



ORIGINAL RESEARCH

EFFICACY OF BENZYLAMINE HYDROCHLORIDE MOUTHWASH VERSUS IBUPROFEN TABLET IN POSTOPERATIVE PAIN AFTER PERIODONTAL SURGERY: A RANDOMISED CONTROLLED STUDY.”

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ABSTRACT

Background: Benzylamine hydrochloride is a non-steroidal anti-inflammatory drug (NSAID) endowed with analgesic and anaesthetic activity, and with antimicrobial and antifungal properties. Its action is mainly localized primarily targets local inflammatory processes and exhibits a membrane-stabilizing effect, which contributes to its anaesthetic and anti-inflammatory properties. The aim of this clinical study was to determine the analgesic, anti-inflammatory, healing and plaque inhibiting effect of benzylamine HCl vs Ibuprofen tablets.

Methods and materials: A randomized controlled clinical trial was conducted on 24 chronic periodontitis patients selected through purposive sampling. Participants undergoing periodontal surgery were assigned to either a Benzylamine hydrochloride mouthwash (MW) group or an Ibuprofen tablet (TB) group. The MW group rinsed with 15 ml undiluted solution for 60 seconds, 3–5 times daily for three days, while the TB group took 400 mg twice daily for the same duration. Pain was assessed using the Visual Analog Scale (VAS) and Wong-Baker Facial Rating Scale (FRS), and gingival status was evaluated using the Gingival Index (GI) at baseline and day seven.

Results: Intra-group comparison showed significant pain reduction on both VAS and Wong-Baker scales for the mouthwash group, indicating greater efficacy. Inter-group analysis also revealed significant pain relief in both groups ($p < 0.05$). Intra-group comparison results for both groups signified the superior efficacy of the mouthwash with p -values 0.022 and 0.001 at day 1 and day 2 for the VAS scale and with p -values 0.036 and 0.002 for WBFRS scale.

Conclusion: Benzylamine HCL and Ibuprofen tablets showed potential reduction in postoperative pain. Intergroup comparison showed comparison at baseline, day 1 and day 2, which suggested that both the products were effective. Intra-group comparison of pain values in both VAS and WBFRS showed significance of mouthwash group, suggesting more efficacy than the tablet.

Keywords: Pain, Periodontal surgery, NSAIDs, Benzylamine Hydrochloride Mouthwash, Ibuprofen.

INTRODUCTION

The foundation of effective periodontal treatment relies not only on employing the correct surgical approach but also on preventing and managing postoperative complications. Pain is among the most frequent symptoms following periodontal

surgery. Consequently, surgeons aim to utilize analgesic methods that offer profound pain relief and are well-tolerated by patients, which helps to ensure patient compliance.

A complication is a secondary condition that develops during the progression of a primary disease or disorder. Postoperative complications of periodontal surgery may include pain, bleeding, swelling, sensitivity, delayed healing, trismus, bruising, and altered taste. These issues can impact the success of periodontal treatment. As a result, it is essential for clinicians to understand their causes and management strategies to ensure successful periodontal therapy.¹

Postoperative pain is influenced by factors such as the surgical site, age, sex, premedication, anaesthetic, analgesics, psychological state, and environment. Different analgesic methods have their own advantages, limitations, effective areas, and vary in effectiveness depending on the pain type. Pain is most intense within the first 48 hours, and various combination therapies can be employed during this period.²

NSAIDS (Non-Steroidal Anti-inflammatory Drugs) are commonly used to manage pain after periodontal surgery due to their analgesic and anti-inflammatory properties. They work by inhibiting the production of prostaglandins, which play a key role in pain and inflammation.

Different methods to administer NSAIDs includes surgery, oral, parenteral, inhalation and transdermal.^{3,4}

In the present study, benzydamine HCl mouthwash was used for analgesic properties. Due to its high lipid solubility in the unionized form and low protein-binding capacity, it is efficiently absorbed by cells. Benzydamine is mainly metabolized via conjugation, dealkylation, and oxidation, producing benzydamine N-oxide as the primary metabolite. It selectively reduces TNF- α and IL-1 β without altering IL-6, IL-8, IL-10, or IL-1ra levels.^{5,6}

Benzydamine shows mild antibacterial activity at mouthwash concentrations. At lower concentrations (3–30 μ mol/L), it can inhibit leukocyte-endothelial interactions and shows activity against certain strains resistant to broad-spectrum antibiotics, potentially helping to prevent secondary bacterial infections. At higher concentrations (10–100 μ mol/L), benzydamine hydrochloride may stabilize mucosal membranes and inhibit neutrophil degranulation, reducing serine protease release and enhancing its anti-inflammatory effect.⁷

This study was aimed to determine which is more effective on managing postoperative pain comparatively after periodontal flap surgery benzydamine hydrochloride mouthwash or ibuprofen tablets.

MATERIALS AND METHODS

This study is a randomized controlled trial conducted in the Department of Periodontology and Implantology, MNR Dental College and Hospital,

Sangareddy, Telengana.

The study was explained to the patients, and was carried out after taking an informed consent from each participant. The study protocol was approved Institutional Review Board (IRB).

Study Population: 24 patients who reported to the department with the complaint of chronic periodontitis were chosen using purposive sampling. 12 patients each were randomized into two groups: 0.15% Benzydamine hydrochloride mouthwash group (COOLORA, ICPA HEALTH PRODUCT, BATCH NO L24148) and 400mg Ibuprofen tablet group. The mouthwash group patients were asked to rinse with 15ml of mouthwash 2-5 times daily for 30secs. Tablet group patients were instructed to take ibuprofen tablets twice daily post-operatively.

The inclusion criteria for the study comprised systemically healthy male and female patients aged between 21 and 60 years, diagnosed with moderate to severe chronic periodontitis. Participants were required to have a minimum pocket depth of ≥ 5 mm and at least 20 teeth present, along with good oral hygiene practices. Only those who had not undergone any surgical or non-surgical periodontal treatment in the past six months were considered. Additionally, participants needed to be mentally capable of understanding and responding to study-related questions and willing to provide informed consent for participation.

The exclusion criteria included patients with current or past systemic conditions that could influence periodontal therapy outcomes, as well as immunocompromised individuals. Those on medications that might interfere with periodontal treatment, smokers, and individuals with a history of hypersensitivity were excluded. Pregnant or lactating women, patients with hormonal imbalances, and those presenting with acute gingival or periodontal conditions were also not considered. Additionally, individuals who had received any drug therapy within the past six months, or who had malocclusion or dental caries, were excluded from the study.

At the start of the study, all patients were instructed to maintain proper oral hygiene, and the Gingival Index was recorded.⁸ Open flap debridement using a mucoperiosteal (Kirkland) flap was performed under 1:80,000 lidocaine anaesthesia, without the use of grafts, mucosal flaps, or bone manipulation. No periodontal dressing was applied to allow better penetration of benzydamine hydrochloride mouthwash into the tissues.⁹ Patients were provided with a printed 100 mm VAS scale and Wong-Baker faces scale to record pain levels, starting the evening of the procedure and continuing twice daily (morning and evening) for seven days.

STATISTICAL ANALYSIS

The data was collected and analyzed using SPSS version 22 (Armonk, NY, USA). Descriptive statistics was performed for assessment of frequencies and a paired and an independent t-test

and Friedmann Two-Way ANOVA Test, Mann Whitney U test was performed to compare means across the variables.

RESULTS

As pain levels dropped to zero in most patients after the second day, analysis was limited to data from the first two days. Intra-group comparison of pain values at day 1 and day 2 in both VAS and WONGBAKER scales demonstrated significance for the mouthwash group, suggesting more efficacy than the tablet group.

Mean comparison of VAS done using Friedmann Two-Way Anova Test where $p \leq 0.05$ was statistically

significant (Table 1 ,1a, Graph 1) showed Group 1 and Group 2 with similar significant p values <0.001 showing the similar efficacy of both mouthwash and tablet in managing post-operative pain.

Table 1. Mean comparison of VAS scores within the groups

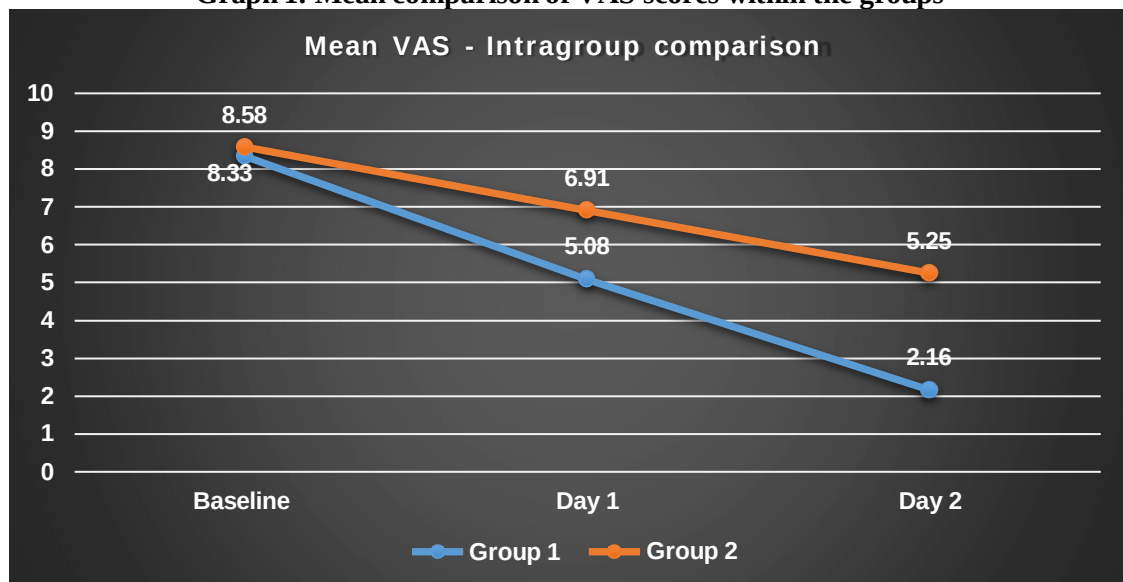
Group	Timeline	n	Mean	SD	Test value	P value
Group 1	Baseline	12	8.3333	1.30268	24.000	<0.001*
	Day 1	12	5.0833	1.92865		
	Day 2	12	2.1667	1.85047		
Group 2	Baseline	12	8.5833	0.99620	23.000	<0.001*
	Day 1	12	6.9167	1.24011		
	Day 2	12	5.2500	0.96531		

Friedmann Two-Way ANOVA Test; $p \leq 0.05$ considered statistically significant

Table 1a. Pairwise comparison -post hoc analysis

Comparison between		P value	
		Group 1	Group 2
Baseline	Day 1	0.014*	0.019*
	Day 2	<0.001*	<0.001*
Day 1	Day 2	0.014*	0.019*

Graph 1. Mean comparison of VAS scores within the groups

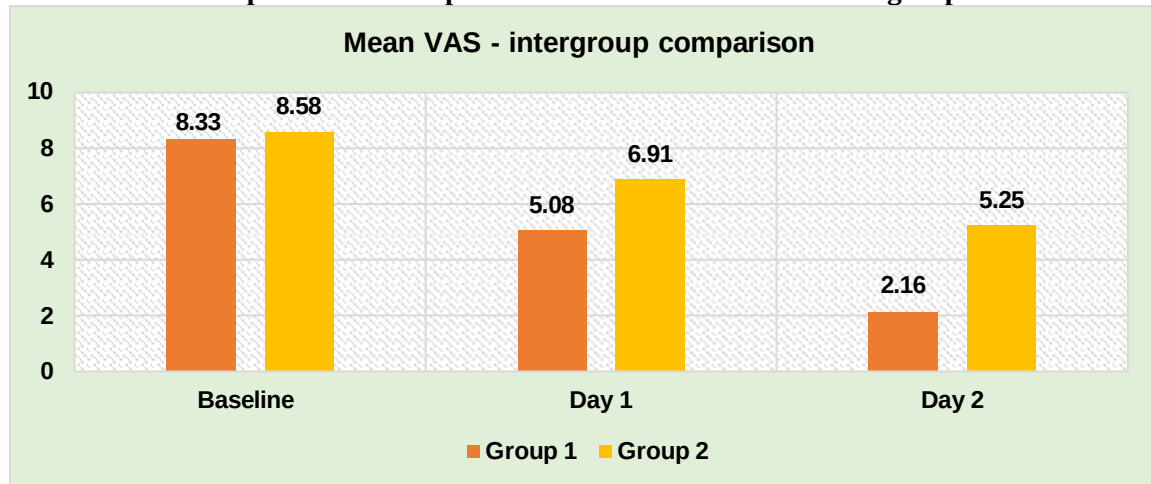


Intra-group comparison done using Mann-Whitney U test showed statistical significance in both groups in pain relief ($p < 0.05$). Intra-group comparison results for both groups signified the superior efficacy of the mouthwash with p-values 0.022 and 0.001 at day 1 and day 2 for the VAS scale (Table 2, Graph 2) and with p-values 0.036 and 0.002 for WBFRS scale. (Table 3, Graph 3)

Table 2. Mean comparison of VAS Scores between the groups

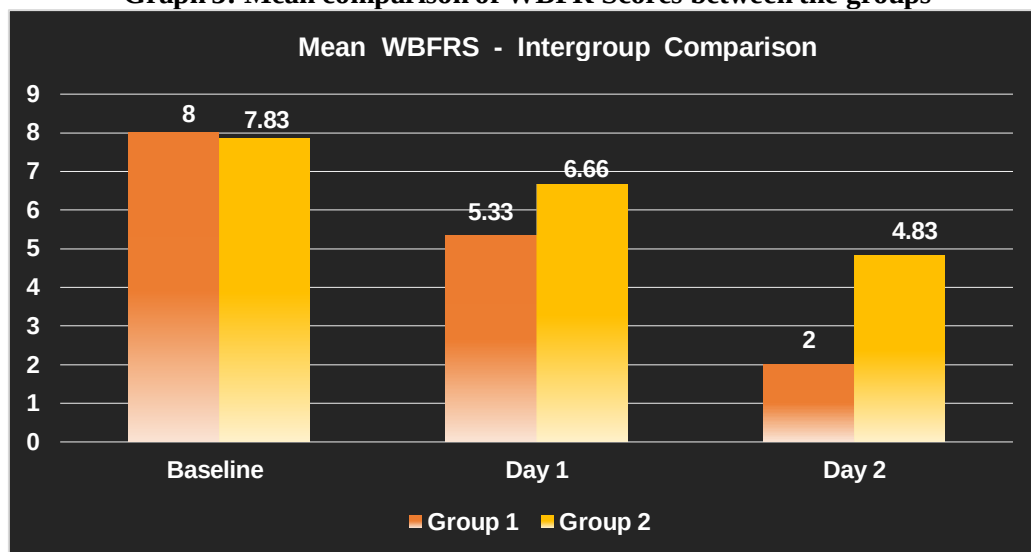
Timeline	Groups	n	Mean	SD	Test value	P value
Baseline	Group 1	12	8.3333	1.30268	-0.361	0.718
	Group 2	12	8.5833	0.99620		
Day 1	Group 1	12	5.0833	1.92865	-2.289	0.022*
	Group 2	12	6.9167	1.24011		
Day 2	Group 1	12	2.1667	1.85047	-3.389	0.001*
	Group 2	12	5.2500	0.96531		

Mann-Whitney U test; $p \leq 0.05$ considered statistically significant

Graph 2. Mean comparison of VAS Scores between the groups**Table 3. Mean comparison of WBFR Scores between the groups**

Timeline	Groups	n	Mean	SD	Test value	P value
Baseline	Group 1	12	8.0000	1.47710	-0.279	0.780
	Group 2	12	7.8333	1.58592		
Day 1	Group 1	12	5.3333	1.30268	-2.093	0.036*
	Group 2	12	6.6667	1.55700		
Day 2	Group 1	12	2.0000	1.70561	-3.104	0.002*
	Group 2	12	4.8333	1.80067		

Mann-Whitney U test; $p \leq 0.05$ considered statistically significant

Graph 3: Mean comparison of WBFR Scores between the groups

Mean comparison of WONGBAKER scale done using Friedmann Two-Way Anova Test where $p \leq 0.05$ was statistically significant. (Table 4 ,4a, Graph 4) showed Group 1 and Group 2 with similar significant p values <0.001 showing the similar efficacy of both mouthwash and tablet in managing post-operative pain.

Table 4. Mean comparison of WBFRS scores within the groups

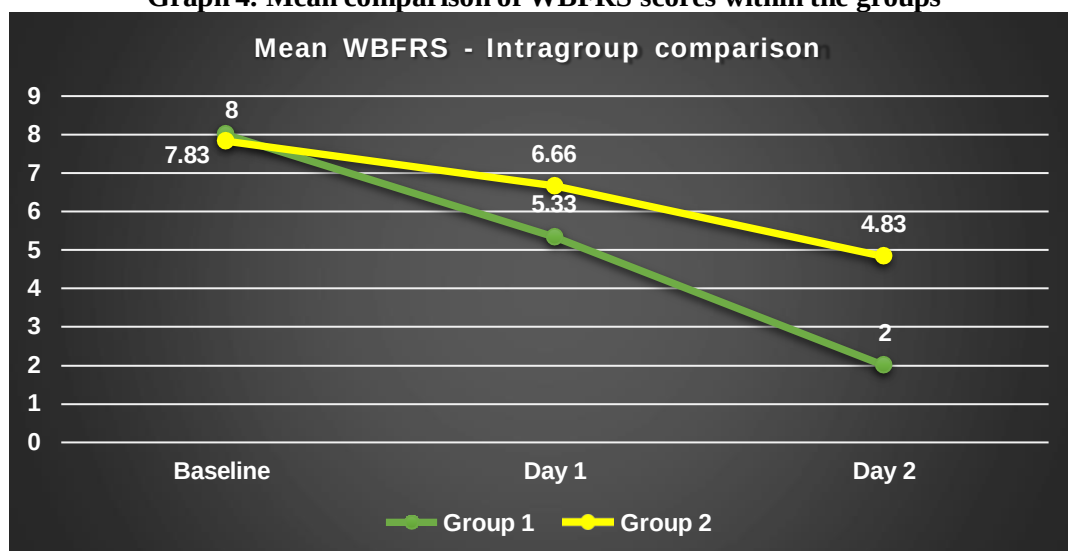
Group	Timeline	n	Mean	SD	Test value	P value
Group 1	Baseline	12	8.0000	1.47710	24.000	<0.001*
	Day 1	12	5.3333	1.30268		
	Day 2	12	2.0000	1.70561		
Group 2	Baseline	12	7.8333	1.58592	20.150	<0.001*
	Day 1	12	6.6667	1.55700		
	Day 2	12	4.8333	1.80067		

Friedmann Two-Way ANOVA Test; $p \leq 0.05$ considered statistically significant

Table 4a. Pairwise comparison -post hoc analysis

Comparison between		P value	
		Group 1	Group 2
Baseline	Day 1	0.014*	0.083
	Day 2	<0.001*	<0.001*
Day 1	Day 2	0.014*	0.019*

Graph 4. Mean comparison of WBFRS scores within the groups



Intra-group comparison of the gingival index was done using paired t-test and independent t-test from baseline to 7 days (Table 5,6 Graph 5,6) has showed reduction in the Mean and SD from 1.97 to 1.9 in Group 1 and 1.9-1.31 in Group 2. A significant decrease in the p values from $p=0.7$ to $p=0.4$ from baseline to 7 days was observed concluding the efficacy benzydamine HCL mouthwash over the tablet.

Table 5: Mean comparison of GI scores within the groups

Group	Timeline	n	Mean	SD	Test value	P value
Group 1	Baseline	12	1.9750	0.47697	10.175	<0.001*
	Day 7	12	1.1500	0.41010		
Group 2	Baseline	12	1.9000	0.60902	9.918	<0.001*
	Day 7	12	1.3167	0.64924		

Paired t-test; $p \leq 0.05$ considered statistically significant

Graph 5. Mean comparison of GI scores within the groups.

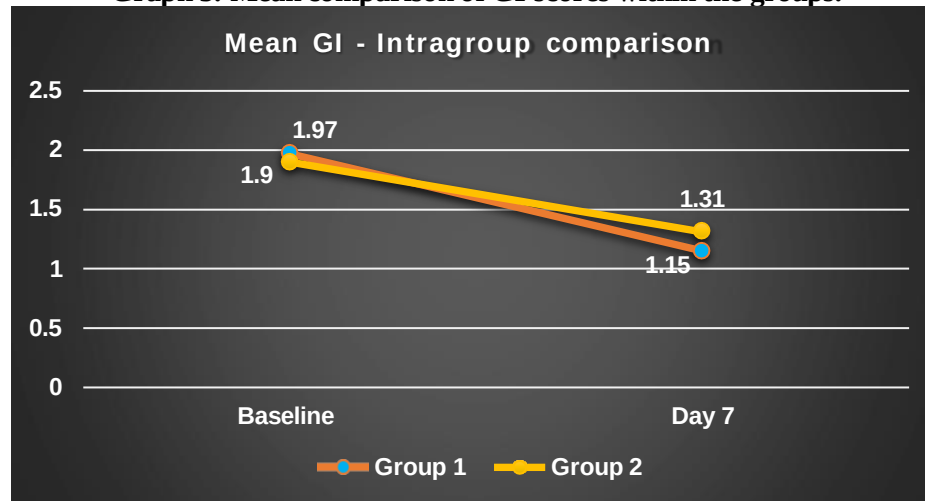
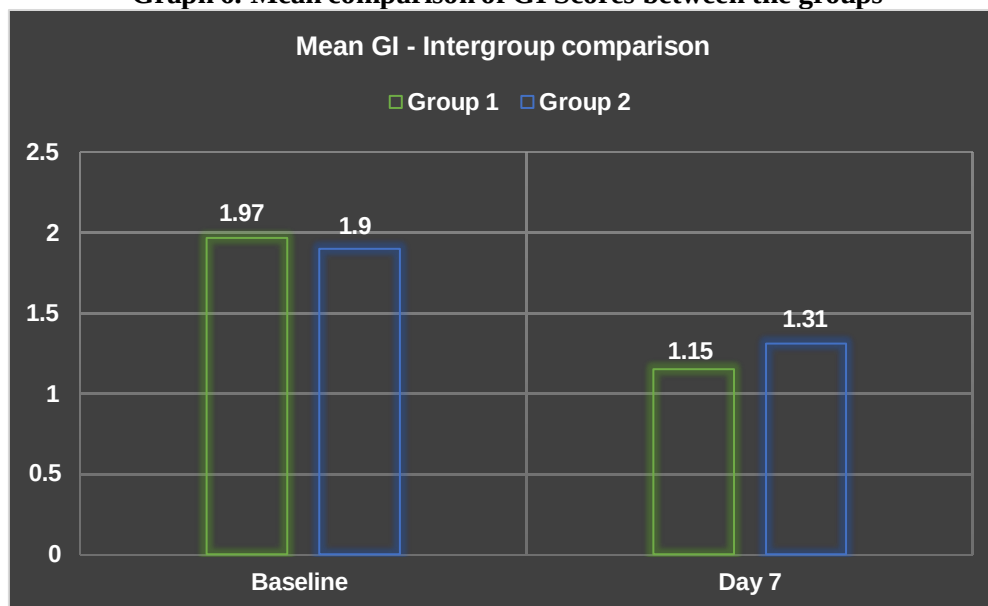


Table 6. Mean comparison of GI Scores between the groups

Timeline	Groups	n	Mean	SD	Test value	P value
Baseline	Group 1	12	1.9750	0.47697	0.336	0.740
	Group 2	12	1.9000	0.60902		
Day 7	Group 1	12	1.1500	0.41010	-0.752	0.460
	Group 2	12	1.3167	0.64924		

Independent t-test; $p \leq 0.05$ considered statistically significant

Graph 6. Mean comparison of GI Scores between the groups



DISCUSSION

In this study conducted, Benzylamine mouthwash was assessed for post periodontal surgery pain relief and evaluated if it would be a better alternative to the systemic administration of the Ibuprofen tablet. Results indicated that pain levels in both groups were highest on the day of surgery and gradually decreased, reaching their lowest by day seven.

The present study has clearly shown that Benzylamine mouthwash (COOLORA™) at a dose of 15ml twice daily, is known to have significant local analgesic

effect, and also effects of it were similar to that of systemic administration of Ibuprofen tablet (40 mg), which had been the primary point in this study. This further improves the patient acceptance and minimize the adverse effects of the orally administered drug. The newer formulation of Benzylamine mouthwash was known to be lipophilic in nature having better solubility and penetrability on contact with oral mucosa.

Benzylamine has low absorption through the skin and non-specialized mucosa, which limits systemic exposure and reduces the risk of side effects. However, when

applied topically, it achieves higher local tissue concentrations than oral administration, making it especially effective for targeted relief in conditions like postoperative oral pain.¹⁰

Postoperative pain not only causes stress on the patient, but also prolongs the recovery period of the disease. Therefore, postoperative pain control is a subject that is continuously studied.^{11,12}

The use of anti-inflammatory medications—whether nonsteroidal (NSAIDs) or steroidal (SAIDs)—following surgery has been shown to effectively reduce postoperative pain intensity and decrease the need for additional analgesics.¹³

According to the findings of Peeva et al., the local application of benzydamine is effective in reducing postoperative inflammation and pain, primarily by inhibiting prostaglandin and cytokine activity. Based on these results, its use in the postoperative period is recommended.¹⁴

In a study by Gülhan Kocaman, patients using benzydamine HCl reported high rates of mild pain relief postoperatively: 81.3% at the 2nd and 6th hours, 87.5% at the 8th hour, and 91.7% by the 12th hour. Pain levels were classified as mild (1–4 points) and moderate (5–6 points). No significant difference was found between the two forms of administration in achieving mild pain. The study concluded that benzydamine HCl is highly effective in controlling postoperative pain after periodontal flap surgery.¹⁵

A recent RCT (Khabazian A et al)¹⁶ compared 0.15% benzydamine HCl mouthwash and 400 mg ibuprofen tablets for postoperative pain relief after crown lengthening. Both showed similar pain reduction within 24 hours. However, benzydamine HCl was favored due to fewer side effects and lower cost. Peddengatagari S et al, in a double-blind RCT in periodontitis patients showed that 0.15% benzydamine HCl was more effective than 50 mg diclofenac sodium tablets in reducing postoperative pain after periodontal surgery which presents similar results to our study.¹⁷

In a study comparing benzydamine and chlorhexidine mouthwashes for managing recurrent aphthous stomatitis, patients favored benzydamine due to its temporary anaesthetic effect. Additionally, a clinical trial showed that the benzydamine group experienced reduced gingival inflammation, likely due to its combined anti-inflammatory and antimicrobial properties.^[18-19]

A study in the *Allergy Journal* found benzydamine HCl to be a well-tolerated NSAID and a suitable alternative for patient intolerant to other NSAIDs.²⁰

Benzydamine has been shown effective in treating aphthous ulcers due to its analgesic and anti-inflammatory properties. It also reduced pain and inflammation when used as a topical spray

postoperatively. However, in a randomized trial on third molar extraction, benzydamine mouthwash did not significantly reduce the need for oral analgesics compared to ibuprofen and paracetamol.^{21,22}

In this study, benzydamine gargle provided analgesic effects comparable to oral ibuprofen in surgeries without bone manipulation, reducing the need for systemic analgesics. No side effects were observed.

CONCLUSION

Both benzydamine hydrochloride mouthwash and ibuprofen tablets demonstrated a notable reduction in postoperative pain. Intergroup comparisons conducted at baseline, Day 1, and Day 2 revealed that both treatment modalities were effective in managing pain following periodontal surgery. However, intra-group analysis of pain scores using both the Visual Analog Scale (VAS) and Wong-Baker Faces Rating Scale (WBFRS) indicated a statistically significant reduction in pain within the benzydamine mouthwash group. These findings suggest that benzydamine hydrochloride mouthwash may offer greater analgesic efficacy compared to oral ibuprofen in the immediate postoperative period.

DECLARATIONS

Acknowledgements

None

Ethical Approval

Approval for the conduction of the study was obtained from institutional scientific review board. [MNREC-BHR-01/25]

Informed consent

Verbal and written informed consent were obtained from the all patients.

Financial support and sponsorship

None

Conflict of Interest

None declared

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