RESEARCH ARTICLE

AN OPEN LABELED, RETROSPECTIVE, CONTROLLED STUDY TO EVALUATE EFFICACY OF DARUHARIDRA KASHAYA (AN HERBAL PREPARATION) IN MANAGEMENT OF BAHUPITTA KAMALA WITH SPECIAL REFERENCE TO NEONATAL JAUNDICE

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RESEARCH ARTICLE

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

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 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 Vagbhatta. 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 astringenent in nature, in high dose it acts laxative.
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 hyperbilirubinemia 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 hyperbilirubinemia 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 ½ 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 = ½ 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-

\[
\text{Weight in pounds} = \frac{90}{\text{Age}} + 40
\]

**Dose of a child** = \(\frac{\text{Weight in pounds} \times \text{Adult’s dose}}{90}\)

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 unpaired’t’ test, shows t’ value 2.493 which is significant. [Table 13]

When patients in both groups are compared for peak level (3rd–1st) by applying unpaired ‘t’ test, shows t’ value - 3.408 which is significant.

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 complete recovery (1st–5th) by applying unpaired ‘t’ test, Experimental group shows t’ value 2.342 which is significant. [Table 15]

When both groups are compared for peak level (3rd–1st) by applying unpaired ‘t’ test, Experimental group [Table 14] shows t’ value - 1.619 which is insignificant, while control group shows t’ value - 1.361 which is also insignificant.

When 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 - 1.619 which is insignificant.

When patients in both groups are compared for complete recovery (1st–5th) by applying unpaired ‘t’ test, Experimental group shows t’ value 9.928 which is significant, while control group shows t’ value 9.914 which is significant, while [Table 12] control group shows t’ value 6.477 which is also significant.

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. Daruharidra is effective in neonatal hyper-bilirubinemia with combination to phototherapy. The fall in conjugated bilirubin drastically. It may be stated on unconjugated value and applying unpaired ‘t’ test for it. There is no significance. The values are included in observation chart. Daruharidra kashaya is very effective in neonatal hyper-bilirubinemia with combination to phototherapy. The fall seems to be in significant level of serum Bilirubin. Is effective in neonatal hyper-bilirubinemia with combination to phototherapy. The fall seems to be in significant

**REFERENCES**

8. Tripathi I. Hindi commentary, Cakradatta Charak tika, 2nd ed, Reprint, Varanasi, India, Chaukhamba Sanskrit sansthan publication, 1994, p.81
16. Singh M. Care of the Newborn, 6th ed, New Delhi, India, Sugar publication, 2004, p.250
17. Parasar SR, Hindi commentary, Sharangddhar Samhita madhyam khandh 3rd ed, Nagpur, India, Shree

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