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EFFICACY OF BENZYDAMINE HYDROCHLORIDE MOUTHWASH VERSUS DICLOFENAC TABLET IN POSTOPERATIVE PAIN AFTER PERIODONTAL SURGERY: A COMPARATIVE STUDY.

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Abstract

Introduction: Benzydamine hydrochloride is an NSAID most often used in radiation induced oral mucositis. The indazole analogue benzydamine has physical, chemical, and pharmacological properties which differ from those of the aspirin-like NSAIDs. Benzydamine specifically act on the local mechanisms of inflammation, granuloma, and exudate.

Methodology: The study was a double-blinded, randomized, controlled clinical trial. A total of 30 chronic periodontitis patients reported to the dental hospital were selected for the study using a purposive sampling technique. Thirty chronic periodontitis patients scheduled for periodontal surgeries were randomized to receive either Benzydamine hydrochloride Mouthwash (MW) or Diclofenac Tablets (TB), post-surgery. The MW group patients were advised to rinse with undiluted 15 ml solution for 60 secs, 2-5 times daily for three days. TB group were asked to take 50 mg tablet twice daily for three days. A 10-point Visual Analog Scale (VAS) and Wong-Baker Facial Rating Scale (FRS) were recorded to measure the pain perception by the patients.Gingival status was assessed by the Modified Gingival Index (MGI) at baseline and seventh day.

Results: 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. Inter-group results showed statistical significance in both groups in relief of pain ($p<0.05$). Intra-group comparison results for both groups signified the superior efficacy of the mouthwash with p-values 0.010 and 0.005 at day 1 and day 2 for the Wong-Baker scale and with p-values 0.020 and 0.017 for VAS scale.

Conclusion: Inter-group comparison at baseline, day 1, day 2 showed significant results on day 1 and day 2, suggesting both the products were effective. Intra-group comparison of pain values in both VAS and WONG BAKER scales showed the significance of the mouthwash group, suggesting more efficacy than the tablet.

Keywords: Pain, Benzydamine hydrochloride mouthwash, Post-periodontal surgery.

Introduction

Postoperative pain is inevitable with any invasive procedure. Especially with periodontal surgery, where the result is not tangible always, the acceptability of the process is low, numerous questions arise from the patients regarding postoperative complications. Among many post-treatment effects, acute pain is one among them.[1] Pre-emptive and post-operative analgesics to minimize post-operative pain were used in many studies.[2] Different routes like intravenous and oral routes of administration of the drugs usage presented with many adverse effects. In the present study, benzydamine hydrochloride NSAID mouthwash was used as an analgesic, which acts locally and has higher absorbability due to the lipid-soluble nature of the drug. And it also can by-pass the complications related to the systemic administration of the drugs.

Benzydamine also possess non-specific anti-bacterial effect at concentrations used as a mouthwash. At levels of 3mmol/L, it is even active against few strains that areresistant to the broad-spectrum antibiotics, which may help in preventing secondary bacterial infections.

Benzydamine acts on local inflammatory factors but does not interact with systemic physiology. Administration of 1.5% oral spray produced analgesia after impaction of third molars. Benzydamine possess membrane-stabilizing effect, which is responsible for anesthetic and anti-inflammatory effect.[3]

Materials and Methodology:

This double-blinded, randomized controlled clinical trial was conducted in the Department of Periodontics, GDCH, Kadapa. Ethical clearance was taken from the institutional ethical committee before the study was conducted; informed consent was obtained from the patients.

Thirty patients who reported to the department with the complaint of chronic periodontitis were chosen using purposive sampling. Fifteen patients each were

randomized into two groups: 50mg Diclofenac tablet group and 0.15% Benzydamine hydrochloride mouthwash group (COOLORA, ICPA HEALTH PRODUCT, BATCH NO L70278). Tablet group patients were instructed to take diclofenac tablets twice daily post-operatively, and mouthwash group patients were asked to rinse with 15ml of mouthwash 2-5 times daily for 30secs.

SELECTION CRITERIA:

- Systemically healthy patients
- Minimum pocket depth of ≥5mm
- Minimum of 20 teeth present.

EXCLUSION CRITERIA:

- Patients with a history of hypersensitivity.
- Pregnant and lactating women and other hormonal imbalances.
- Patients with acute gingival or periodontal conditions.
- Patients with a history of drug therapy in the last six months.
- Patients who smoke.
- Malocclusion and dental caries.

PROCEDURE:

Patients were evaluated for anxiety by using Corah's questionnaire before Phase I treatment.[4] In all the 30 subjects, open flap debridement with mucoperiosteal flap (Kirkland flap) was opted under 1:80,000 lidocaine local anesthesia. Usage of grafts and mucosal flaps were avoided. Any procedures involving manipulation of bone were also avoided. Surgery was completed in a stipulated time.

The periodontal dressing was not given, facilitating the penetration of Benzydamine hydrochloride mouth wash into the periodontal soft tissues.[5,6] Patients were given a printed VAS scale having a horizontal 100mm scale for identifying the intensity of pain and Wong- Baker faces, and they were asked to record them from the evening (baseline) of the procedure and twice daily (morning and evening) for the next seven days.

STATISTICAL ANALYSES:

•SPSS software version 21 was used for data analysis.

•p-value of <0.05 was considered as statistically significant.

• Independent STUDENT'S t-test was used for Inter-group comparisons. (Table 1 & 2)

•Intra-group comparison of pain scores at different intervals was analyzed using ANOVA with LSD-POST HOC test. (Table 3)

•For association of VAS with dental anxiety scores, SPEARMAN RANK CORRELATION was used . (Table 4 & 5)

Results:

After the second day, the pain intensity was reduced to zero in almost all the patients; hence, the analysis was limited to the second day. Intra-group comparison of pain values at day 1 and day 2 in both VAS and WONGBAKER scales demonstrated p-values; (p=0.021and p=0.006)

INTER-GROUP COMPARISON WAS DONE USING INDEPENDENT STUDENTS T-TEST (TABLE 1 & 2)

Table 1:

Group	Baseline VAS		P value	Day1VAS		P value	Day2VAS		P value
	MOUTH WASH	TABLET		MOUTH WASH	TABLET		MOUTH WASH	TABLET	
Mean	4.40	3.60	0.504	3.00	5.67	0.020	2.13	4.13	0.017
Std. Deviation	2.667	3.719		2.070	3.619		1.598	2.615	

Table 2:

-Group	Baseline WBFP scale		P value	Day1WBDP		P value	Day2 WBFP		P value
	MOUTH WASH	TABLET		MOUTH WASH	TABLET		MOUTH WASH	TABLET	
Mean	2.07	1.87	0.743	1.20	2.60	0.010	.80	2.00	0.005
Std. Deviation	1.223	1.995		1.014	1.682		.862	1.254	

WBFPS: Wong-Baker Faces Pain Scale

ANOVA WITH LSD-POST HOC FOR INTRAGROUP VARIATIONS AND SIGNIFICANCE (TABLE 3)

Table 3:

Groups		Mean	Std. Deviation	P-Value
VAS- Mouth wash	Day 1	4.40	2.667	0.021
	Day 2	3.00	2.070	
	Day 3	2.13	1.598	
VAS Tablet	Day 1	3.60	3.719	0.22
	Day 2	5.67	3.619	
	Day 3	4.13	2.615	
WBF -Mouth wash	Day 1	2.07	1.223	0.006
	Day 2	1.20	1.014	
	Day 3	.80	.862	
WBF Tablet	Day 1	1.87	1.995	0.447
	Day 2	2.60	1.682	
	Day 3	2.00	1.254	

Respectively for mouthwash group suggesting more efficacy than tablet group (p=0.22 and p=0.447). Inter-group results have shown statistical significance in both groups in relief of pain (p<0.05). Intra-group comparison results for both groups signified the superior efficacy of the mouthwash with p-values 0.010 and 0.005 at day 1 and day 2 for the Wong-Baker scale and with p-values 0.020 and 0.017 for VAS scale.

CORRELATION TESTS (TABLE 4 & 5)

Table 4:

Dental Anxiety score VS Vas score with Mouth Wash

			DAS total score	vas score
Spearman's rho	DAS total score	Correlation Coefficient	1.000	.608*
		Sig. (2-tailed)		.016
		N	15	15
	vas score	Correlation Coefficient	.608*	1.000
		Sig. (2-tailed)	.016	
		N	15	15

*. Correlation is significant at the 0.05 level (2-tailed).

Table 4:

Dental Anxiety score VS Vas score with Tablet

			DAS total score	VAS score
Spearman's rho	DAS total score	Correlation Coefficient	1.000	.539*
		Sig. (2-tailed)		.038
		N	15	15
	VAS score	Correlation Coefficient	.539*	1.000
		Sig. (2-tailed)	.038	
		N	15	15

*. Correlation is significant at the 0.05 level (2-tailed).

DAS: Dental Anxiety Score VAS: Visual Analogue Score

Discussion:

In this study, Benzydamine mouthwash was assessed for post periodontal surgery pain relief and evaluated if it would be a better alternative to the systemic administration of the Diclofenac tablet. Results indicated that maximum amount of pain in both the groups was on the day of surgery that reached its lowest levels on day seven. The present study has clearly shown that Benzydamine 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 diclofenac tablet, which had been the primary point in this study. This further improvises the patient acceptance and minimize the adverse effects of the orally administered drug. The newer formulation of Benzydamine mouthwash was known to be lipophilic in nature having better solubility and penetrability on contact with oral mucosa. The prospect of dental surgeries is a powerful anxiety-provoking stimulus. The fear of pain as a result of dental procedures can stop patients from seeking

treatments.[7,8] The majority (71%) of patients anticipating periodontal therapy reported apprehension and fear of appointments and described themselves as highly anxious.[9,10] High pre-treatment anxiety levels were reported because of pain caused during periodontal scaling/non-surgical periodontal treatment and after periodontal surgery.[11]

Few factors like sex, location of surgery do not affect the intensity of pain. Increase in duration of the procedure leads to an increase in the post-operative swelling which is statistically significant when antibiotics were not used.[12]

Patients with higher pre-surgical anxiety have reported experiencing more pain following the surgery.[13] In the present study, the pain values coincided with the pre-surgical anxiety levels.

Patients who reported to have more pain after periodontal surgery also reported using more pain pills.[14] Mouthwash was used to eliminate the side effects due to the increased consumption of the systemic administration of NSAIDs. The experience of the surgeon determines the intensity of pain; patients experienced mild pain post-surgery, when done by an experienced surgeon and those who got the procedure done by an inexperienced surgeon had moderate-to-severe pain post-surgery.[15] In this study, that variable was eliminated by having all surgeries performed by one periodontist.

Benzydamine was not well absorbed through the skin, and non-specialized mucosa and hence had the advantage of limiting undesired systemic exposure to the drug while allowing local therapeutic tissue exposure which is reported to be higher for topical application than oral administration.[8]

Post-operative administration of different anti-inflammatory medications, either nonsteroidal anti-inflammatory drugs (NSAIDs) or steroidal anti-inflammatory drugs (SAIDs), are shown to minimize post-operative pain intensity and the need for supplementary analgesics.[16] Stress and anxiety determine the perception of pain/discomfort since this is subjective and varies a lot between individuals.[17]

Evidences have shown that it is likey a patient expecting a higher amount of pain will also experience more pain. Significant amount of pain experienced by patients occur on the day of surgery, with a substantial decrease in the following days.[18]

In a study, it was found that Benzydamine was effective in reducing oral mucositis induced by radiation therapy.[19]

In a clinical trial comparing Chlorhexidine mouthwash and Benzydamine mouthwash, a reduction in gingival inflammation can be attributed to its anti-inflammatory and antimicrobial effects was found in Benzydamine mouthwash group.

This study also revealed its beneficial effect on reduction in the plaque formation at subsequent visits.[20] In a study comparing Benzydamine and Chlorhexidine mouthwash in management of recurrent aphthous stomatitis, patients preferred Benzydamine mouthwash due to its temporary anesthetic effect.[21]

In a study, Benzydamine was used in the treatment of aphthous ulcers was proven to be effective. The reasons for the effectiveness are the analgesic and anti-inflammatory actions.[22] In a study to evaluate the post-operative anti-inflammatory and anti-plaque effect, topical spray of Benzydamine was proved to be effective in alleviating pain and suppressing inflammation.[23]

In a randomized controlled trial, patients undergoing extraction of fully erupted 3rd molar comparing Benzydamine hydrochloride mouthwash and oral ibuprofen and paracetamol for analgesia, it was confirmed that using Benzydamine did not significantly reduce the intake of oral analgesics.[24]

In the present study, where all surgical procedures in which no bone manipulation was carried, the use of Benzydamine gargle as an analgesic was comparable to the oral Diclofenac sodium, which favoured reduced intake of oral analgesics and by-passing the side effects of systemically administered analgesics. No side effects were noted.

Conclusion:

Benzydamine mouthwash is safe and efficient in the treatment of oral/periodontal postoperative pain. It can be concluded that Benzydamine mouthwash could be a better alternative in terms of patient acceptance and to minimize the adverse effects of orally administered drugs. Long term clinical trials are required with larger sample size. As Benzydamine mouthwash has less systemic side effects it can be prescribed after periodontal flap surgery as an alternative to other analgesics.

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