



## COMPARATIVE EVALUATION OF CLINICAL AND MICROBIOLOGICAL EFFICACY OF CHLORHEXIDINE AND A HERBAL (HIORA) MOUTH RINSE IN PATIENTS WITH GINGIVAL INFLAMMATION - A CLINICAL & MICROBIOLOGIC STUDY

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### ABSTRACT

**Aims:-** The aim of the present study was to assess the clinical efficacy as an anti plaque agent & effect on gingival inflammation of Hiora mouthwash and compared with 0.2% Chlorhexidine Gluconate. The present study also aimed to assess & evaluate the difference in the total microbial load with use of Hiora mouthwash and 0.2% Chlorhexidine Gluconate mouthwash.

**Objectives:-** The objective of this randomized controlled cross over study was to comparatively assess, evaluate and compare the clinical and antimicrobial effects of the Hiora mouthwash in comparison with 0.2% Chlorhexidine on plaque & gingival inflammation.

**Materials & Methods:-** 60 subjects were randomly divided into 3 groups. For group-A & group B (25 subjects each), at baseline, a detailed case history along with plaque index and gingival index was recorded. Group A was prescribed Hiora mouthwash & group B was prescribed Chlorhexidine mouthwash for 3 weeks. Subjects were assessed for plaque and gingival index. For group-C, at baseline case history & plaque and gingival index was recorded. Plaque samples were collected at baseline. Subjects were given Hiora mouthwash for 3 weeks. After 3 weeks, plaque samples were collected & plaque and gingival index were recorded.

After a wash out period of 1 month, plaque samples were collected. Plaque index and gingival index were recorded. Then the subjects were prescribed 0.2% Chlorhexidine mouthwash for 3 weeks. After 3 weeks, plaque and gingival index were recorded. Plaque samples were collected.

**Results:** Our results showed that herbal mouthwash was effective in treatment of gingivitis when compared with Chlorhexidine Gluconate mouthwash.

**Conclusion:** Herbal mouth rinses may be as effective as chlorhexidine as an anti-plaque agents with fewer side effects.

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### INTRODUCTION

Gingivitis is the mildest form of periodontal disease generally caused by insufficient oral hygiene. Gingivitis is characterized by inflammation and bleeding of the gums. Since 1900 dental plaque was considered as a main etiological factor for gingival and periodontal disease. A direct relationship has been demonstrated between dental plaque and the severity of gingivitis.

Plaque control measures include mechanical and chemical methods. Mechanical methods include brushing, use of interdental cleansing aids such as flossing and oral prophylaxis carried out by professionals. These methods have proven to be time consuming and their effectiveness would depend on skills and technique of the individual carrying out these procedures. Different chemicals have been advocated for plaque reduction. These include beer, wine, honey, alum, vinegar, myrrh etc. Several antimicrobial chemical agents such as Chlorhexidine<sup>1</sup> have been used. These artificial drugs have unpleasant side

effects<sup>2,3</sup>. So the search for alternative products led to the evolution of natural phytochemicals isolated from plants used in traditional medicine.

Phytotherapy has a long history and has been used worldwide. Many plant-derived medicines used in traditional medicinal systems have been recorded in pharmacopeias as agents used to treat infections. A number of these have been recently investigated for their efficacy against oral microbial pathogens. Natural herbs like neem, tulsi, triphala, clove oil, ajwain, etc. have been used alone or in combination and have been scientifically proven to be safe and effective medicine against various oral microbes<sup>4</sup>.

Hiora is one such herbal combination of medicinal extracts which act in a synergistic manner within the human body and provide unique therapeutic properties. This herbal mouthwash contains extracts of Pilu (*Salvadora Persica*), Bibhitaka (*Terminalia Bellerika*), Nagavalli (*Piper Betel*), Gandhapura taila (*Gaultheria fragrantissima*), Ela (*Elettaria cardamomum*)

and powers of Peppermint satva (*Mentha* spp), Yavani satva (*Trachyspermum ammi*).

**Aims**

The aim of the present study was to assess and compare the clinical efficacy of Hiora mouthwash as an anti plaque agent & its effect on gingival inflammation, with 0.2% Chlorhexidine Gluconate. The present study also aimed to assess & evaluate the difference in the total microbial load with use of Hiora mouthwash and 0.2% Chlorhexidine Gluconate mouthwash.

**Objectives**

The objective of this randomized controlled cross over study was to comparatively assess, evaluate and compare the clinical and antimicrobial effects of the Hiora mouthwash in comparison with 0.2% Chlorhexidine on plaque & gingival inflammation.

**MATERIALS AND METHODS**

Following the approval from the Ethical Committee of Bharati Vidyapeeth dental college Pune, 60 systemically healthy subjects aged 18 years and above were recruited for this randomized controlled crossover study.

**Inclusion criteria**

1. No H/o periodontal treatment in past 6 months.
2. Not participated in similar investigations in past 4 weeks.
3. Subjects systemically healthy.
4. Subjects with moderate to severe gingivitis

**Exclusion criteria**

1. History of systemic diseases.
2. Pregnant or lactating females.
3. History of antibiotic therapy in past 30 days.
4. Known allergies to any mouth wash, pharmaceutical products or its components or ingredients in the test products.
5. Subjects with deleterious habits like smoking, tobacco chewing.

The subjects were examined in a dental chair under standard conditions of light using diagnostic instruments (mouth mirror, probe, explorer and tweezer) for plaque and gingival inflammation by recording plaque index (Turesky-Gilmore-Glickman modification of Quigley Hein 1970) and gingival index (Loe and Silness 1963). Total microbial count by standard spread plate count method where Phosphated buffer solution (P.B.S.) 10 ml with plaque samples were serially diluted as  $10^{-1}$ ,  $10^{-2}$ ,  $10^{-3}$ ,  $10^{-4}$ ,  $10^{-5}$  and  $10^{-6}$ . From each dilution, 0.1 ml sample was spread on nutrient agar plates. These plates were incubated at 37°C for 48 hours and number of colony forming units was recorded after 48 hours.

60 subjects with moderate to severe gingivitis were included in this study. They were randomly divided into 3 groups. An informed written consent was obtained from each subject.

For group-A (25 subjects), at baseline, case history along with plaque index and gingival index was recorded. Scaling was carried out in the same appointment. Oral hygiene instructions were given. This group was prescribed Hiora mouthwash 15 ml twice daily for 3 weeks. Subjects were assessed again after 3 weeks for plaque index and gingival index.

For group-B (25 subjects), at baseline, case history along with plaque index and gingival index was recorded. Scaling was carried out in the same appointment. Oral hygiene instructions were given. This group was prescribed 0.2% Chlorhexidine mouthwash by ICPA company. Subjects were asked to rinse twice daily with 10 ml mouthwash for one minute for 3 weeks. Subjects were assessed again after 3 weeks for plaque index and gingival index.

Remaining 10 subjects were included in group-C. At baseline case history & plaque and gingival index was recorded. Plaque samples were collected at baseline. Scaling was carried out in the same appointment. Oral hygiene instructions were given. Subjects were given Hiora mouth wash and told to use it 15 ml twice daily for 3 weeks. After 3 weeks, plaque samples were collected & plaque index and gingival index were recorded.

After a wash out period of 1 month, again plaque samples were collected from the same subjects. Plaque index and gingival index were recorded. Then the subjects were prescribed 0.2% Chlorhexidine Gluconate mouthwash and instructed to use 10 ml twice daily for 3 weeks. After 3 weeks, plaque index and gingival index were recorded. Plaque samples were collected and sent for microbial count. Subjective and objective criteria were assessed. The data obtained was arranged in a master chart & subjected to statistical analysis.

**RESULTS AND DISCUSSION**

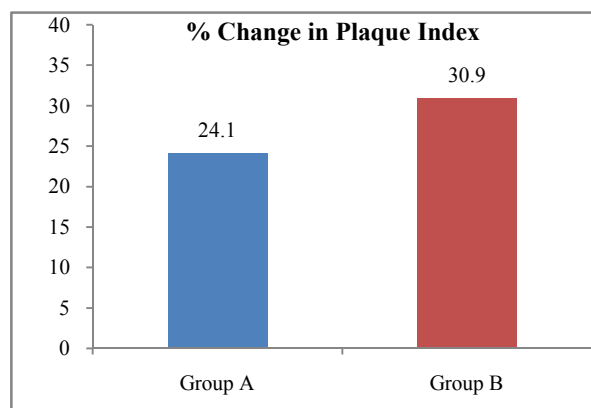
For Group A & B

**Plaque index:- (Turesky-Gilmore-Glickman modification of the Quigley Hein 1970)**

**Table 1** Intragroup & intergroup comparison between of plaque index between Group A & Group B.

Plaque Index (PI)	Group A (n=25) [HiOra Mouthwash]	Group B (n=25) [Chlorhexidine Mouthwash]	Inter Group Comparison (P-value)
Pre-treatment (Baseline)	1.86 ± 0.32	1.91 ± 0.29	0.566 (NS)
3-Weeks Post-treatment	1.39 ± 0.25	1.32 ± 0.32	0.132 (NS)
% Change	24.1%	30.9%	0.071 (NS)
<b>Intra-Group Comparisons</b>			
Pre-treat v Post-treat	0.001 (S)	0.001 (S)	--

**Table 2-% Change in plaque index (PI) between group A & group B**



Group A – HiOra mouthwash  
Group B- Chlorhexidine mouthwash



Figure 1 Assessment of Plaque of Group A Subjects At Baseline



Figure 2 Assessment of Plaque of Group a Subjects At 3 Weeks



Figure 3 Assessment of Plaque of Group B Subjects At Baseline



Figure 4 Assessment of Plaque of Group B Subjects at 3 Weeks

Statistically significant reduction in plaque index was observed between baseline and 3 weeks in group A & group B (Table 1 & 2).

At baseline, the mean plaque index of group A was  $1.86 \pm 0.32$  and for group B was  $1.91 \pm 0.29$ . At 3 weeks, both the groups showed significant reduction in mean plaque index  $1.39 \pm 0.25$  for group A and  $1.32 \pm 0.32$  for group B (Figure 1, 2, 3 & 4).

When intergroup comparison for plaque index was carried out, statistically significant ( $P < 0.001$ ) reduction in plaque index between groups A & B was observed. The results obtained in

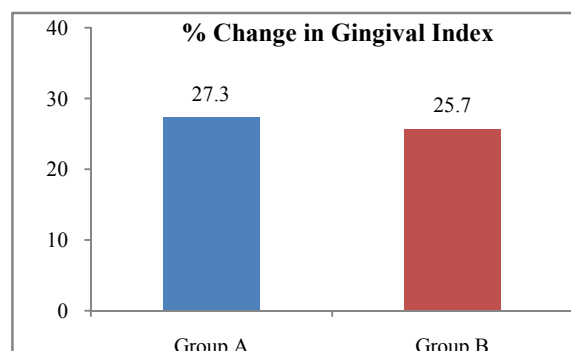
the present study are comparable to the study carried out by Arun Narayan, Chaya Menon (2012)<sup>5</sup>. They compared use of different mouth rinses (Triphala, HiOra, Colgate Plax and Chlorhexidine) on plaque formation. They concluded that Triphala, HiOra, Chlorhexidine were equally effective in inhibiting plaque regrowth. They observed lowest efficacy with Colgate Plax mouthwash.

**Gingival index (Loe and Silness 1963)**

Table 3-Intra & inter group comparison between of gingival index between Group A & Group B

Gingival Index (GI)	Group A (n=25) [HiOra Mouthwash]	Group B (n=25) [Chlorhexidine Mouthwash]	Inter Group Comparison (P-value)
Pre-treatment (Baseline)	$1.44 \pm 0.25$	$1.40 \pm 0.21$	0.793 (NS)
3-Weeks Post-treatment	$1.03 \pm 0.15$	$1.03 \pm 0.16$	0.954 (NS)
% Change	27.3%	25.7%	0.594 (NS)
<b>Intra-Group Comparisons</b>			
Pre-treat v Post-treat	0.001 (S)	0.001 (S)	--

Table 4-% Change in gingival index (GI) between Group A & B



Group A – HiOra mouthwash  
Group B- Chlorhexidine mouthwash

Statistically significant reduction in gingival index was observed between baseline and 3 weeks in group A & group B (Table 3 & 4).

At baseline, the mean gingival index of group A was  $1.44 \pm 0.25$  and for group B was  $1.40 \pm 0.21$ . At 3 weeks, both the groups showed significant reduction in mean plaque index  $1.03 \pm 0.15$  for group A and  $1.03 \pm 0.16$  for group B (Table 3 & 4).

When intergroup comparison for gingival index was carried out, it was observed that there was statistically significant ( $P < 0.001$ ) reduction in gingival index between both groups A & B. Similar observations were made by Shivanand Aspalli, V Sudhir Shetty *et al* (2014)<sup>6</sup>. They compared the efficacy of herbal mouthwash on reduction of plaque and gingivitis. They randomly divided 100 subjects into 2 groups, group A (patients treated by scaling alone) and the group B (patients treated by scaling along with HiOra mouthwash). They found significant reduction in gingival score in group B ( $0.724 \pm 0.2$ ) than group A ( $0.896 \pm 0.311$ ).

**Group C (Crossover group)**

Subjects of group C were evaluated in two phases. In the first test phase C-1, subjects were advised to use HiOra mouthwash and were evaluated for plaque index (PI), gingival index (GI), total microbial count at baseline and at 3 weeks. The second test phase C-2 was after a wash out period of 1 month, in



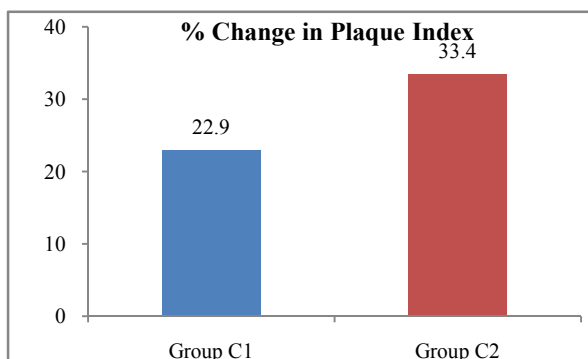
which the subjects were advised to use Chlorhexidine mouthwash and were evaluated for plaque index (PI), gingival index (GI), and total microbial count at new baseline and at 3 weeks.

**Plaque Index**

**Table 5-** Intra and inter group comparison of plaque index (PI) in crossed-over group (C-1, C-2)

Plaque Index (PI)	Group C-1 (n=10) [HiOra Mouthwash]	Group C-2 (n=10) [Chlorhexidine Mouthwash]	Inter Group Comparison (P-value)
Pre-treatment (Baseline)	2.46 ± 0.51	2.26 ± 0.39	0.405 (NS)
3-Weeks Post-treatment	1.88 ± 0.44	1.51 ± 0.44	0.034 (NS)
% Change	22.9%	33.4%	0.112 (NS)
<b>Intra-Group Comparisons</b>			
Pre-treat v Post-treat	0.001 (S)	0.001 (S)	--

**Table 6 -** % Change in plaque index (PI) between crossed over study groups.



Group C-1 – HiOra mouthwash  
Group C-2- Chlorhexidine mouthwash

Statistically significant reduction in plaque index between baseline and 3 weeks in HiOra mouthwash & Chlorhexidine mouthwash were seen in the crossover group.

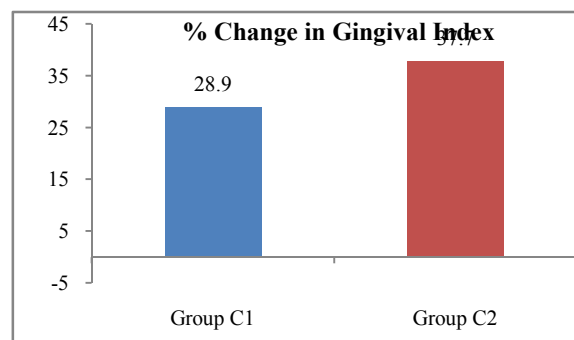
In the crossover group, statistically there was no significant difference in mean plaque index when HiOra mouthwash was compared with Chlorhexidine mouthwash. The results of the present study are in accordance with Neeti Bajaj and Shobha Tandon (2011)<sup>7</sup>. They conducted a study to assess the effects of a mouthwash prepared with *Triphala* on dental plaque, gingival inflammation, and microbial growth and compared it with *Chlorhexidine* mouthwash where *Triphala* & *Chlorhexidine* group showed progressive decrease in plaque scores from baseline to 9 months, whereas distilled water group showed increase in plaque scores.

**Gingival index (GI) -Loe and Silness 1963**

**Table 7-** The intra and inter group comparison of Gingival Index (GI) in crossed-over group (C-1, C-2)

Gingival Index (GI)	Group C-1 (n=10) [HiOra Mouthwash]	Group C-2 (n=10) [Chlorhexidine Mouthwash]	Inter Group Comparison (P-value)
Pre-treatment (Baseline)	1.75 ± 0.14	1.78 ± 0.16	0.677 (NS)
3-Weeks Post-treatment	1.24 ± 0.28	1.10 ± 0.12	0.622 (NS)
% Change	28.9%	37.7%	0.121 (NS)
<b>Intra-Group comparison</b>			
Pre-treat v Post-treat	0.001 (S)	0.001 (S)	--

**Table 8-**% change in gingival index (GI) between crossed over study groups (C-1, C-2).



Group C-1 – HiOra mouthwash  
Group C-2- Chlorhexidine mouthwash

Statistically significant reduction in gingival index between baseline and 3 weeks in HiOra mouthwash & Chlorhexidine mouthwash was seen in the crossover group when intragroup comparison was carried out (Table 7&8). However, when intergroup comparison was carried out, statistically there was no significant difference in mean gingival index when HiOra mouthwash was compared with Chlorhexidine mouthwash.

Our results are consistent with the results of study carried out by Madhumita Mazumdar, Swapan Mazumdar (2010)<sup>8</sup> and Shivanand Aspalli, V Sudhir Shetty *et al* (2014)<sup>9</sup>. In a study conducted by Dr. Shreya Shetty, Dr. Surya Pillai (2014)<sup>10</sup>, 40 subjects with mild to moderate chronic gingival inflammation were divided into 2 groups. At baseline scaling was carried out for all the subjects. Test group was prescribed HiOra mouthwash and control group was prescribed Chlorhexidine Gluconate mouthwash. Plaque index, gingival index, oral hygiene index, gingival bleeding index and cultures were done. The test group (HiOra mouthwash) & control group (Chlorhexidine Gluconate mouthwash) showed 2.74±1.14 and 2.63±0.89 significant reduction in gingival index respectively.

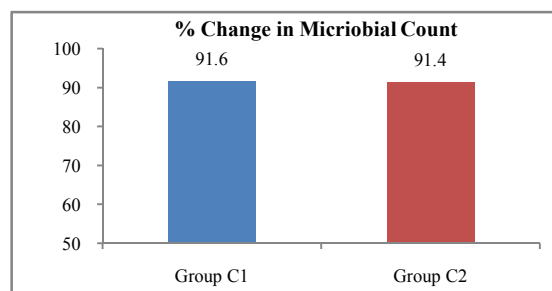
**Microbiological study**

Total microbial count was done by spread plate technique. Nutrient agar plates were used for growth of microorganisms

**Table 9** The intra and inter group comparison of Microbial count in crossed-over group (C-1, C-2)

Microbial count	Group C-1 (n=10) [HiOra MW] cfu/ml	Group C-2 (n=10) [Chlorhexidine MW] cfu/ml	Inter Group Comparison (P-value)
Pre-treatment (Baseline) x 10 <sup>4</sup>	202.7 ± 23.5	189.9 ± 21.6	0.174 (NS)
3-Weeks Post-treatment x 10 <sup>3</sup>	168.9 ± 16.2	161.7 ± 16.7	0.364 (NS)
% Change	91.6%	91.4%	0.705 (NS)
<b>Intra-Group Comparisons</b>			
Pre-treat v Post-treat	0.001 (S)	0.001 (S)	--

**Table 10-** % Change in total microbial count between group C-1 & C-2.



Group C-1 – HiOra mouthwash  
Group C-2- Chlorhexidine mouthwash



Figure: 5 Assessment of Microbial Count of Group C-1 Group At Baseline



Figure: 6 Assessment of Microbial Count of Group C-1 Group At 3 Weeks



Figure: 7 Assessment of Microbial Count of Group C-1 Group At Baseline



Figure: 8 Assessment of Microbial Count of Group C-1 Group At 3 Weeks

Statistically significant reduction was observed in total microbial count in both the groups (C-1, C-2) from baseline to 3 weeks ( Table 9 & 10).

Statistically no significant difference was observed in total microbial count when HiOra mouthwash was compared with Chlorhexidine mouthwash (Figure 5,6,7 & 8).

Acceptability of HiOra mouthwash by all the subjects in taste & comfort was good.

Good biological acceptability was observed with herbal mouthwash, as there was no evidence of burning sensation, dryness/sourness, and ulcer formation.

The findings of the present study suggest that HiOra has definite antimicrobial property<sup>8,9</sup>. In the present study, it was observed that there was no statistically significant difference in total microbial count between both (C-1 & C-2) groups. Thus, it can be concluded HiOra mouthwash has anti-microbial property comparable to Chlorhexidine mouthwash.

## DISCUSSION

Maintenance of good oral hygiene is the key to prevent periodontal diseases. Dental plaque is a known etiologic factor for development of gingivitis and periodontal disease. Optimal plaque control is essential to prevent and/or arrest the gingival inflammation. Mechanical measures such as tooth brushing and other home devices are the most commonly used methods to clean the teeth<sup>1</sup>. However, it has been revealed that majority of patients will not always completely remove the plaque by these ways. Furthermore, for handicapped or elderly individuals use of mechanical plaque control methods is more challenging due to their compromised dexterity or lack of motivation.

To overcome those shortcomings, antimicrobial rinses have been considered safe in reducing plaque and gingivitis. Chlorhexidine is the most common and extensively studied chemical agent for plaque control<sup>2</sup>. It is considered as the gold standard amongst anti-plaque agents. In spite of potent antimicrobial and anti plaque properties of Chlorhexidine, its widespread and prolonged use is limited by its local side effects. The adverse effects of Chlorhexidine include extrinsic staining of teeth, transient impairment of taste sensation and taste perturbation<sup>3</sup>. In view of this, herbal products are steadily gaining interest in the present era as they are naturally occurring, hence economical. They also claim to have little or no side effects. Herbal (HiOra) mouth rinse has shown antibacterial and anti-inflammatory effect in a few studies. The present study was therefore carried out to evaluate whether the clinical and antimicrobial efficacy of herbal (HiOra) mouth rinse was as good as or better than Chlorhexidine mouth rinse. HiOra is a herbal cocktail of medicinal extracts which act in a synergistic manner within the human body and provide unique therapeutic properties. This herbal mouthwash contains extracts of Pilu (Salvadora Persica), Bibhitaka (Terminalia Bellerika), Nagavalli (Piper Betel), Gandhapura taila (Gaultheria fragrantissima), Ela (Elettaria cardamomum) and powers of Peppermint satva (Mentha spp), Yavani satva (Trachyspermum ammi)<sup>8</sup>.

Salvadora Persica exhibits excellent antimicrobial activity against common oral pathogens like streptococcus mutans, candida albicans which may be a contributing factor for plaque formation. Terminalia Bellerika is a rich source of tannins and ellagic acid and is helpful in inhibiting the growth of Streptococcus mutans and other gram-positive cocci involved in plaque formation. Piper Betel inhibits common oral bacteria like Streptococcus sanguinis, Streptococcus mitis and

Actinomyces species. Gaultheria fragrantissima is a rich source of essential oils which is used for its antimicrobial activity. Elettaria cardamomum and Mentha spp. also have an inhibitory activity against common pathogens like E.coli, Candida albicans. Mentha spp. has essential oils which have analgesic action (which can be attributed to thymol). Elettaria cardamomum and Gaultheria fragrantissima impart a fragrant, refreshing effect and help in management of halitosis. The efficacy of this formulation can be attributed to the synergistic effects of the formulations like antimicrobial activity of Salvadora persica, antiplaque action of Elettaria Cardamomum and fragrant, refreshing effect of Mentha spp.

This herbal mouthwash showed no adverse effects and no staining of teeth with the usage of mouthwash. Limitations of the study were it was dependent on the patient compliance and the study was of short duration.

## CONCLUSION

Within the limits of this clinical study, it may be concluded that the ingredients in the herbal oral rinse were effective in controlling plaque and gingivitis. Furthermore, it may serve as a natural antimicrobial mouthwash alternative for patients who wish to avoid mouthwashes containing alcohol, artificial preservatives flavors and colors.

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