

CLINICAL STUDY OF THE EFFICACY OF WOODFORDIA FRUTICOSA FOR THE PREVENTION OF DENTITION DISORDERS IN INFANTS

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ABSTRACT

Dentition (*Dantodbhed*) is believed to disturb the equilibrium of all *Dhatus* (body tissues), leading to dentition disorders (*Dantodbhedjanya Vyadhi*). This condition encompasses various symptoms, including *Jwara* (fever), *Atisara* (diarrhea), *Kasa* (cough), *Chardi* (vomiting), *Shira Shoola* (headache), and *Netra Abhishyanda* (conjunctivitis). These symptoms effectively are essential for the infant's overall health and comfort during teething. This study aimed to explore the efficacy of *Woodfordia fruticosa Churna* in managing these teething symptoms. The *Churna* was mixed with pasteurized honey and applied to the gums of 40 infants, though 5 dropped out. Parents were trained to perform this application thrice daily for six months, with follow-ups every 15 days for the first three months and monthly for the next three. The study assessed six parameters:

diarrhea, cough, vomiting, conjunctivitis, skin lesions, and fever. Observations showed a significant reduction in teething-related disorders with the use of *Woodfordia fruticosa Churna*. Correlation analysis indicated that while weight was somewhat affected by illness during teething, the relationship between age and weight remained significant, suggesting that the *Churna* helped prevent significant weight loss. *Woodfordia fruticosa Churna* proved effective in reducing teething-related symptoms and maintaining weight during tooth eruption. The mean age of tooth eruption stages (central incisor, upper central incisor, upper lateral incisor, and lower lateral incisor) matched typical developmental timelines. This study supports the use of *Woodfordia fruticosa Churna* as a safe and effective therapy for

managing teething symptoms in infants and encourages further research to enhance its efficacy.

KEYWORDS: Dantodbhed, Dantodbhedjanya Vyadhi, Dentition, Dentition disorders, Woodfordia fruticosa, Teething, Ayurvedic Medicine, Pediatric Health.

INTRODUCTION

The emergence of an infant's first tooth is typically recognized by parents as one of several important developmental milestones; hence it is one of the most frequent causes of parent concern. Every child experiences it usually beginning around the age of 6 months. Kashyap Samhita elaborates a description of dentition in one of the separate chapters.^[1] One crucial milestone in evaluating an infant's growth is their dentition. Germination of teeth occurs at the time of gestation period and eruption of teeth occurs in childhood. According to Vagbhata, dentition during the eighth month onwards is an indication of longevity whereas dentition during the fourth month is not desirable because the child cannot withstand the agony of dentition at such a tender age.^[4] The aggregate prevalence of diseases during a dental eruption in infants was found 70.5% from various articles and studies in various countries.^[2] Ayurvedic texts have reported the occurrence of pain during dentition. The intensity of pain during dentition has been compared with the pain that occurs in cats due to injury of the spinal cord or the pain experienced by peacocks at the time of crowning. (A.H.U 2/26-28).^[3] Acharya Vagbhata described many dentition disorders (*Dantodbhedjanya Vyapad*) e.g. *Jwar* (pyrexia), *Atisar* (Diarrhoea), *Kasa* (Cough), *Chardi* (Vomiting), *Shirashool* (Headache), *Abhishyand* (Conjunctivitis), *Pothaki* (Trachoma), *Visharp* (Erysipelas), *Trushna* (Thirst), *Bhrama* (Delirium).^[4] During dentition, these symptoms are originated. This period disturbs the growth of infants.

It is important to search for safe therapy for the prevention of dentition disorders in infants. In Ashtanga Sangraha, Vagbhata has mentioned, the massage of gums with different drugs as well as oral medication related to this. Pratisaran of Woodfordia fruticosa (Dhataki Pushpa) Churna mixed with honey is one of them.^[5] Only one related study was performed, and it concluded that the *Kashyap Ghrita* when administered orally is effective which reducing the disorder caused during the dentition period.^[6] There is one related review article on the prevention of dentition disorders, but this study is still in process.^[2] On *Woodfordia fruticosa* (*Dhataki Pushpa*) Churna, no research work has been carried out, therefore, to evaluate its efficacy in the prevention and the management of dentition disorders (*Dantodbhedjanya*

Vyapad) as *Pratisaran* during dentition. Considering the above problems *Dhataki Pushpa Churna* (*Woodfordia fruticosa*) is easily available and is less irritant and equally affected.

MATERIAL AND METHODS

Design – This study was a single-arm open interventional clinical trial.

Participants – Infants visiting the pediatric outpatient department of Bharati Vidyapeeth Ayurved Hospital, Pune for regular checkups But not having any pre dental eruption signs and symptoms were selected and registered from pediatric outpatient departments of Bharati Vidyapeeth Ayurved College, Pune between April 2023 to April 2024. Before starting the study, ethical Clearance was obtained from the Ethical Committee and CTRI registration was done. The written informed consent was taken before enrollment from the parent or caretaker of infants.

Inclusion criteria

1. Infants between the age group of 06-12 months but not having any signs and symptoms of dental eruption.
2. Infants who were born with full term gestation.

Exclusion criteria

1. Infants suffering from any systemic disease at the time were excluded.
2. Pre-term babies
3. Infants with metabolic disorders based on newborn/new-born metabolic screening.
4. Infants with any anatomical or congenital anomalies related to GIT.
5. Suspicion of any syndromic phenotype like (Down's syndrome).
6. Infants with bleeding disorder if any, previously diagnosed.

Study Drug – *Woodfordia fruticosa* (*Dhataki Pushpa*) was collected from the market, authenticated and standardized from GMP Certified pharmacy and prepared as a *Churna* (Fine powder sieved through 120 mesh) and kept in the air-tight container.

The exact *matra* of *Churna* for *Pratisaran* was not found in the literature. Therefore, the dose of *Churna* was decided by the experienced practitioner and administered to the infant for *Pratisaran* on the gums. The requisite amount of *Churna* (Approx. 60 mg) was mixed with pasteurized honey and was applied on infant's gums thrice a day for 6 months.

Interventions

Out of the enrolled 40 patients, 5 patients dropped out as they were unable to come for the follow-up physically.

Trial Methodology

On the 1st day visit, parents were trained for procedure of external application (*Pratisaran*) of *Dhataki Pushpa Churna* mixed with honey on infant's gum of selected age group. (6-12 months) The requisite amount of *Churna* was mixed with pasteurized honey to make a paste to apply on the gums of infants for 15-20 sec in the presence of the investigator/by the parents

Once the investigator confirmed, counseling was done to perform the same procedure thrice a day at home for 6 months.

The infant's parents/caretaker were asked to visit every 15th day for the first 3 months and monthly for the next 3 months and will be asked about acceptance of the research drug.

Follow-up will be taken physically/Electronically by Telephone, mostly preferred physically (At least 4 follow up will be taken On every physical follow-up, the infant will be checked for subjective and objective parameters till completion of the study. The assessment was based on the gradation of both subjective and objective clinical features during treatment.

Criteria for patient drop out

Parent/caretaker of registered infants unwilling to perform regularly for 6 months.

Parents who are being transferred to another city and unable to come for follow-ups physically. *Pratisaran* of *Woodfordia fruticosa Churna* missed for 10 consecutive days and was treated as a dropout patient.

Observation-based criteria Subjective Parameter

1. Conjunctivitis (*Netra Abhishyanda*)
2. Cough (*Kasa*)
3. Skin Lesions (*Visphota*).

(Conjunctivitis and Skin Lesions are mentioned in *Kashyap Samhita* but practically may not see during dentition period.)

Objective Parameter

1. Diarrhea (*Atisara* - Number of Episodes)
2. Vomiting (*Chhardi* - Number of Episodes)
3. Temperature (*Jwara* Range of fever measured with thermometer).

Assessment of sign and symptoms was done on 15th, 30th, 45th, 60th, 75th, 90th, 120th, 180th day of follow-up. The severity of the disease was assessed based on gradation. (0, 1, 2, 3....) Table No. 1. Assessment of objective parameters was done based on Number of frequency of diseases during teeth eruption.

Statistical analysis

Karl Pearson's test, the f-test, the regression approach, and the mean median were the statistical techniques used in this study. The mean and median techniques were used to calculate the average age at which teeth erupted in the research population. To summarize and comprehend the average value of the given data, a mean is merely a measure of central tendency. The age-weight association has been discovered using Karl Pearson's test. Regression analysis is a method used to examine and identify coincidental correlations between different kinds of clinical data. Additionally, we performed the F test—which is frequently used to compare two variances by dividing them—to examine the mean age and mean weight at tooth eruption.

RESULT

According to statistical analysis, out of 35 infants, 14 (40.0%) were from lower socioeconomic status, 18 (51.4%) were middle; and 8.6% of infants from the upper class participated in this study. A maximum number of patients are from the Middle Class. Hindus 24 (68.0%), Jains 1(3.0%), and Muslims 10 29.0% infants have participated in this study. We found that the maximum number of patients were from Hindus.

Data Analysis

The mean and median age for tooth eruption:

TYPE OF TEETH	MEDIAN AGE IN MONTH	MEAN AGE IN MONTH
Lower central incisor	8.44	8.44
Upper central incisor	9.12	9.23
Upper lateral incisor	11.05	11.13
Lower lateral incisor	12.33	12.59

Incidents of disorders in tooth eruption

In this study, it has been observed that prominent two diseases observed in Lower Central Incisor are diarrhea in 28.6% of kids and temperature in 25.7% of kids. In the upper central incisor, diarrhea decreases to 25.7% of kids, and vomiting in 20% of kids. In the upper lateral incisor, diarrhea decreases to 14.3% of kids, and vomiting and cough in 8.6% of kids. In lower lateral incisor teeth eruption cough is seen only in 4.5 % of kids. The proportion of patients who suffer from diseases during the tooth-eruption process is decreasing. In the initial stage with the Lower central incisor, 54.3% of kids face illness. It has been reduced to 40 % in the upper central incisor. In the second stage of tooth eruption, it reduces to 25.7%. In the upper lateral incisor, while it drops to 4.5% only in the lower lateral incisor. As per statistical analysis, it has been observed that no. of children (in %) who suffered from various diseases while teeth eruption goes on decreasing.

Correlation Analysis between tooth eruption and weight

Karl Pearson's Test has been used for testing the Significance of the Correlation coefficient with Null Hypothesis H_0 : True correlation is ZERO (i.e. Tooth Eruption does not affect weight) against

H_1 : True correlation is not equal to 0 (i.e. Tooth Eruption affects weight).

1. Lower Central Incisor and Weight -The Simple Correlation coefficient between age at the time of Lower Central Incisor and Weight has been 0.5345, which is significant since the p- value is 0.013. The correlation coefficient has been moderate, it may be due to around 54.3% of kids suffering from different types of illness, which affect the age and weight relationship but not strongly.
2. Upper Central Incisor and Weight -The Simple Correlation coefficient between age at the time of Upper Central Incisor and Weight has been 0.5675, which is significant since the p- value is 0.007. Here correlation has a little increased but is still moderate only. It may be due to around 40.0% of kids suffering from different types of illness, which affect the age and weight relationship but not strongly.
3. Upper Lateral Incisor and Weight - The simple Correlation coefficient between age at the time of Upper Lateral Incisor and Weight has been 0.5289 which is significant Since p- value is 0.014. Here correlation is a little decreased as compared to the last stage but still moderate only. This may be due to around 24.5% of kids suffering from different types of illness, which affect the age and weight relationship but not strongly.
4. Lower Lateral Incisor and Weight: The simple Correlation coefficient between age at the

time of Lower Lateral Incisor and Weight has been 0.6310, which is significant since p-value is 0.002, Here correlation has significantly increased as compared to the last stage. It may be due to only 4.5% of kids suffering from a different type of illness. Which has reduced the overall effect of the age and weight relationship.

Weight and age relationships in tooth eruption process

Type of tooth eruption	Observed mean age in months	Observed weight in kg	Expected weight (50 th percentile)
Lower central incisor	8.44 months (8M 13 D)	7.38	8.25 kg
Upper central incisor	9.21 months (9M 6 D)	7.65	8.8 kg
Upper lateral incisor	11.13 months (11 M 4 D)	8.32	9.05 kg
Lower lateral incisor	12.59 months (12M 18D)	8.82	9.5 kg

Drug effectivity

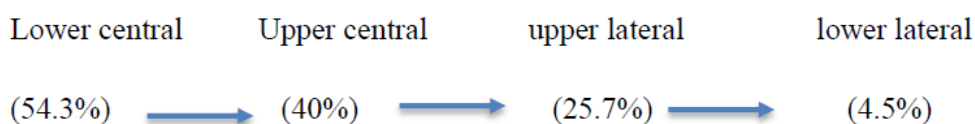
The following Hypothesis has been tested at each stage: Null Hypothesis H₀: Drug is effective for 50% of patients i.e. $P = 0.5$ Against Alternative Hypothesis H₁: Drug is effective for more than 50% of patients i.e. $P > 0.5$. It has been concluded that as we use the Drug *Woodfordia fruticosa Churna* is effective for at least 50% of patients in the teeth eruption process in the central incisor and more than 50% of patients in the teeth eruption process in the Lateral Incisor time.

DISCUSSION

Pathogenesis of dentition disorders (*Dantodbhad-janya Roga*) is caused by the maturation of two *Dhatus*, *Asthi* and *Majja*, which eventually become localized in the gums. This causes mild swelling of the upper and lower teeth due to an irritable effect on the muscles, which in turn causes horripilation in the body. Aggravated *Vaayu* is localized in the teeth's root, penetrating both bone and bone marrow (*Asthi* and *Majja*) at the site where *Kapha* is previously placed. From these sites, *Vata* and *Kapha* both disperse in all directions; being associated with *Pitta*, vitiate the *Dhatu* and *Mala*, causing a variety of health complications in the body. These include *Jwar* (fever) *Vid-bhada* (diarrhea), *Kasa* (cough), *Shiroruja*, *Abhisyanda* (conjunctivitis), *Pothaki* (trachoma), and *Visarpa* (Erysipelas) *Trishna* (thirst), *Shiroabhita*, *Kukunak* (conjunctivitis), *Bhruma* (giddiness) 22 (63%) Female & 13 (37%) male infants have participated in this study. As per *Samhita* primary dentition is

comparatively easier and has less trouble in female children than in male children, which resembles our analysis as 68% of female and 75 % of male child suffer from dentition disorders. We found that maximum numbers of patients were from Hindus. Religion, gender do not influence tooth eruption process. Socioeconomic status has the potential to affect the nutrition due to economic barrier as nutrition plays an important role in dentition.

As per the chronology of human dentition, central incisor teeth eruption begins at an average of 10 months (range 8 to 12 months) and lateral incisor teeth eruption begins at an average of 11 months (range 9 to 3 months) which resembles with this observation. Mean age for Lower Central Incisor is 8.44 months, Upper Central Incisor 9.12 months, Upper Lateral Incisor 11.13 months and for Lower Lateral Incisor it is 12.59 months. As per statistical analysis, it has been observed that no. of children (in %) who suffered from various diseases while teeth eruption goes on decreasing.



In the initial stage of treatment, moderate incidences of diseases have been seen but later on no. of the proportion of diseases significantly decreases with continuous treatment of *Woodfordia fruticosa* (*Dhataki pushpa Churna*). *Ruksha*, *Laghu guna* of *Dhataki* flowers draw moisture and *Kleda* from the wound by their *Kashaya*(astringent) *Rasa*, thus helping in conjunctivitis and skin lesion. *Kashaya (astringent) Rasa* is *Stambhak*, *Kledshoshak* and *Shothahar* in nature. These properties help to decrease swelling, increase intestinal absorption and stop the loose stool. Its *Kasahaya*, *Laghu*, *Ruksha* and *Sheeta Virya* properties balance vitiated *Kapha* and *Pitta Doshas* and decrease vomiting. *Woodfordia fruticosa* pacifies *Kapha* and *Pitta*. It has antimicrobial, anti-inflammatory, and antipyretic properties thus helping to uphold normal body temperature. *Woodfordia fruticosa* helps to balance *Kapha* and removes excess mucus from the lungs thus helping in cough. The astringent qualities of *Woodfordia fruticosa* help to tighten the gum tissues, which may make children's tooth eruptions less painful and more uneventful. *Woodfordia fruticosa* yields a variety of chemical substances, such as tannins, flavonoids, anthraquinone, glycoside and polyphenols. These substances have several pharmacological properties, including antioxidant^[7], hepatoprotective^[8] antimicrobial^[9], cardioprotective^[10], antiulcer^[11], immunomodulatory^[12],

antifertility^[13], antitumor^[14], antibacterial^[15], antileukorrhea, wound healing, antiviral, analgesic^[16], antipyretic, anti-inflammatory.^[17]

CONCLUSION

The process of dental eruption has been in detail explained in both Ayurveda and modern medical science. A dentition is considered to be the root cause of various diseases arising during the dentition period process of dental eruption is quite painful. Diseases of the GI system and respiratory system are commonly found to be present among these diseases. Modern medicine has a curative aspect to cure these diseases. Whereas Ayurveda has a preventive approach to these diseases. Of the diseases that arise during dentition, mentioned in *Ayurveda* two diseases are not seen in a modern-day perspective. They are *Kukunak* (dentitional conjunctivitis) and skin diseases. In ancient times, it might have been because of unhygienic conditions that could have spread. Multiple herbs have been promoted in Ayurveda which can prevent or reduce the incidence of the diseases. *Woodfordia fruticosa* (*Dhataki Pushpa*,) one of the drugs that can prevent dentitional diseases. The mean age, in today's era, for dental eruption still follows the dental eruption window period and follows the sequence of eruption. GI diseases are more common than respiratory disorders during the eruption of central Incisors whereas respiratory symptoms were more common during the eruption of lateral incisors in this study. *Dhataki* (*Woodfordia fruticosa*) being *Kashaya* (astringent) in *Rasa* prevents severe diarrhea in children. Being astringent, it also helps in the healing of wounds that come up during dentition. Because of its astringent nature and *Shothahar* activity it helps in reducing inflammation of the gums. It also reduces the frequency of the disease in subsequent dental eruptions. It has been concluded that *Woodfordia fruticosa* is effective for at least 50% of patient during central incisor eruption and more than 50% of patients during lateral teeth eruption process in the prevention of dentition disorders. A large sample size study is required to validate the findings of this study.

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