

“Role of Rasanjana Ointment in Napkin Rash”

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Abstract - In Ayurveda, Ahiputana has been described as a condition developed due to improper cleaning of peri-anal region after defecation or after passing urine or after excessive sweating in an neonate/infant. This etiology leads to alleviation of Pitta Dosha and Kapha Dosha leading to itching sensation at that region. In neonates, infancy and early childhood period, children are prone to be sick due to delicate skin and less immunity power. In infants, the of diaper rash ranges from 7 to 35 percent. Diaper rash can develop as early as one week of age, but the peak incidences occurs between 9 and 12 months. To Evaluate the effectiveness of Rasanjana Ointment in napkin rash. The present study is designed as a Randomized comparative controlled open label prospective clinical trial, in which minimum of 15 patients will be enrolled in two groups. In Group A (Standard control) –Ezynapi Ointment will be administered and in Group B (Trial)–Rasanjana Ointment will be administered twice a day for 7 days. Assessment will be recorded on 3, 7th and 14th day. Changes will be observed in subjective parameters and objective parameters outcomes. Suitable conclusion will be drawn post completion of the trial.

Keyword- Ahiputana, Napkin Rash, Skin disorder, Rasanjana Ointment, Ayurveda therapy

I. Background

Napkin rash is one of the most common skin disorders in infants and children. Ahiputana is a Kapha Rakta predominant disorder mentioned in Ayurveda text books, which shows the symptoms like itching which leads to oozing blisters and later they join to form big Vranas.¹ It is caused due to the unhygienic conditions like absence of proper cleaning after defecation and urination. Napkin Rash is a similar clinical condition told in the contemporary science which is caused due to unhygienic conditions and use of diapers.² As mentioned in the above definition by Acharya Sushruta, Kaumarbhritya tantra deals with the Balak or Kumar who is on breast feed by his mother or Dhatri. It deals with diseases arising due to Dushtastanyapana, Asuchita i.e. unhygienic conditions such as Kupaicharya of child in which mother fails to keep perianal region dry, clean timely after every mala, mutra visarjan etc.² Many diseases occurring due to child negligence are documented in the literature. One of the most common and well documented of these is Ahiputana referred as Diaper Rash.³ In present days due to hectic life style parents fail to provide round the clock attention to their progeny. This responsibility is shouldered by hived hands, such an arrangement some time results in neglect and hygiene is not meticulously maintained. Regularly used napkins and diapers causes irritation to delicate skin.⁴ leading to development of rashes in the perianal region.⁵ Hence, it was decided to address this common phase problem as it makes the child

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more prone to many other serious complications. By suitable Ayurveda intervention the symptoms of Ahiputana described in text are Kandu (itching), Daha (burning), Tamravarna (ulcer), sphot (pustules), Strava (discharge) etc.⁶ So remedy which would be easy to follow, provide result in short duration and cost effective as well as easy for application and also free from side effects was needed. For treatment of Ahiputana, Kapha-Rakta-Pittashamak, Vrananashak, Twachya, Kledaghadrugs are used.⁷ There are many Lepa & Malahara described in Ayurveda Samhita, Bhaishajya Ratanavalid describes treatment for Ahiputana with Rasanjana Ointment.⁸ The content of Rasanjana are Vranashothhar, Vranaropan and Vranashodhan. These properties help in subsiding the diseases. The application of Rasanjana might be useful in management of Ahiputana.⁹ It is yellowish semisolid extract obtained by processing the decoction of Daruharidra (Berberis aristata) with milk.¹⁰ Its Rasa (taste) is Katu (pungent), Tikta (bitter), Virya (potency) is Ushna (hot), Karma (actions) is Chedana (scraping property) and Rasayana (rejuvenative), it balances Kaphadoshas, Vrana Ropan (heals chronic wounds), Shotha (swelling), Varnya (improves skin complexion), Raktashodhak (it purifies the blood) etc. Rasanjana is used both for external application and as oral medication.¹¹ It is caused due to the unhygienic conditions like absence of proper cleaning after defecation and urination. Napkin Rash is a similar clinical condition told in the contemporary science which is caused due to unhygienic conditions and use of diapers. The reported (number of times something happens) and age of beginning change/differ worldwide, related to differences in diaper use, toilet training, (keeping yourself/something clean), and raising children practices in different countries.¹² In paediatric practice, diaper rash represents 10 to 20 percent of all skin sicknesses/problems (figured out the worth, amount, or quality of) by the general doctors for children. According to the 1990-1997 National Able to walk around Medical Care Survey, there were 8.2 million (child-related) visits for diaper rash, and the calculated risk of developing diaper rash throughout (the time when a person is a child) was one in four. In infants, the guessed (number) number of diaper rash ranges from 7 to 35 percent. Diaper rash can develop as early as one week of age, but the peak (number of times something happens) happens between 9 and 12 months¹³. *Many drugs are mentioned for internal use, for external application and preventive measures have been described in detail in Modern Science to overcome Napkin Rash.*¹⁴ *So a remedy which would be easy to follow, efficacious, cost effective and also free from all side effects should be adopted. In all the allopathic medications (ointments) Zinc Oxide is a main content used for treating Napkin Rash*¹⁵. *The available medication in market is commonly compound of with the contents like Zinc Oxide, Cetylated Fatty Acid complex, D-Panthenol (Vit. B5) which is a proven allopathic drug used in the treatment of Ahiputana/Napkin Rash. Rasanjana is more cost effective to the patients than Ezynapi ointment, the value of Rasanjana is almost 2 Times cheaper than Ezynapi ointment. It can be easily prepared at home if patients want to prepare it on his own. where azynapi ointment can not be prepared. In present days due to hectic life style parents fail to provide round the clock attention to their progeny.*¹⁶ *This responsibility is shouldered by hived hands, such an arrangement some time results in neglect and hygiene is not meticulously maintained.*¹⁷ *Regularly used napkins and diapers causes irritation to delicate skin, leading to development of rashes in the perianal region.*¹⁸ *Hence, it was decided to address this common phase problem as it makes the child more prone to many other serious complications.*¹⁹ *In neonates, infancy and*

early childhood period, children are prone to be sick due to delicate skin and less immunity power.²⁰ Itching at perineal region, maculo-papular lesion, discoloration of skin are main symptoms of Napkin rashes, which are similar to Ahiputana described in Ayurveda.^{21 22}

II. Methodology

Trial design : Randomized comparative controlled open label prospective clinical trial

Study setting : OPD of the Department of Kaumarabhritya, OPD of Civil Hospital Wardha, Special camps will be conducted and AVBRH Hospital, Sawangi, Wardha.

Registration Number: REF/2020/ 01 /031086

IEC no: 8032

Inclusion Criteria

- i.** Patients aged group upto 3yrs with sign and symptoms of Ahiputana irrespective of caste, religion, sex or socio-economic status,
- ii.** Irrespective of sex, caste, religion & socio-economic background and Irrespective of Prakriti, Desh, Kal, Bala, Satwa, Satmya, Ahara.

Exclusion criteria

1. Children who have generalized skin infections and other systemic diseases than Ahiputana.
2. High risk – Neonates and Neonatal sepsis

Criteria for discontinuing or modifying allocated interventions: If the symptoms get aggravated during treatment such subjects will be withdrawn from study and suitable alternative will be provided free of cost till they become healthy.

Follow up period after treatment: 3rd, 7th& 14th day after treatment.

Primary Outcomes: we will see the effect of interventional drug on Kandu (itching), Daha (burning), Tamravarna (ulcer), sphot (pustules), Strava (discharge)

Secondary Outcomes: we will see reoccurrence and any side effect of interventional drug.

Statistical analysis: The collected data will be analyzed using Wilcoxon signed rank test

Time duration till follow up: The patient will be followed up during treatment 7th days.

Follow up period – 3rd, 7th and 14th day

Time schedule of enrolment, interventions: Diagnosed patients will be enrolled in the present study after fulfilling the inclusion criteria.

Interventions-

Drug	Dose	Route	Site	Frequency

Group A – Ezynapi Ointment	Quantity Sufficient	Local Application	Affected area	Two times a day
Group B – Rasanjana Ointment	Quantity Sufficient	Local Application	Affected area	Two times a day

Sample size:30 (15 in each group)

Recruitment:The patient will be recruited by randomly through computer generated number.

Method:The patient will be recruited by simple random sampling (lottery method.)

Implementation :Principal invigilator will allocate and enroll the patient.

Methods : Data collection, management, and analysis

Data collection methods :Data collection methods:Research proforma by interview and examination.Assement will done under criteria:Subjective Criteria:Kandu (Itching)Objective Criteria: Rash, Tamravarna(ulcer),Strava(Discharge),Irritability, Sphot (Pustules)

Data management: The data entry coding will be done by Principal Invigilator.

Assement criteria :

Subjective Criteria-

1) Kandu (Itching)

Objective

criteria-

1)

Rash

2)Tamravarna(ulcer)3)Strava(Discharge) 4) Irritability 5)Sphot (Pustules)

Data management :

The data entry coding will be done by Principal Investigator

Ethics and dissemination :Research ethics approval ; approval from research ethicscommittee has taken....no-DMIMS (DU)/IEC/Jun-2019/8032.

Consent or assent : The written consent will be taken from the patient before starting the study.

During the study the confidentiality of each patient will be maintained.

Dissemination policy :The data will be disseminated by paper publication.Authorship eligibility guidelines and any intended use of professional writers

Informed consent materials : Model consent form and other related documentation will be given to participants and authorised surrogates with all the information.

Expected Results: At the time of protocol writing analysis is notcomplete.The expected result of this study is that group A with intervention ispotentially equal to group B with intervention.It is effective in subsiding the symptom of Napkin Rash Kandu (itching),Daha (burning),Tamravarna(ulcer),sphot (pustules),Strava(discharge).Patient who will take all follow up by following conductive for healthduring treatment will have less chance of reoccurrence of symptom.

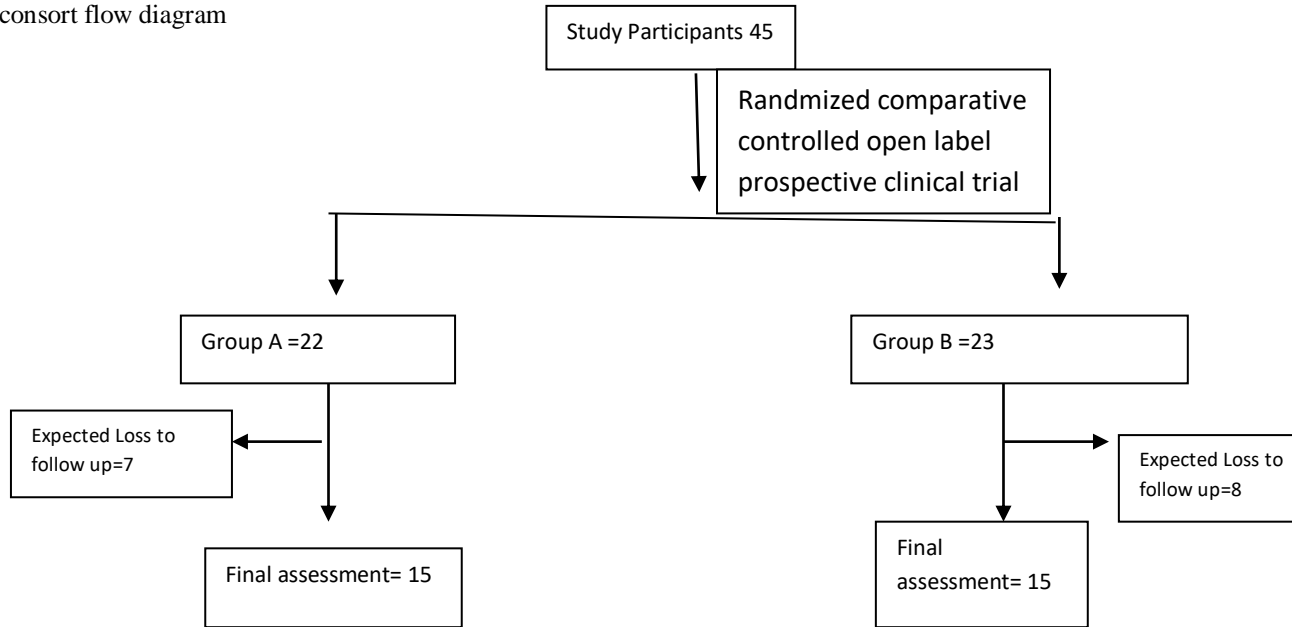
III. Discussion

In this protocol two formulation intervention will done in two groups consisting 15 in each group. One group will receive Trial drug while another will receive the standard drug. The assessment will be done on the basis of subjective and objective parameters, after that data will be analyzed by using statistical test and present in form table and chart. A number of studies on different aspects of Child Health in this region were reviewed ²³⁻²⁹.

IV. Conclusion

The interventional drug group 1 is equal effective as group 2 with least side effects.

Figure 1 consort flow diagram



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