

Efficacy of *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* orally in the management of *Shitada* (Gingivitis)- An open labelled randomized comparative clinical trial

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Abstract

Shitada (Gingivitis), a *Dantamulagataroga* of varying severities is nearly universal. Acharya Sushruta has mentioned including *Gandusha*, a *Pratisarana* in the management of *Shitada*. This study mainly focused to compare the efficacy of *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* orally in the management of *Shitada* (Gingivitis) and the treatment period is one month. In this clinical trial, 32 patients were registered and all the patients completed the treatment. In Group A, 16 patients had been prescribed *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* orally and in Group B, 16 patients had been prescribed *Triphaladi kwatha gandusha* and *Priyangavadi churna pratisarana*. The assessment was done on the basis of signs and symptoms i.e. *Akasmata Rakta Srava* (Bleeding), *Shotha* (Inflammation), *Krishnata* (Discoloration of gums), *Mukha daurgandhya* (Halitosis), *Vedana* (Pain), *Dantamamsa prakledata* (Moistness), *Paka* (Pus discharge), *Dantamamsa mriduta* (Sponginess), Gingival Index and Bleeding Index. The results showed that complete remission was observed in 31.25% and 6.25% of patients in groups A and B, respectively. The study concludes that the administration of *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* orally is more effective in the management of *Shitada* (Gingivitis).

Keywords: *Shitada*, *Gandusha*, *Pratisarana*

Introduction

Shitada is one of *Dantamulagataroga*. Sudden bleeding from gums which are foul-smell, blackish, moistened, softened, and get necrosed and suppurated one after the other are signs and symptoms of *Shitada* caused by the vitiated *Kapha* and *Rakta dosha*¹. Gingivitis is an inflammation of the marginal, unattached terminal end of gingivae which results mainly from the accumulation of debris, plaque and calculus at the tooth margin². Based on signs and symptoms, *Shitada* can be correlated with Gingivitis in contemporary science. *Shitada* is the possible result that takes place due to the lack of oral hygiene and the adoption of improper hygienic methods. The epidemiological studies conducted by the American Academy of Periodontology show that gingivitis of varying severities is nearly universal and it is estimated that over 80% of the world's population suffers from gingivitis³. In India, data from the national oral health survey (2002-2003) states that in children aged 12 years, the prevalence of periodontal disease was 57% and in the 15 years of age group, it was 67.7%. The prevalence was 89.6% and 79.9% in the 35-44 year and the 65-74-year age group respectively⁴. In Gujarat, the prevalence of Gingivitis was found to be 74.45%⁵. Currently, the modern medical management of Gingivitis is not sufficient. Acharya Sushruta has mentioned a *Gandusha* which is in the form of decoction containing *Shunthi* (rhizomes of *Zingiber officinalis* Rosc), *Sarshapa* (seeds of *Brassica campestris*

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Linn.), *Triphala* (fruits of *Terminalia chebula* Retz., *Terminalia bellerica* Roxb, and *Terminalia chebula* Retz.), *Musta* (tubers of *Cyperus rotundus* Linn.) and *Rasanjana* (extracts of *Berberis aristata* Roxb. ex. DC.) in the management of *Shitada*. Also, he advises applying locally (*Pratisarana*), the combination of *Priyangu* (flowers of *Callicarpa macrophylla* Vahl.), *Musta* (tubers of *Cyperus rotundus* Linn) and *Triphala* (fruits of *Terminalia chebula* Retz., *Terminalia bellerica* Roxb, and *Terminalia chebula* Retz.)⁶. *Triphala* represents the combination of *Haritaki*, *Bhibhitaka* and *Amalaki*, a medicinal preparation being used in Ayurveda since ancient times. *Triphala* possesses the properties of *Pancha rasa* except *Lavana rasa*. *Laghu* and *Ruksha guna*, *Tridosha Shamaka*, *Shothahara* and *Rasayana*. It pacifies *Kapha* and *Pitta dosha* and is known to have various therapeutic effects such as anti-inflammatory, anti-caries, antioxidants and antimicrobial activities. Hence in this research work, above mentioned *Triphaladi kwatha gandusha* and *Priyangavadi churna pratisarana* were selected as per the guidance of Sushruta Samhita and *Triphala churna* (orally) was selected according to the properties of the drug for the management of *Shitada*. The aim of this study was to compare the efficacy of *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* orally in the management of *Shitada* (Gingivitis).

Materials and Methods

Study design

32 patients from the Out-patient Department of *Shalaky Tantra*, I.P.G.T. & R.A. Hospital, who was suffering from the disease *Shitada* (Gingivitis) and fulfilling the inclusion criteria of the present study were registered and divided randomly into two groups. All participants in the study were volunteers and they were informed of the outline, purpose and duration of the study and signed an informed consent form before enrolment. All the patients completed the treatment. A carefully arranged research proforma was specially designed for the purpose of incorporating all aspects of the disease

on Ayurvedic and modern aspects. This clinical study was initiated after obtaining clearance from Institutional Ethics Committee under the letter No. PGT/7/-A/Ethics/2019-20/2588, dated 08/01/2020 and the study was registered in the Clinical Trial Registry of India under the CTRI No. CTRI/2020/02/23278 [Registered on: 04/08/2018]. Selected patients were randomly divided into two groups and Informed consent was taken from each patient. Following drug schedule was carried out in each particular group for one month time.

Group A:

16 patients were administered local application of 2gm of *Priyangavadi churna* (for 05 minutes) with bee honey two times per day after meals, 20ml of *triphaladi kwatha gandusha* (continued till the patient develops *Kaphapurnaasayata* (mouth is filled with *Kapha*), *Ghranasrava* (watering with nose) and *Akshisrava* (eyes watering) two times per day after meals and 5gm of *Triphala churna* with lukewarm water two times per day after meals.

Group B:

16 patients were administered local application of 2gm of *Priyangavadi churna* (for 05 minutes) with bee's honey two times per day after meals and 20ml of *Triphaladi kwatha gandusha* (continued till the patient develops *Kaphapurnaasayata*, *Ghranasrava* and *Akshisrava*) two times per day after meals.

Follow-up period

Follow-up was done after the completion of clinical trial for period of 1 month at the interval of 15 days.

Inclusion Criteria

Patients between the age of 18 to 60 years, presented with signs and symptoms of *Shitada* (Gingivitis) described as per Ayurveda and Modern Science were registered irrespective of their gender, occupation, education and religion.

Exclusion Criteria

Patients below 18 years and more than 60 years of age, patients with evidence of malignancy, history of hypersensitivity to the trial drugs, patients taking any other systemic drugs which can alter the result of the study and the patient with periodontal pocket with pus discharge were not included in the study.

Investigations

Hematological Examinations (Hb%, TC, DLC, ESR) were carried out before treatment to rule out any systemic disease and after treatment to note any changes in these parameters.

Urine analysis (Physical, Chemical and Microscopic urine examination) and Biochemical –RBS were carried out before treatment to rule out any systemic disease.

Trial drugs

The trial drugs namely *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* and *Triphala churna* were prepared at the pharmacy of GAU, Jamnagar.

Criteria for assessment

Improvement in symptoms obtained in the patients was considered for assessment. A scoring pattern is adopted for assessment of the total effect of the therapy as mentioned below in Tables 1 to 10.

Table 1: Akasmata rakta srava (Bleeding from gums)

<i>Akasmata rakta srava</i>	Score
Absence of bleeding	0
Slight bleeding on brushing or occasional bleeding	1
Moderate bleeding on brushing or eating hard articles	2
Severe bleeding on brushing or even on chewing food	3
Spontaneous bleeding	4

Table 2: Vedana (Pain)

<i>Vedana (Pain)</i>	Score
Absence of pain	0
Occasional pain with low intensity-dull ache	1
Frequent pain with a moderate intensity-continuous dull ache	2
Continuous pain with severe intensity which increases during mastication-lancinating pain-radiating type of pain	3

Table 3: Mukha daurgandhya (Halitosis)

<i>Mukha daurgandhya</i>	Score
Absence of bad odour	0
Slight bad odour which decreases after mouth wash	1
Moderate bad odour rarely decreases after mouth wash	2
Persistent bad odour even after repeated mouth wash	3

Table 4: Shotha (Inflammation)

<i>Shotha</i>	Score
Absence of inflammation	0
Mild inflammation, a slight change in colour and in the texture of the marginal or papillary gingival unit	1
Moderate inflammation, glazing redness, oedema of the marginal or papillary gingival unit	2
Severe inflammation, marked redness, oedema of the marginal or papillary gingival unit	3

Table 5: Krishnata (Discoloration of Gums)

<i>Krishnata</i>	Score
Normal (Pinkish Red)	0
Slight discoloration of gums, reddish	1
Moderate discoloration of gums, reddish blue	2
Severe discoloration of gums, bluish red, or blue	3

Table 6: *Dantamamsa prakledata* (Moistness)

<i>Dantamamsa prakledata</i>	Score
Absence of moistness	0
Slight moistness is visible	1
Moderate moistness is visible	2
Severe moistness is visible	3

Table 7: *Paka* (Pus discharge)

<i>Paka</i>	Score
Absence of pus discharge on examination	0
Slight pus discharge on examination	1
Moderate pus discharge on examination	2
Severe pus discharge on examination	3

Table 8: *Dantamamsa mriduta* (Sponginess)

<i>Dantamamsa mriduta</i>	Score
Absence of spongy gums	0
Slight spongy gums	1
Moderate spongy gums	2
Severe spongy gums	3

Table 9: Gingival Index (GI)⁷

Symptom	Score
Absence of inflammation/ normal gingivae	0
Mild inflammation; slight change in colour, slight oedema; no bleeding on probing.	1
Moderate inflammation; redness, oedema, moderate glazing, hypertrophy; bleeding on probing	2
Severe inflammation; marked redness, oedema and hypertrophy; ulceration tendency to spontaneous bleeding.	3

Table 10: Bleeding Index (BI)⁷

Symptom	Score
No bleeding on probing.	0
Bleeding point appear on probing	1
Several isolated bleeding points or a single fine line of blood appears.	2
The interdental triangle fills with blood shortly after probing.	3
Profuse bleeding occurs after probing; blood flows immediately into the marginal sulcus.	4

Statistical Analysis

The therapeutic effects were evaluated in both groups by applying a t-test. The results obtained are considered highly significant for $P < 0.001$, significant for $P < 0.05$ and insignificant for $P > 0.05$.

Observations and Results**Demographic data**

The majority of the patients 34.37% belonged to the age group of 18-30 years. 65.62% of the patients were females. 59.37% of patients were having education up to the school level. 81.25% of patients were taking tea as a supplementary diet. 62.5% of the patients were having regular bowel habits. Positive family history was found in 37.5% of patients. All the patients (100%) were using toothbrushes as an oral hygiene method. In 90.62% of the patients, the frequency of cleansing the teeth was only once a day. 93.75% of the patients were practicing improper methods of brushing their teeth. Among the improper method followers, 78.12% of patients had done only horizontal movement of brushing their teeth. In 50% of patients, the frequency of changing their toothbrush was after 6 months. 53.13% of patients were addicted and 46.87% were not addicted to any addiction. Among the addicted patients, 46.87% were addicted to chewing *Pan* (A mixture of areca nut with slaked lime, catechu and other favouring agents). Supari/Betel nut (*Areca catechu*), cigarette and tobacco addiction were observed 9.37% in each. Alcohol and Bidi consuming patients were observed 3.12% in each. 56.25% of patients were found with

Calculus deposition. 43.75% of patients were found with carious teeth and filled teeth. Food impaction was found in 34.37% of patients.

Clinical profile

All the patients (100%) had chief complaints of *Akasmata rakta srava* (bleeding), *Shotha* (inflammation) of gums, *Dantamamsa mriduta* (sponginess), *Krishnata* (discoloration) of gums and *Mukha daurgandhya* (halitosis). 96.87% of patients were having *Dantamamsa prakledata* (Moistness) and 28.12% of patients were having *Vedana* (Pain).

Effect of therapy

Group A

The percentage of relief in *Akasmata rakta srava* (Bleeding) was reduced by 92.85%, *Mukha daurgandhya* (Halitosis) was reduced by 90%, *Shotha* (Inflammation) was reduced by 62.96%, *Krishnata* (Discoloration of gums) was reduced in 86.36% of patients. 82.75% of patients got relief in *Dantamamsa prakledata* (Moistness) and *Dantamamsa mriduta* (Sponginess) was reduced in 65.38% of the patients. All above-mentioned results were statistically highly significant ($p < 0.001$) except in *Vedana* (Pain), the relief was 100% of patients and the result was statistically insignificant (> 0.05).

Group B

The percentage of relief in *Akasmata rakta srava* (Bleeding) was 51.72%, *Mukha daurgandhya* (Halitosis) was reduced by 92%, *Shotha* (Inflammation) was reduced by 41.4%, *Krishnata* (Discoloration of gums) was reduced in 75% of patients. 55.2% of patients got relief in *Dantamamsa prakledata* (Moistness) and *Dantamamsa mriduta* (Sponginess) was reduced in 61.5% of the patients. All above-mentioned results were statistically highly significant ($p < 0.001$) except in *Vedana* (Pain), the relief was 71.42% of patients and the result was statistically significant (< 0.05).

Comparative Effect of Therapy

The percentage of relief (Table 11) in *Akasmata rakta srava* (Bleeding) shows better results in Group A (92.85%) compared to Group B (51.72%) and the comparative result was found as statistically highly significant ($p < 0.001$). The percentage of relief in *Shotha* (Inflammation) shows better results in Group A (62.96%) compared to Group B (41.4%) and the comparative result was found as statistically significant ($p < 0.05$). Group A shows better percentage (82.75%) of relief in *Dantamamsa prakledata* (Moistness) in contrast to Group B (55.2%) and the comparative data was found as statistically significant ($p < 0.05$). Group A shows better percentage (86.36%) of relief in *Krishnata* (Discoloration of gums) in comparison to Group B (75%) and the comparative data was found as statistically insignificant ($p > 0.05$). Group A shows better percentage (65.38%) of relief in *Dantamamsa mriduta* (Sponginess) in contrast to Group B (61.5%) and the comparative data was found as statistically insignificant ($p > 0.05$). Group A showed a 90% of relief percentage in *Mukha daurgandhya* (Halitosis) while it was 92% in Group B. The comparative data is statistically insignificant ($p > 0.05$). The percentage of relief in *Vedana* (Pain) shows better results in Group A (100%) compared to Group B (71.42%) and the comparative data was found as statistically insignificant ($p > 0.05$).

The percentage of improvement (Table 12) in Gingival Index in Group A was 62.96% and in Group B 41.37% of the patients and the comparative data was found as statistically significant ($p < 0.05$).

Group A shows a better percentage of improvement in the Bleeding Index (50%) in comparison to Group B (22.58%) of the patients, which was found as statistically significant ($p < 0.05$).

Overall effect of therapy

In Group A, 31.25% of patients obtained complete remission and 62.5% of patients obtained marked improvement. Moderate improvement was 6.25%. There were no patients in the category of mild improvement and unchanged (Figure 1).

In Group B, the percentage of complete remission was 6.25% and marked improvement was 62.5%. Moderate improvement was 25% and mild improvement was 6.25%. There were no patients in the category of unchanged.

Probable Mode of Action of drug combination was presented in Figure 2.

Table 11: Comparative effect of therapy

Complain	Group	N	Mean Diff.	SD ^{1±}	S.E.± ¹	't' ¹	P ¹	Sign.
<i>Akasmata rrakta srava</i> (Bleeding)	A	16	1.625	0.619	0.155	4.119	<0.001	HS
	B	16	0.938	0.250	0.0625			
<i>Mukha daurgandhya</i> (Halitosis)	A	16	1.688	0.479	0.120	1.426	>0.05	IS
	B	16	1.438	0.512	0.128			
<i>Shotha</i> (Inflammation)	A	16	1.063	0.250	0.0625	2.440	<0.05	S
	B	16	0.750	0.447	0.112			
<i>Krishnata</i> (Discoloration of gums)	A	16	1.188	0.544	0.136	0.338	>0.05	IS
	B	16	1.125	0.500	0.125			
<i>Dantamamsa prakledata</i> (Moistness)	A	16	1.500	0.730	0.183	2.070	<0.05	S
	B	15	1.000	0.632	0.158			
<i>Dantamamsa mriduta</i> (Sponginess)	A	16	1.063	0.929	0.232	0.222	>0.05	IS
	B	16	1.000	0.632	0.158			
<i>Vedana</i> (Pain)	A	03	1.333	0.577	0.333	1.528	>0.05	IS
	B	06	0.833	0.408	0.167			

SD: Standard deviation, SE: Standard error, t: t-test value, P: Significance values

Table 12: The percentage of improvement of the Gingival Index and Bleeding Index

Complaint	Group	N	Mean Diff.	SD ±	S.E.±	't'	P	Sign.
Gingival Index	A	16	1.063	0.250	0.0625	2.440	<0.05	S
	B	16	0.750	0.447	0.112			
Bleeding Index	A	16	1.063	1.063	0.266	2.119	<0.05	S
	B	16	0.438	0.512	0.128			

SD: Standard deviation, SE: Standard error, t: t-test value, P: Significance values

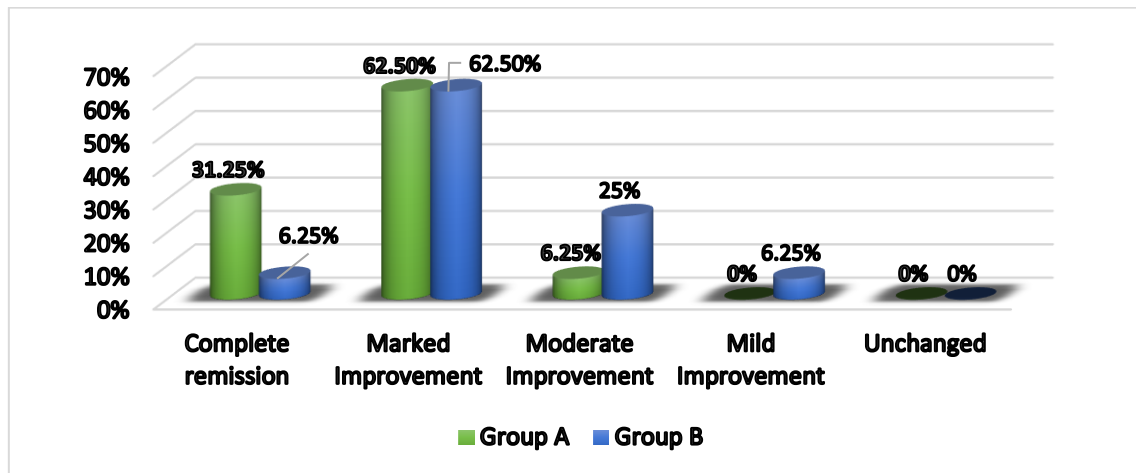


Fig. 1: Overall effect of therapy (n=32)

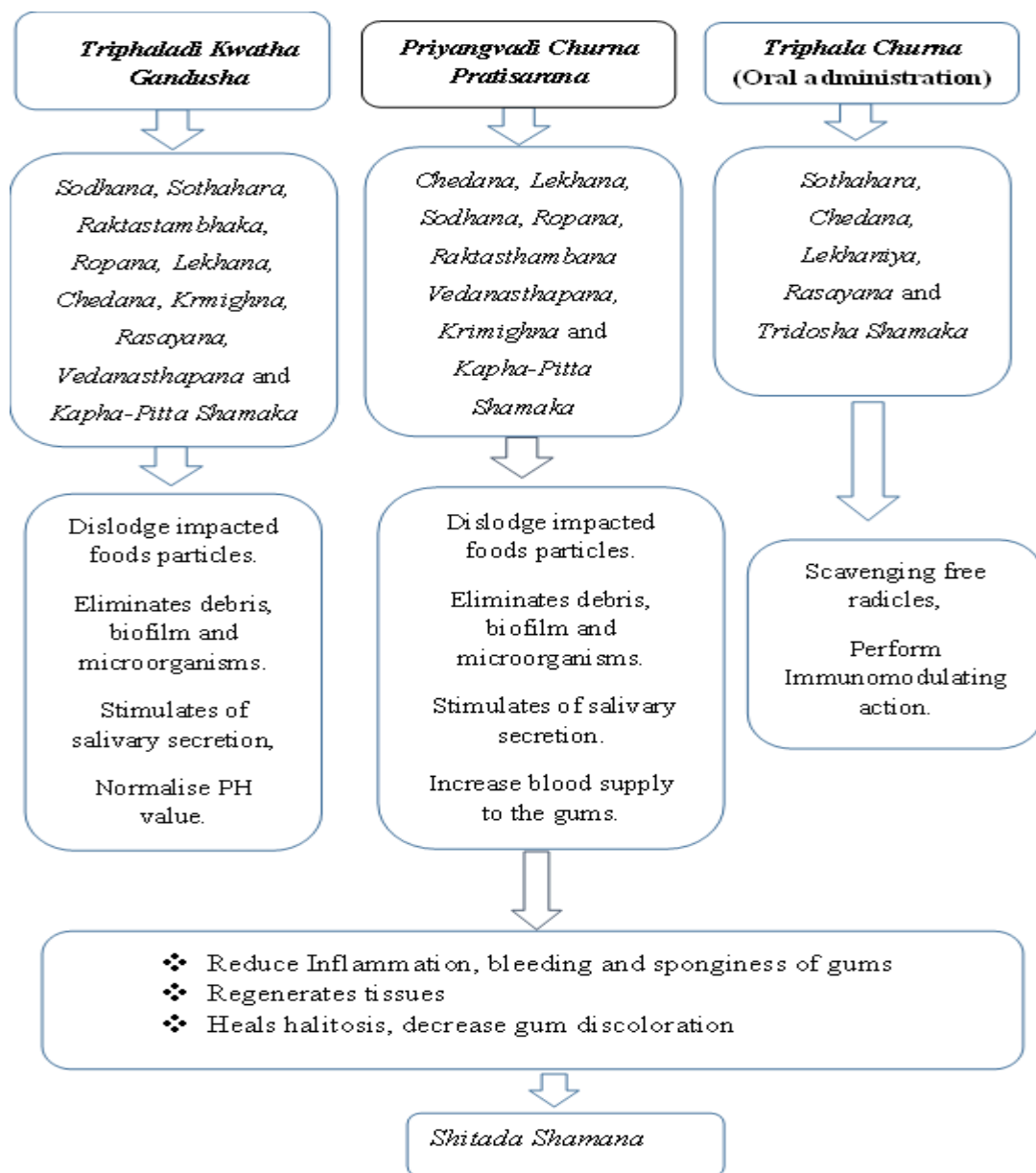


Fig. 2: Probable mode of action of drug combination

Unawareness of the disease condition and improper methods of oral hygiene are seeming to be the higher prevalence in the group. Improper method of brushing the teeth causes inadequate cleaning and results in insufficient removal of plaque leading to Gingivitis. It is said that the toothbrush should be changed every 3 to 4 months, or whenever it appears to be getting worn out. Old toothbrushes are not effective in cleaning the oral cavity properly and fail to eliminate pathogenic microorganisms and plaque sufficiently leading to Gingivitis. Considerable consumption of sweets, oily food, milk and *Takra* etc. leading to vitiation of *Kapha dosha* which can cause *Shitada* (Gingivitis). Sugar is added to tea which is highly favourable for the growth of bacteria in the oral cavity and leads to plaque formation and develops gingivitis⁸. Intake of a diet that is rich in *Madhura rasa*, *Lavana rasa*, *Amala rasa*, *Guru guna* and *Snigdha guna* vitiates *Kapha dosha* and can develop the disease. Addictions increase the risk of developing Gingivitis. Positive family history was found in more than 1/3 of the patients having an influence of genetic predisposition to develop the disease. Calculous-derived endotoxins act as irritants or antigens in both nonspecific acute inflammatory response and immune mechanism of defense which lead to inflammation of gums. Therefore, Calculous plays a causative factor in Gingivitis. Food impaction suggests a positive environment for bacterial colonization and it is a major cause of developing Gingivitis. Discoloration of the gums depends upon the chronicity of Gingivitis. The earliest manifestation of chronic Gingivitis consists of a slight alteration in the colour as Pinkish red and it will progress to red or reddish blue as the hyperemia and inflammatory infiltrate become more intense.

Conclusion

According to this current study, it can be concluded that the administration of *Triphaladi kwatha gandusha*, *Priyangavadi churna pratisarana* with *Triphala churna* orally is more effective than that of administration of *Triphaladi kwatha gandusha*,

Priyangavadi churna pratisarana alone in the management of *Shitada* (Gingivitis).

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Conflicts of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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