimen for mother

Following advice is given to mother -

- Maintain Hygiene.
- On demand breast feeding with proper burping.
- S/o dehydration, excessive loose motions, pyrexia, septicaemia if present should be promptly informed.
- Eyes and scrotal shielding during Phototherapy.
- No water, another drugs, (except antibiotics and antipyretics) are allowed according to situation.
- No bath, care of eyes, cord, skin.
- Baby should be kept warm.

OBSERVATIONS & RESULTS

The records of study were interrupted into the results on the basis of observations which is summarized in [Table 1 to 16]. When patients in both groups were compared for complete recovery (1st–5th) by applying paired 't' test, experimental group shows 't' value 10.369 which is significant, while in control group 't' value was 6.054 which is also significant. [Table 11] When patients in both groups are compared for peak level (3rd–1st) by applying paired 't' test, experimental group shows 't' value -1.692 which is insignificant, while control group shows 't' value 0.090 which is significant. When patients in both groups are compared for Slope (3rd–5th) by applying paired 't' test, Experimental group shows 't' value 9.914 which is significant, while [Table 12] control group shows 't' value 6.477 which is also significant.

When patients in both groups are compared for complete recovery (1st–5th) by applying unpaired 't' test, shows 't' value 2.493 which is significant. [Table 13]

When both groups are compared for peak level (3rd–1st) by applying unpaired 't' test, shows 't' value -1.361 which is insignificant.

When patients in both groups are compared for Slope (3rd–5th) by applying unpaired 't' test, shows 't' value 1.129 which is insignificant.

When patients in both groups are compared for complete recovery (1st–5th) by applying paired 't' test, Experimental group shows 't' value 9.928 which is significant, while control group (Table no.15) shows 't' value 6.007 which is also significant. [Table 14]

When patients in both groups are compared for peak level (3rd–1st) by applying paired 't' test, Experimental group [Table 14] shows 't' value -1.617 which is insignificant, while control group shows 't' value -0.352 which is also insignificant.

When patients in both groups are compared for Slope (3rd–5th) by applying paired 't' test, Experimental group shows 't' value 7.921 which is significant at p=0.05 significant level, while control group [Table no.15] shows 't' value 5.980 which is also significant at p=0.05 significant level.

When patients in both groups are compared for complete recovery (1st–5th) by applying unpaired 't' test, shows 't' value 2.342 which is significant. [Table 16]

When both groups are compared for peak level (3rd–1st) by applying unpaired 't' test, shows 't' value -1.361 which is insignificant.

When patients in both groups are compared for Slope (3rd–5th) by applying unpaired 't' test, shows 't' value 1.089 which is insignificant.

DISCUSSION

Ayurveda, a fine solution for healthy life, treats neonatal jaundice as *bahupitta kamala*. While treating neonatal jaundice by *Daruharidra kashaya* with honey showed high significance with 95% effectiveness. Pathology of jaundice in neonates is different from adult. In neonatal jaundice one of the etiological factors is entero-hepatic circulation which can be cut off by *Daruharidra* given at morning as suggested by *Charaka*. Both groups received phototherapy so their SBL decreased considerably. But the level of decrease in SBL of Experimental group was much greater than control group.

The status of relief is judged by decreased level SBL. Overall 20% patient got cured out of which 58.33% are from Experimental group and 41.66% are from control group. 65% cases were relieved out of which 51% are from Experimental group and 48.71% are from control group. 15% patients were Not Cured out of which 33.33% are from Experimental group and 66.66% are from control group. The overall effect of treatment is assessed by TSB level analysis, for that

the observations on 1st day and 5th day are subtracted from each other. The value remained is denoted X_1 for Experimental group and X_2 for control group and unpaired 't' test applied which after solving states that the difference is highly significant. Unpaired 't' test is also applied to 'UCB' level and by subtracting the values as processed previously with TSB. There is no significance. The values are included in observation chart. The effect on peak development is assessed by TSB analysis, subtracting 1st day value from 3rd day value and applying unpaired 't' test for it. There is no significance. The values are included in observation chart. Unpaired 't' test is applied to 'UCB' level also and by subtracting the values as processed previously with TSB. There is no significance. The values are included in observation chart. The effect on slope is assessed by TSB analysis, subtracting 5th day value from 3rd day value and applying unpaired 't' test for it. There is no significance. The values are included in observation chart. Unpaired 't' test is applied to 'UCB' level also and by subtracting the values as processed previously with TSB. There is no significance. The values are included in observation chart. *Daruharidra* is effective in neonatal hyper-bilirubinaemia with combination to phototherapy. The fall in TSB is enhanced as compared to control group. The fall seems to be in significant by unpaired 't' test with level 0.05% (i.e.95%). Increase in peak level of SBL in middle of treatment is also falls in Experimental group. It states that there is continuous fall in TSB within treatment period. Same results are stated on unconjugated values. No effect seen on conjugated fraction of bilirubin drastically. It may be due to continued unconjugated bilirubin load on hepatocytes making excessive conjugation. The fall in unconjugated bilirubin may be increased as there is cut off of enterohepatic circulation. *Daruharidra kashaya* was well tolerated by neonates. No sign of dehydration observed. No evidence of vomiting; aspiration; pneumonitis observed during treatment span.

Thus owing to the point that *yakrit* (liver) & *pleeha* (spleen) are the root of *ras-raktavaha srotus* is as stated in text *Charaka Samhita*. Hence *yakrit* is *Udhabhav sthan* of *Kamala*. The over secretion of *pitta* is responsible in *bahupitta kamala* while its obstruction is the causes of *ruddhapatha kamala* (obstructive jaundice). *Daruharidra* having action on *yakrit* as stated by *Bhavprakash*; increases the activity of *yakrit* and thus make person symptom free. As per Ayurvedic texts *Bahupitta Kamala* occurs due to vitiated *pitta dosha*. *Daruharidra kashaya* is very useful in the *dosh-dushya sammurchana (pitta dosha & rakta dhatu)*

CONCLUSION

Aim of this study was to observe the effect of *Daruharidra kashaya* on Sr. Bilirubin level. Significant reduction in the level of serum Bilirubin

was observed by the oral administration of *Daruharidra kashaya*. Due to its properties *Daruharidra* acts as *Deepana*, *Yakritottejak* (stimulates liver) and *pittasarak* (removes excess bile through faces) in patients of *Bahupitta Kamala* and helps in *sampraptibhanga*, as *virechana* is best treatment in *bahupitta kamala*. Skin colour of neonate may be improved due to *shodhana* of *raktagata pitta* and *Kleda* by *daruharidra kashaya* with *madhu*. In the present study the patients treated with *Daruharidra kashaya* shown significant relief in signs and symptoms over control group.

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