RESEARCH PAPER

Clinical Efficacy of Chirabilva (*Holoptelea integrifolia*) Leaf Extract in Danta Shula Associated with Krimidanta (Dental Caries): A Prospective Single-Arm Clinical Study

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ABSTRACT

Background:
Chirabilva (*Holoptelea integrifolia*) is an important medicinal plant described in Ayurvedic classics. In certain tribal parts of Nashik District, Maharashtra, its leaves are traditionally used for relief of toothache. The present study was undertaken to clinically evaluate this traditional use in toothache associated with Krimidanta (dental caries).

Objectives:
To assess the clinical efficacy and safety of Chirabilva (*Holoptelea integrifolia*) leaf extract in relieving toothache caused by Krimidanta (dental caries).

Materials and Methods:

This was a prospective single-arm clinical study done with Institutional Ethics Committee clearance and written informed consent obtained. This study involved 332 patients aged 18–65 years who had been diagnosed with dental caries. The local application of Chirabilva Arka lotion was done in lotion form at a dose of 1 g thrice a day for 5 days for the participants. Laboratory analysis of formulation was also done as part of the study.

Results:
The median Visual Analogue Scale (VAS) score for pain before and after treatment was 4 (3–5) and 0 (0–4), respectively, with a statistically significant difference ($P < 0.0001$). The median scores for global assessment of overall safety by investigator were 1 (1–2) and for global assessment of overall improvement by the subject were 1 (0–4). Median time to pain relief was 3 (1–5) days and the minimum duration of pain relief after a single dose was 60 (45–90) min.

Conclusion:
A statistically significant reduction in VAS pain score was observed following local application of Chirabilva Arka lotion. The study also recorded the reported safety and overall improvement assessments following local application.

Keywords: *Holoptelea integrifolia*; Chirabilva; Toothache; Dental caries; Ayurveda; Krimidanta

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INTRODUCTION

According to Charaka Samhita, the four components of treatment are *Bhishak* (physician), *Dravya* (medicine), *Upasthata* (attendant), and *Rogi* (patient), and their appropriate attributes contribute to the successful management of disease.[1] Among these four components, *Dravya* should possess qualities such as adequate availability, efficacy, suitability for different pharmaceutical preparations, and preservation of its inherent properties.[2] Several medicinal plants described in Ayurvedic classical literature and traditional healthcare practices fulfil these requirements, including *Chirabilva* (*Holoptelea integrifolia*).

Charaka Samhita states that the communities like goat-herds, shepherds, cowherds and forest-dwellers knew the names and identification of the forest plants. But knowing what a plant is is not enough to know how it is used medicinally.[3] Traditional medicine remains a significant component of health care in various communities.[4]

Chirabilva is one of the medicinal plants mentioned in Ayurvedic literature. Bhavaprakasha Nighantu describes *Chirabilva* among the varieties of *Karanja*.[5] Sushruta Samhita describes *Putika* which has been identified as *Holoptelea integrifolia* Planch.[6] A review of H. integrifolia recorded ethnobotanical uses and reported pharmacological activities.[7] Ayurvedic and ethnobotanical uses of *Chirabilva* also documented in literature.[8]

The various pharmacological characteristics of H. integrifolia have been assessed in experimental studies. It has been reported that the leaf extract is anti-inflammatory,[9] while experimental studies have been carried out on its antidiabetic,[10] anthelmintic,[11] antimicrobial, antioxidant and wound healing,[12] antidiarrhoeal,[13] adaptogenic[14] and antitumour activity.[15] These studies supply experimental information about different biological activities of the plant.

Teeth are important in mastication, speech, their skeletal shape and appearance.[16] Sushruta Samhita mentions of eight dental disorders of which *Krimidanta* is a dental disorder that is related to progressive damage to the tooth. Described with features such as blackness of the skin, cavity formation, swelling, pus and bloody discharge and severe pain.[17]

In certain tribal areas of Nashik District, Maharashtra, *Chirabilva* leaves are traditionally used for relief of toothache. This traditional method was clinically investigated in the present study in the participants involved in the study, who suffered from toothache related to dental caries. Study design was a prospective single arm clinical study in age groups 18-65 years having confirmed dental caries. *Chirabilva Arka* was given to the participants as lotion (1g) three times daily for 5 days.

Materials and Methods

Study design and setting

The present study was an interventional, prospective, single-arm open clinical study conducted in the Shalakya OPD of Arogyashala Rugnalaya, Ganeshwadi, Panchavati, Nashik, Maharashtra. The study was conducted over a total period of 1 year, with an intervention period of 5 days for each participant. Institutional Ethics Committee approval was obtained vide outward no. 632 dated 04-10-2022. Written informed consent was obtained from the participants before their inclusion in the study.

Participants

Participants attending the Shalakya OPD with toothache associated with dental caries were screened for eligibility. The study included participants of either sex aged 18–65 years who had toothache due to dental caries.

The calculated sample size was 353, including a 10% dropout rate. A total of 332 participants completed the study.

Inclusion criteria

1. Patients of both sex aged 18–65 years.
2. Patients with toothache due to dental caries.

Exclusion criteria

Participants were excluded if they had:

1. Systemic disorders such as uncontrolled diabetes or renal disorders.
2. Other diseases of the oral cavity, including fractured tooth, periodontal abscess, or oral cancers.
3. Known hypersensitivity to any drug or herbal product.
4. Congenital deformity of teeth, including hypomineralization or hypoplasia.
5. A history of psychiatric disorders.

6. Dental caries but were unwilling to participate in the trial.

Withdrawal criteria

Participants were withdrawn from the study if a serious condition or serious adverse event requiring urgent treatment occurred during the trial, or if the participant wished to withdraw from the study.

Intervention

Drug under study: *Chirabilva*

The drug used in the study was *Chirabilva* (*Holoptelea integrifolia*). The Ayurvedic properties of *Chirabilva* are *Tikta* and *Kashaya Rasa*, *Laghu* and *Ruksha Guna*, *Ushna Virya*, *Katu Vipaka*, and *Kapha-Pitta Shamaka* action.

Preparation of *Chirabilva* lotion

The alcoholic extract of *Chirabilva* leaves was mixed with glycerine (1,2,3-propanetriol) to facilitate application in the oral cavity at the site of toothache. A 5% solution of *Chirabilva* extract was prepared by mixing the extract with glycerine. A total of 100 g of *Chirabilva* extract was mixed with 2 L of glycerine. The prepared solution was packed in 5-mL sterile containers and sealed.

Dose and route of administration

The intervention was applied locally at a dose of 1 g three times daily for 5 days. The source article states that 10 g of *Kalka* was used to prepare 1 g of ethanol extract; therefore, 1 g of extract was selected as the dose for local application.

Study tools and assessment

Participants presenting to the Shalakya OPD with toothache associated with dental caries were considered for inclusion. Screening included clinical examination of the oral cavity by the physician and assessment of the signs and symptoms of dental caries. Participants with toothache and inflammation who fulfilled the inclusion criteria were included.

Diagnostic assessment

The following assessments were performed:

1. Visual Analogue Scale (VAS) for assessment of dental pain.
2. Oral cavity examination for assessment of inflammation.
3. Dental X-ray for assessment and confirmation of dental caries.

Pain assessment

Pain was recorded using the VAS. Participants recorded the time of administration of the morning, afternoon, and evening doses and the corresponding time of pain relief over the 5-day treatment period.

Safety assessment

Safety was assessed through clinical review of safety parameters, including adverse-event reporting, vital signs, allergic reactions, skin infections, and global assessment of safety and tolerability by the investigator and participant.

The investigator's global safety assessment was categorized as:

- Grade 1: Excellent overall safety - no adverse event reported.
- Grade 2: Good overall safety - mild adverse event(s) reported, subsiding with or without medication.
- Grade 3: Fair overall safety - moderate to severe adverse event(s) that subsided with or without medication and did not require discontinuation.
- Grade 4: Poor overall safety - severe or serious adverse event(s) requiring discontinuation of treatment.

Global assessment of improvement

The participant's global assessment of overall improvement was recorded on the following scale:

Score	Assessment
0	Not assessed
1	Very much improved
2	Much improved
3	Minimally improved
4	No change
5	Minimally worse
6	Much worse
7	Very much worse

Laboratory analysis of the formulation

The *Chirabilva* lotion was subjected to laboratory analysis. The investigations performed were Fourier Transform Infrared Spectroscopy (FTIR), pH, and spreadability.

The reported pH of the lotion was 7.46, and its spreadability was 62.5% (g/cm).

Statistical analysis

A non-probability sampling technique, convenience sampling was used. Collected data were analysed using statistics. Tables and graphs were used to present demographic data. Data of discrete variables were presented as frequencies and percentages, and data of continuous variables were presented as the mean ± standard deviation. Data were statistically analysed using GraphPad InStat version 3.6. The P value < 0.05 was defined as statistically significant. When the data did not pass the normality test, intra-group comparison was done using Wilcoxon matched-pairs signed-ranks test.

Ethical considerations

The study received approval from the Institutional Ethics Committee vide outward no. 632 dated 04-10-2022, and written informed consent was obtained from each participant before enrolment.

5. Results

The results are presented under two sections: laboratory analysis of the *Chirabilva arka* lotion and clinical findings.

A. Laboratory analysis of *Chirabilva arka* lotion

The prepared *Chirabilva arka* lotion was subjected to FTIR, pH, and spreadability analysis.

The reported qualitative chemical analysis indicated the presence of secondary metabolites including alkaloids, flavones, and phenolic compounds. This study also discusses flavonoids in relation to antioxidant activity and the possible involvement of prostaglandins in pain perception.

The pH of the lotion was 7.46, and the reported spreadability was 62.5% (g/cm).

B. Clinical results

The Data collected from clinical study was analysed under two headings:

- Demographic analysis
- Clinical efficacy of the therapy under study

Demographic analysis

A total of 332 participants with toothache associated with dental caries were included in the clinical analysis.

Age-wise distribution

Among the 332 participants:

Table 1: Age-wise distribution

Age group (years)	n	%
18–20	11	3.31
21–30	38	11.45
31–40	24	7.23
41–50	104	31.33
51–60	150	45.18
61–65	5	1.51
Total	332	100.00

Out of total 332 study participants, 11 (03.31%) participants were in the age group of 18 – 20 years, 38 (11.45%) participants were in the age group of 21 – 30 years, 24 (07.23%) participants were in the age group of 31 – 40 years, 104 (31.33%) participants were in the age group of 41 – 50 years, 150 (45.18%) participants were in the age group of 51 – 60 years whereas 05 (01.51%) participants were in the age group of 61 – 65 years.

Table 2: Sex-wise distribution

Sex	n	%
Male	69	20.78
Female	263	79.22
Total	332	100.00

Out of total 332 study participants, 69 (20.78%) participants were males whereas 263 (79.22%) participants were females.

Table 3: Marital-status distribution

Marital status	n	%
Married	312	93.98
Unmarried	20	6.02
Total	332	100.00

Out of total 332 study participants, 312 (93.98%) participants were married whereas 20 (06.02%) were unmarried.

Table 4: Religion-wise distribution

Religion	n	%
Hindu	310	93.37
Muslim	19	5.72
Christian	3	0.90
Total	332	100.00

Out of total 332 study participants, 310 (93.37%) participants were following Hindu religion, 19 (05.72%) were following Muslim religion whereas 03 (00.90%) participants were following Christian religion.

Table 5: Educational status

Educational status	n	%
Uneducated	7	2.11
Primary	27	8.13
SSC	105	31.63
HSC	99	29.82
Graduate	94	28.31
Total	332	100.00

Out of total 332 study participants, 07 (02.11%) participants were uneducated, 27 (08.13%) participants were studied till primary school, 105 (31.63%) participants were studied till SSC,99

(29.82%) participants were studied till HSC whereas 94 (28.31%) participants were studied till graduation.

Table 6: Occupational distribution

Occupation	n	%
Housewives	168	50.60
Job	107	32.23
Students	3	0.96
Businessmen	43	12.95
Farmers	7	2.11
Total	332	100.00

Out of total 332 study participants, 168 (50.60%) participants were housewives, 107 (32.23%) participants were doing job, 03 (00.96%) participants were students, 43 (12.95%) participants were businessmen whereas 07 (02.11%) were farmers.

Assessment of Clinical efficacy of the therapy under study

1. **Assessment of Visual Analogue Rating Scale in Study Participants:**

The VAS results were as follows:

Table 7: Assessment of Visual Analogue Rating Scale in Study Participants

Parameter	Before treatment	After treatment	Difference
Sample size	332	332	332
Mean ± SD	4.012 ± 0.7615	0.5753 ± 0.7190	3.437 ± 1.045
Median (range)	4 (3–5)	0 (0–4)	4 (0–5)

The data did not pass the normality test. Therefore, the Wilcoxon matched-pairs signed-ranks test was used. The sum of signed ranks (W) was 54615, the sum of positive ranks (T+) was 54615, the sum of negative ranks (T−) was 0.000, and the number of pairs was 330. The two-tailed P value was <0.0001which is extremely significant.

The median VAS score decreased from 4 (3–5) before treatment to 0 (0–4) after treatment, with a statistically significant difference ($P < 0.0001$). Hence the *Chirabilva Arka* lotion is found to be effective in relieving *Dantashula.*

Table 8: Other clinical outcome measures

Outcome	Mean ± SD	Median (range)
Global assessment of overall safety by investigator	1.02 ± 0.12	1 (1–2)
Global assessment of overall improvement by subject	1.17 ± 0.55	1 (0–4)
Complete pain relief on day	4.84 ± 0.43	3 (1–5)
Minimum duration of pain relief after a single dose (min)	59.55 ± 6.44	60 (45–90)

Table 9: Global assessment of safety

Grade	Global assessment of overall safety by investigator		Global assessment of overall safety by subject	
	No. of Study Participants	Percentage	No. of Study Participants	Percentage
0	00	00%	02	0.60%
1	327	98.49%	293	88.25%
2	05	01.51%	23	06.93%
3	00	00%	08	02.41%
4	00	00%	06	01.82%
	332	**100%**	**332**	**100%**

Out of the total 332 study participants, 327 (98.49%) were assigned Grade 1 and 5 (1.51%) were assigned Grade 2 in the investigator's global assessment of overall safety.

In the subject's global assessment of overall safety, 2 (0.60%) participants were assigned Grade 0, 293 (88.25%) Grade 1, 23 (6.93%) Grade 2, 8 (2.41%) Grade 3, and 6 (1.82%) Grade 4.

Overall, the global safety assessments indicated that the trial drug was found safe during the study period.

Summary of clinical findings

The study therefore reported a reduction in median VAS pain score from 4 (3–5) to 0 (0–4) after treatment, with $P < 0.0001$. The reported median duration to complete pain relief was 3 days, while the median minimum duration of pain relief following a single dose was 60 min (45–90).

6. Discussion

DISCUSSION

Discussion on Review of Literature

In classical ayurvedic literature, dental caries, known as *Krimidanta*, is mentioned as one of the dental diseases and both systemic and local therapeutic measures prescribed for its treatment. Anti-inflammatory and antimicrobial activity of *Chirabilva* have been reported in the available literature of pharmacology as well as pharmacognostic literature. Analgesic activity of *Chirabilva* bark has also been reported, through experimental investigations.

Traditionally tribal people of Nashik districts use the leaves of *Chirabilva* for toothache. The leaves are crushed and applied topically on the affected tooth. But for regular use it may not be always possible to collect fresh leaves. Hence, in the present study, extract of *Chirabilva* leaf (Arka) was prepared and then formulated as lotion by adding some amount of glycerine so that the formulation can be applied locally.

Discussion on Methodology

In the present study, an alcoholic extract of *Chirabilva* leaves was prepared using a Soxhlet apparatus. The prepared extract was subsequently mixed with glycerine to formulate a lotion intended for local application over the affected tooth. The resulting *Chirabilva Arka* lotion was subjected to laboratory analysis.

A total of 353 participants were enrolled according to the specified inclusion and exclusion criteria, of whom 332 participants completed the treatment protocol and were assessed according to the predefined study parameters.

The study was single-arm clinical, in which all participants were given the trial intervention. The local dosage of *Chirabilva* was 1 g thrice daily for 5 days. Time of application and time of feeling relief from pain were recorded. The Visual Analogue Scale (VAS) was used to measure the intensity of pain. Dental X-ray examination was carried out prior to the treatment to confirm the diagnosis of dental caries rather than other complications and oral cavity examination was carried out to assess local inflammation. X-rays were taken before and after treatment to determine if any complications occurred with the tooth and/or jaw structure. Pre- and post-observations were taken.

Discussion on Laboratory Analysis of *Chirabilva Arka* lotion

The prepared formulation was qualitatively chemically analyzed and alkaloids, flavones, and phenolic compounds were detected in the formulation. Flavonoids are known as antioxidants and their biological activities are studied in the context of inflammatory and pain-related processes. The mechanism of action of the observed analgesic response was not studied in the present experiment. Hence, the proposed modulation of prostaglandin mediated pain pathways in the case of flavonoids should be considered as a pharmacological hypothesis and not one confirmed by the present study.

The lotion made was at pH 7.46. So, the formulation was an alkaline type. The spreadability reported 62.5% (g/cm) was related to the physical feature of the prepared lotion which was assessed in the present study.

Discussion on Demographic Characteristics

A total of 332 participants with toothache associated with dental caries were included in the clinical assessment.

Age-wise distribution

The age group with the highest proportion were found to be those aged 51–60 followed by those aged 41–50. The age group composition of participants may be related to the clinical significance of dental problems in the study population. Although the original interpretation in Ayurveda pointed towards possible association with the predominance of Vata in later age, the present study was not designed to establish an association between age, toothache and predominance of Vata. So, it is important to view this observation as a descriptive result and not as a causal inference.

Sex-wise distribution

Females constituted a greater proportion of the study population than males. However, because the study did not include a comparative population group or an epidemiological design, no inference regarding sex-specific risk or susceptibility can be drawn from this distribution.

Marital status

The distribution of participants according to marital status was recorded as part of the demographic assessment. No inference regarding the relationship between marital status and toothache associated with dental caries can be drawn from the present study.

Religion-wise distribution

The study centre was located in a predominantly Hindu locality, and the majority of participants belonged to the Hindu religion. No inference regarding the relationship between religion and dental caries can be drawn from these data.

Educational status

Among the 332 study participants, 7 (2.11%) were uneducated, 27 (8.13%) had studied up to primary school, 105 (31.63%) had studied up to SSC, 99 (29.82%) had studied up to HSC, and 94 (28.31%) were graduates.

These findings describe the educational distribution of the participants included in the study. Since the study was not designed to assess educational status

as a determinant of dental caries, no causal inference can be drawn from these observations.

Occupational status

Among the 332 study participants, 168 (50.60%) were housewives, 107 (32.23%) were employed, 3 (0.96%) were students, 43 (12.95%) were businessmen, and 7 (2.11%) were farmers.

The occupational distribution represents the characteristics of the study population and was not intended to establish an association between occupation and toothache.

Discussion on Clinical Efficacy

Visual Analogue Scale

The median VAS score for pain for the 332 study participants was 4 (3–5) before treatment, and 0 (0–4) after treatment. This difference was significant ($P < 0.0001$).

The mean decrease in VAS score data is representative of a decrease in pain intensity as reported by the patients after the intervention. But since this was a single arm clinical study without a simultaneous control group, the statistical significance of the pre- and post-treatment comparison indicates a difference between the two times within the study group, and does not reflect a comparative superiority with another treatment.

Global assessment of overall safety by investigator

The median score for the investigator's global assessment of overall safety was 1 (1–2).

Among the 332 study participants, 327 (98.49%) were assigned Grade 1 and 5 (1.51%) were assigned Grade 2 in the investigator's global assessment of overall safety. No additional interpretation beyond these observed safety grades is made.

Global assessment of overall improvement by subject

The median score for the subject's global assessment of overall improvement was 1 (0–4). This represents the participants' assessment of their overall improvement following the intervention.

Time to complete pain relief

The median time to complete pain relief was 3 days (1–5). This indicates that the participants who experienced complete pain relief reported it within the observed treatment period, with a median of 3 days.

Minimum duration of pain relief after a single dose

The median minimum duration of pain relief following a single dose was 60 min (45–90). This represents the duration of relief reported by participants following individual applications of the intervention.

Global assessment of overall safety by subject

In the subject's global assessment of overall safety, 2 (0.60%) participants were assigned Grade 0, 293 (88.25%) were assigned Grade 1, 23 (6.93%) were assigned Grade 2, 8 (2.41%) were assigned Grade 3, and 6 (1.82%) were assigned Grade 4.

These findings represent the participant's reported global safety assessment during the study period. The investigator's assessment and the participant's assessment are therefore presented separately, as they represent two different sources of safety evaluation.

Overall Discussion

The present study aimed to assess the efficacy of *Chirabilva Arka* lotion applied locally in the patients suffering from toothache due to dental caries. The intervention was applied as a single arm intervention for 5 days and clinical evaluation consisted of pain intensity, global improvement, duration of pain relief and safety assessment.

The median VAS score decreased from 4 (3–5) before treatment to 0 (0–4) after treatment, with a statistically significant difference ($P < 0.0001$). The median duration to achieve pain relief was 3 days (1-5) and the median minimum duration of pain relief after one dose was 60 minutes (45-90).

Thus, it is significant that the findings showed that there was a reduction in the amount of pain reported within the groups during the study period. The results should be interpreted to reflect clinical improvement as a result of the intervention, not superiority over the current standard treatment since there was no control group.

Based on the previously reported pharmacological properties of *Chirabilva*, the reported results in the present study give a foundation for further studies. However, the present study failed to demonstrate the molecular mechanism underlying the observed clinical response. Longer term safety and comparative efficacy of the intervention would require further controlled clinical studies, with an appropriate comparator and longer follow-up.

Limitations

There are some limitations in the present study. It was a single arm clinical study with no concurrent control group, so the pre- and post-treatment improvement observed cannot be used to prove comparative efficacy or to conclude that the observed pain reduction was only due to *Chirabilva Arka* lotion. The intervention period was 5 days, and the study does not give information about long or short-term effectiveness or safety. Convenience sampling was used, which could be a limitation of the generalizability of the findings. The primary measure of pain was the Visual Analogue Scale (VAS) but a validated clinical comparator-based outcome measure was not used.

Future Directions

Future studies should replicate the *Chirabilva Arka* lotion using a randomized controlled design with an appropriate comparator, preferably with adequate allocation procedures and a predetermined sample size calculation. Longer duration of follow-up would provide a better understanding of the duration of pain relief and longer-term safety. Additional pharmaceutical and phytochemical studies could be

conducted to further describe the formulation and to determine what constituents may be related to its activity. Comparative clinical studies could also be useful in evaluating its effectiveness when compared to accepted methods of dental pain reduction.

7. Conclusion

The present prospective single arm clinical study was undertaken to assess the effect of *Chirabilva Arka* lotion applied locally in subjects having toothache with dental caries. Statistically significant decrease in pain was seen with the median VAS score dropping from 4 (3–5) prior to treatment to 0 (0–4) following treatment ($P < 0.0001$). The median time reported for complete pain relief was 3 days (range 1-5) and the median minimum duration of pain relief after a single dose was 60 min (45-90). Overall, the 98.49% of participants were assessed as Grade 1 and 1.51% were assessed as Grade 2, while no participants were assessed as Grade 3 or Grade 4. Based on the limitations of the design of the study and the five-day intervention period, the study results suggest that there was a decrease in toothache in the study participants when *Chirabilva Arka* lotion was applied topically. Additional controlled clinical trials would be needed to compare its effects with a proven therapy and ascertain its relative clinical effectiveness.

Declarations

Ethical approval

The study was conducted after obtaining approval from the Institutional Ethics Committee. Ethical approval was granted vide Outward No. 632 dated 04-10-2022.

Informed consent

Written informed consent was obtained from the participants before their enrolment in the study.

Funding

None

Conflict of interest

None

Author's Contributions

SGK: Conceptualization, methodology, investigation, data curation, formal analysis, and writing – original draft preparation. **LGJ:** Conceptualization, supervision, methodology, and writing – review and editing. **TAN:** Investigation, validation, and writing – review and editing. **PI:** Supervision, resources, validation, and writing – review and editing. All authors read and approved the final manuscript.

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