A RANDOMISED CONTROLLED CLINICAL TRIAL TO EVALUATE EFFECT OF BALA (Sida Cordifolia Linn.) TAILA IN FULL TERM NEONATE’S SKIN.

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ABSTRACT

Neonates get ill due to delicate skin. Neonatal skin is prone to various allergies, fungal infections, erythema toxicum etc. Abhyanga nourishes skin, maintain hydration of skin and reduces infections. 40 neonates were selected for study, randomly divided in two groups. 20 neonates (Group-A, Trial group) were given Bala (Sida Cordifolia Linn.) taila while other 20 neonates (Group-B, control group) were given Tila (Sesamum Indicum Linn.) taila abhyanga. After end of treatment in later follow ups it was observed that patients from Trial Group (Group A) developed less skin allergies and infections as compared to patients from Control Group (Group B). It was observed that Bala taila abhyanga was more effective than Tila taila in maintaining skin health and prevention of disease. Mann-Whitney’s U test has shown insignificant difference between efficacy of two drugs (P>0.05). Though we found insignificant difference statistically, based on observations it is found Bala taila should be used for abhyanga instead of using Tila taila alone.

Keywords: Abhyanga, Bala (Sida Cordifolia Linn.) taila, Tila (Sesamum Indicum Linn.) taila, Erythema Toxicum, Neonate’s skin.

1. INTRODUCTION

It is well-known that neonate’s skin is delicate in nature and prone to allergies and various infections bacterial as well as fungal. Skin is outermost layer of body that prevents entry of pathogens into the body, we need to pay special attention on health of skin. Dryness, erythema, itching are signs of unhealthy skin. Taila Abhyanga is known to protect skin from getting dry thus protecting it from infections. Body massage is culturally accepted in India and neighbouring countries and has several scientifically proven benefits. Also, in Jatamatra paricharya Sushrutacharya has advised Bala (Sida Cordifolia Linn.) taila abhyanga for neonate immediate after birth. Prevalence of various skin disorders in children ranges from 8.7 to 35% in India. There is no specific treatment that gives permanent solution to skin issue of neonate. Recurrence is also common. Everybody may not afford the cost of treatment. Applied Bala tail gets absorbed through the skin it has direct effects on all skin of neonate. Bala taila abhyanga has emollient and demulcent properties as other oils, that act as barrier against allergens that reduces chances of skin allergies, prevent irritability in neonate that causes stress to parents. It also prevents expenditure on medicines for allergies and skin diseases. Considering

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these points this study was undertaken. The aim of this study is to assess the effects of Bala taila abhyanga on skin of neonate.

2. MATERIAL & METHODS

2.1. Objectives

♦ To study effects of Bala tail abhyanga on neonate’s skin.
♦ To study skin (twacha) in detail

2.2. Study design

A prospective randomized, open, controlled clinical trial was conducted on 40 neonates and which were divided into two groups. Proposed clinical study was presented in form of synopsis in front of Institutional Ethical Committee of PMT’s Ayurveda College, Shevgaon. The clinical trial was started after approval from Chairman of Ethical Committee. Detailed case record proforma was prepared including complete general examination of mother. Case was taken according to case format. Informed written consent was taken from the mother or father on same day of delivery to enrol neonate in the study for Abhyanga. Mothers were taught and trained to do abhyanga of neonate. Abhyanga was done in hospital for first 10 days. After discharge mothers were advised to do abhyanga at home daily for next 20 days. Total duration of treatment (abhyanga) was 30 days. Final assessment was done on the basis of before treatment (1st day) and after treatment (30th day) scores.

2.3. Consent

A voluntary, signed, witness, informed consent obtained from the parents / guardian after explaining them study details.

2.4. Selection of patients

2.4.1. Inclusion criteria

♦ Full term baby delivered normally or by caesarean section
♦ Child which is from consanguineous or non-consanguineous marriage couples.
♦ Male or Female neonate.
♦ Hemodynamically stable.
♦ Only exclusively breast feed baby.
♦ Babies who has full family support, has been taken for study
♦ Baby with any one or all symptoms i.e. Erythema toxicum, Cracks on skin and dryness of skin.

2.4.2. Exclusion Criteria

♦ Pre term (before 36 weeks of Gestational age).
♦ Baby with birth asphyxia.
♦ Congenital anomaly which is life threatening like congenital heart disease etc.
♦ Intruterine growth retarded babies are avoided.
♦ If mother has D.M. or any infective disease like Koch’s etc.
♦ Post mature neonate.

2.4.3. Withdrawal of subjects

♦ Parents not willing to continue treatment.
♦ If neonate develops other illness during treatment.
♦ If abhyanga is not done regularly at home.

2.4. Grouping and Randomization

Group A (Trial group)
20 patients of this group were given Abhyanga with Bala taila for first 10 days at hospital after that mother was trained to do Abhyanga at home for remaining period of study.

Group B (Control group)
20 patients of this group were given Abhyanga with Tila taila for first 10 days at hospital after that mother was trained to do Abhyanga at home for remaining period of study.

2.5. Drug Review

Moorchchhita Tila taila was used for abhyanga and to prepare Bala Taila because moorchchhana procedure increases therapeutic value and life span of taila. Tila taila was purchased from market. Preparation of Bala taila was done as per classical text at Rasashastra Bhaishajya Kalpana Department, PMT’S Ayurved College, Shevgaon. With the reference of Abhyanga in Ayurveda Khara pak
or Madhyam pak Sneha is used. Details of drugs are mentioned in Table No. 1.

2.4 Criteria of assessment
- Erythema Toxicum (Grade 1: Present, Grade 0: Absent)
- Cracks on skin (Grade 1: Present, Grade 0: Absent)
- Dryness of skin (Grade 1: Present, Grade 0: Absent)

3. RESULTS AND DISCUSSION
After completion of study we gathered data and analyzed it to find facts and fallacies. By this we could find drawbacks, limitations and future goals on this topic. With observations we found, few inferences and interpretations were drawn and discussed here. It is studied that Abhyanga by taila is effective to treat skin disorders in adults.

3.1. Demographic Observations
All participants from both groups belong to same age group as trial was conducted on neonates from day 1 to 30 days of age. As trial did not involve any parental or oral administration of drug parent’s compliance was good, no one exited trial before completion. Out of 40 neonates 24 (60%) were female neonates and remaining 16 (40%) were male neonates (Table No.1). 26 (65%) belong to poor economic class, 10 (25%) belong to medium economic class and only 4 (10%) belong to higher economic class. (Table No. 2). Patients from higher economic class tend to take care of their babies well, but in this study, it was observed that poor and medium economic class parents also paid attention to their children as per provided guidelines. We observed good response and active participation of mothers for daily abhyanga. It was also resulted in early diagnosis of various skin condition.

3.2. Changes in symptoms

In case of Erythema toxicum, out of 12 neonates of Group A, 11 neonates got complete relief; while out of 13 neonates of Group B, 10 neonates got complete relief. In case of Cracks on skin, out of 10 neonates of Group A, all 10 neonates got complete relief; while out of 9 neonates of Group B, 8 neonates got complete relief.

In case of Dryness of skin, out of 11 neonates of Group A, 10 neonates got complete relief; while out of 10 neonates of Group B, 8 neonates got complete relief. Percent relief observed in Group A was – Erythema toxicum 91.66%, Cracks on skin – 100%, Dryness of skin 90.90% and percent relief observed in Group B was – Erythema toxicum 76.92%, Cracks on skin – 88.88%, Dryness of skin 80%. Average % relief in Group A was 94.18% while average % relief in Group B was 81.93%. As per observations Bala taila abhyanga was found more effective than Tila taila abhyanga to improve skin condition in neonates.

3.3. Statistical Analysis
Both groups were separately analysed by Wilcoxon Signed Ranks test. In group A significant difference between BT and AT score was observed in case of all symptoms viz. Erythema toxicum, Cracks on skin and Dryness of skin (P<0.001). Likewise, in group B also significant difference between BT and AT score was observed in case of all symptoms viz. Erythema toxicum, Cracks on skin and Dryness of skin (P<0.001). Comparison between two groups was done by Mann-Whitney’s U test. This test has shown insignificant difference between effects two therapies. Hence statistically it was concluded that there is no significant difference between efficacy of Bala taila abhyanga and Tila taila abhyanga to improve skin condition in neonates.

3.4. Mode of action
Bala enhances snigdha guna of Tila taila thus becomes more potent demulcent and emollient than Tila taila alone. Hence Bala taila might have resulted in better results as compared to Tila taila alone. Bala taila counters Ruksha guna of Vata that reduces skin dryness prevents
cracking of skin that results in less infections. Bala and Taila both are snigdha, guru and brihan in nature, they nourish the skin and improves immunity of skin.

3.5. Scope and limitations

Daily Bala Taila abhyanga protects babies’ skin from various diseases. Oil gets absorbed from the thin skin of the baby, provides additional energy to baby. It prevents dryness and chaffing of skin. It reduces trans epidermal water loss and improves thermoregulation. As study was over small sample size which was drawn from limited population, results of study need to be verified further with large sample size to gain strong evidence.

5. CONCLUSION

Application of oil on skin is the Abhyanga, in Ayurveda different Paricharyas are mentioned to maintain Swasthya (health) Abhyanga is one of the important Upakrama in these Paricharyas. Skin is the first layer of defence of body. Skin prevents internal organs from injuries. Abhyanga with Bala taila reduces allergic reaction, dryness due to its emollient and demulcent property thus reduces chance of infection. Skin remains snigdha and healthy. Both Bala Taila and Tila taila found to significantly improve neonate’s skin health. Though statistically insignificant difference observed in both groups Bala taila produced better results. Bala taila is also Twak prasadan, Balya, Brihana and provides its additional advantage. Abhyanga is helpful to improve overall health of neonatal skin. Daily Abhyanga increases emotional bond between mother and child that in turn helpful for babies emotional, intellectual and physical growth.

REFERENCES

TABLES

Table No. 1. Drug Review

<table>
<thead>
<tr>
<th>Head</th>
<th>Bala (Sida Cordifolia Linn.)</th>
<th>Tila (Sesamum Indicum Linn.)</th>
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<tbody>
<tr>
<td>Family</td>
<td>Malvaceae</td>
<td>Pedaliceae</td>
</tr>
<tr>
<td>Gana</td>
<td>Balya, brihinya, Prajastha-pan, madhurskand, vatashaman</td>
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<td>Latin Name</td>
<td>Sida cordifolia Linn.</td>
<td>Sesamum indicum Linn.</td>
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<td>Ras</td>
<td>Madhur</td>
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Table No. 2. Sex wise distribution of cases

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<tr>
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Table No. 3. Economic status of parents

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<td>%</td>
<td>No.</td>
<td>%</td>
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<td>10</td>
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<tr>
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<td>100</td>
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Table No. 4. Changes in symptom scores

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<td>BT</td>
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<tr>
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<td>Dryness of skin</td>
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