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A COMPARATIVE STUDY OF EFFICACY OF 2% POVIDONE-IODINE VERSUS 0.15% BENZYDAMINE TOPICAL GARGLES IN PATIENTS WITH CHRONIC PHARYNGITIS

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ABSTRACT: Background: Chronic pharyngitis, often associated to Gastroesophageal reflux disease (GERD) and Laryngopharyngeal reflux disease (LPRD), presents significant therapeutic challenges. **Objective:** To compare the clinical efficacy of 2% w/v Povidone-Iodine (PI) and 0.15% w/v Benzydamine Hydrochloride (BZ) gargles in patients with chronic pharyngitis secondary to LPRD/GERD. **Methods:** This prospective, randomized, open-label study compared the efficacy of PI and BZ topical gargles, combined with Omeprazole (20 mg) and Cinitapride (3 mg) once daily orally. Clinical outcomes were evaluated using the Reflux Symptom Index (RSI) and Visual Analogue Scale (VAS) at baseline, day 15, and day 30. **Results:** Both groups exhibited significant improvement ($p<0.05$) in RSI and VAS scores over 30 days. BZ group showed effective pain reduction (VAS: 0.48±0.58 vs. 0.62±0.70; *p=0.014) and higher rates of complete pain resolution (56% vs. 50%) compared to PI group. PI achieved 100% resolution in reflux-associated symptoms (heartburn, postprandial cough), while BZ mainly improved neurogenic symptoms (globus sensation: 96.9% vs. 90%; hoarseness of voice: 92% vs. 78.3%). However, composite RSI reduction was comparable (BZ: 85.6% vs. PI: 82.8%; *p=0.095). **Conclusion:** This study concludes that BZ rapid analgesic effect makes it ideal option for immediate symptom management, whereas PI antimicrobial property may help in reflux- dominant cases. Both PI and BZ gargles, when combined with anti-reflux medications, are effective in relieving chronic pharyngitis symptoms associated with LPRD/GERD - supported by lifestyle modifications. These observations suggest the importance of personalized treatment strategies in the management of chronic pharyngitis.

INTRODUCTION: Pharyngitis is an inflammatory or infectious condition affecting mucosa and submucosa of the throat, presenting in acute and chronic states.

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The etiology of pharyngitis is multifactorial, including allergic reactions, asthma, chronic irritant exposure, gastroesophageal reflux disease (GERD), laryngopharyngeal reflux disease (LPRD), smoking, and bacterial, viral, or fungal infections [1].

Chronic granular pharyngitisis the major factor (10-30%) which drives the people to consult an Otrhinolaryngologist. It is clinically characterized by hypertrophy of sub epithelial lymphoid follicles, mucosal thickening, seruminous gland hyperplasia and the muscular layer involvement in the pharynx

[2]. A significant contributor to chronic non-infectious pharyngitis is reflux conditions, especially LPRD and GERD. Unlike the mucosal layer of esophagus and stomach, the laryngeal and pharyngeal mucosa lack protective mechanisms like bicarbonate secretion and peristalsis movements, rendering them more susceptible to mucosal damage. Patients with chronic pharyngitis often show the symptoms including throat irritation, hoarseness in voice, globus sensation, etc., significantly affecting their quality of life [3].

There are various treatment approaches available for chronic pharyngitis includes antiseptics, topical antibiotics, and local anaestheics. Among these, Povidone-Iodine 2% w/v(PI) serves as a broad-spectrum antiseptic mouth gargle, releasing active metabolites such as molecular Iodine and hypoiodous acid, which produce antimicrobial actions [4]. Another effective drug, Benzydamine Hydrochloride 0.15% w/v (BZ), is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and local anaesthetic properties. It modulates the inflammatory response by inhibiting proinflammatory cytokines such as tumor necrosis factor (TNF-α) and Interlukin- 1β (IL-1 β), thereby alleviating the pain, and decreasing granuloma formation or oedema [5].

Mouth gargling has been an effective strategy in managing upper respiratory tract infections or inflammations [6]. Despite the availability of these treatments, none of the prior studies have directly compared the efficacy between 2% PI and 0.15% BZ topical gargles in patients with chronic pharyngitis secondary to GERD/ LPRD. Therefore, this study aims to evaluate and compare the efficacy of these two drugs in alleviating symptoms and improving clinical outcomes in this patient population.

MATERIALS AND METHODS: This is a prospective, randomized, open-label and parallel group study. This study was performed on patients suffering from chronic pharyngitis secondary to GERD/LPRD visiting the outpatient department (OPD) of Otorhinolaryngology in a tertiary care hospital, India. The study protocol was approved by the Institutional Ethics Committee (No. RVMIMS & RC-2022-08530). All patients with chronic nonspecific pharyngitis secondary to GERD/LPRD were included in the study after taking an adequate consent. A total of 100 patients have been incorporated by using random sampling method and divided them into two groups each containing 50 subjects. Patients in Group 1 were advised to gargle for 30 seconds with PI (2% w/v) whereas Group2 subjects with BZ (0.15% w/v) 4 times in a day for 30 days. In addition, patients were advised to take Omeprazole (20mg) and Cinitapride (3mg) orally once in a day (30min before breakfast) for 30 days. All the subjects with chronic pharyngitis were suggested to make lifestyle modifications i.e. avoid spicy food, dinner 2 hours before bedtime, etc. Patient assessment was done on visit 1(at baseline), visit 2 (15^{th} day) and visit 3 (30^{th} day) during the study period.

Clinical improvement in symptoms like irritation in throat, difficulty in swallowing food, breathing difficulties, sensation of a lump in throat, need to clear throat, hoarseness of voice, heart burn, chest pain, indigestion etc. were assessed by using Reflux Symptom Index(RSI) and Visual Analogue Scale(VAS) [7, 8]. All patients have undergone laryngoscopy for the evidence of complications.

Inclusion Criteria:

1. Patients of either sex aged 21-60 years with complaints of chronic pharyngitis
2. Diagnosed with chronic pharyngitis secondary to GERD/ LPRD, confirmed by clinical assessment and history of reflux symptoms.
3. Symptoms of chronic pharyngitis for at least 3 months.
4. Patients who gave written informed consent and willing for a 30 days follow up

Exclusion Criteria:

1. Paediatric & geriatric age groups
2. Patients with globus pharynges
3. Acute condition of pharyngitis
4. Infective state of pharyngitis/laryngitis
5. Space occupying lesions in throat
6. History of hypersensitivity to PI or BZ.

7. Pregnant or breastfeeding women.
8. Presence of severe comorbid conditions (e.g., active cancer, uncontrolled diabetes).
9. Inability to perform gargling due to cognitive or physical limitations.

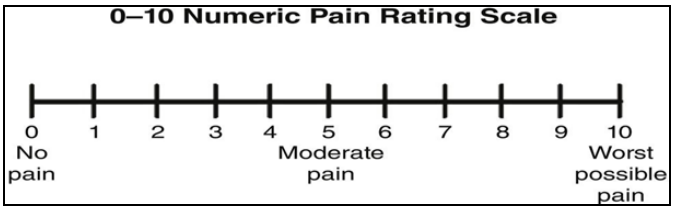
Primary Outcome Measures: Clinical diagnosis of symptomatic improvement was assessed by using following parameters;

Reflux Symptom Index (RSI):

Reflux symptoms	Score
Hoarseness or a problem with your voice	0-1-2-3-4-5
Clearing your throat	0-1-2-3-4-5
Excess throat mucus or post-nasal drip	0-1-2-3-4-5
Difficulty in swallowing food, liquids or pills	0-1-2-3-4-5
Coughing after you ate or after lying down	0-1-2-3-4-5
Breathing difficulties or choking episodes	0-1-2-3-4-5
Troublesome or annoying cough	0-1-2-3-4-5
Sensation or something sticking in your throat or a lump in your throat	0-1-2-3-4-5
Heartburn, chest pain, indigestion, or stomach acid coming up	0-1-2-3-4-5

The RSI is a type of questionnaire used to assess the severity of chronic pharyngitis with LPRD/GERD symptoms. The RSI a 9-item self-administered tool demonstrates high validity and reproducibility in quantifying reflux symptoms. It is more rapid and convenient tool to use for clinicians and patients. The overall score from RSI was calculated based on the patient's response to the clinician questions on various reflux symptoms. For each symptom, the score is counted from 0 to 5 based on the severity experienced by the subject. The Scores range from 0 (best) to 45 (worst), with >13 is considered as diagnostic for LPRD. The RSI provides a useful score-card for confirming the diagnosis, counseling patients, and tracing gradual symptom resolution [9].

Visual Analogue Scale (VAS): A VAS was used to assess the chronic pharyngitis. This scale has 10cm line in which the left end of the line i.e. 0cm indicates minimal or no severity and right end of the line i.e. 10cm signifies the maximum severity of the pain. This scale is useful as a quantitative measure to understand the severity of disease [10].



Statistical Analyses: The results of the study were statistically evaluated using SPSS version [20]. Results were expressed as Mean±SD and Percentages. Comparison between two individual groups was performed using the Mann Whitney U test. Wilcoxon signed-rank test was used to assess within group to compare visits. In all the analyses, a probability value of $p<0.05$ was considered as statistically significant.

RESULTS AND DISCUSSION: Chronic pharyngitis is one of the common complaints seen in Otorhinolaryngology clinic. The factors like exposure to allergens, smoking, drinking, snoring and most importantly LPRD/GERD are the main causes of above condition. The patients suffering from laryngopharyngeal reflux may benefit from lifestyle modifications such as changes in diet, losing weight and stress control. Proton-pump inhibitors like Omeprazole can help to treat symptoms associated with this condition [11].

TABLE 1: DEMOGRAPHIC DATA

Age Range (in years)	No. of Cases/Frequency
21-30	16%
31-40	24%
41-50	29%
51-60	31%

Various age group of patients were expressed as percentage

The patient's age recruited in this study ranging from 21-30yrs (16%), 31-40yrs (24%), 41 -50yrs (29%) and 51-60yrs (31%) respectively summarized in **Table 1.**

TABLE 2: VAS SCORE ANALYSIS OF TREATMENT GROUPS

Group	Visit 1	Visit 2	Visit 3	%VAS=0 at Visit 3
Povidone-Iodine	8.42 ± 1.25	5.72 ± 0.95	0.62 ± 0.70	50%
Benzydamine	8.32 ± 1.43	5.52 ± 1.06	0.48 ± 0.58	56%

All the values were expressed in Mean±SD. Both groups showed significant pain reduction ($p < 0.005$ for all visits). -Within-group: Wilcoxon signed-rank test. - Between-group: Mann-Whitney U test.

To assess the severity of chronic pharyngitis, our study utilized the VAS and RSI scales to evaluate both pain intensity and quality-of-life impact. Baseline assessments of both groups have shown no significant difference at visit 1(PI: 8.42±1.25 vs BZ: 8.32±1.43**)**. All the patients in both treatment groups presented significant reduction in VAS scores from visit 1 to visit 3 ($p<0.001$). However, the BZ group demonstrated statistically superior efficacy ($p<0.001$) at visit 3 compared to the PI group (0.48±0.58 vs 0.62±0.70; $p=0.014$), though both therapies yielded substantial clinical improvement. The proportion of patients achieving complete pain relief (VAS=0) was greater in the BZ group (56% vs 50%), though this difference was not statistically significant ($p=0.539$). BZ group exhibited a slightly quick initial response compared to PI group (Visit 2: 5.52 vs 5.72). The statistical comparisons of results were presented in **Table 2.** Earlier study by *Chaitanya V et al*. also evidenced that BZ gargle had better control compared to PI gargle to manage post tonsillectomy pain [12]. BZ is a topical non-steroidal anti-inflammatory drug acts by inhibiting prostaglandin synthesis thereby inhibiting the synthesis of pro-inflammatory cytokines such as tumor necrosis factor-α and interlukin-1β [13].The enhanced therapeutic effect of PI may be attributed to its dual antiseptic and anti-inflammatory properties, which modulate pro-inflammatory cytokines and promote tissue healing [14].

TABLE 3: RSI OFPOVIDONE-IODINE (2%W/V) GROUP

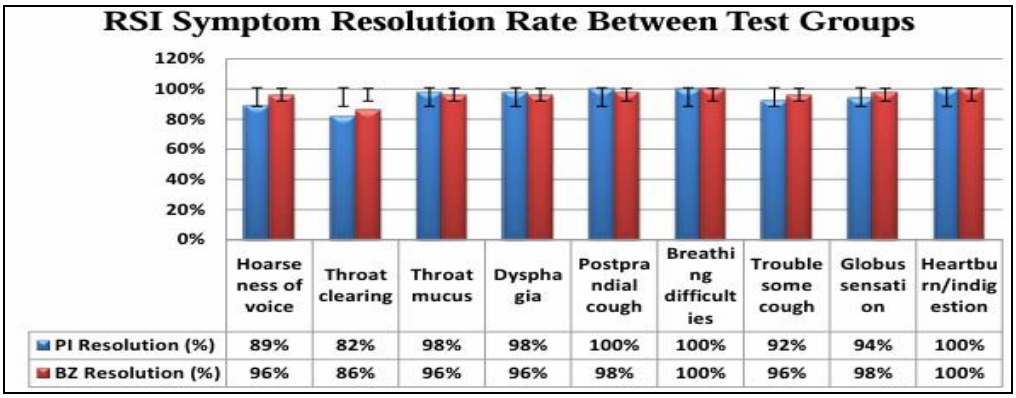
Symptom	Visit 1 Number (%)	Visit 2 Number (%)	Visit 3 Number (%)	Reduction (%)
Hoarseness	23(46)	14(28)	05(10)	78.3
Throat clearing	18(36)	12(24)	09(18)	50.0
Excess mucus	17(34)	06(12)	01(02)	94.1
Dysphagia	10(20)	06(12)	01(02)	90.0
Postprandial cough	16(32)	04(08)	00(00)	100.0
Breathing difficulties	14(28)	06(12)	00(00)	100.0
Troublesome cough	26(52)	15(30)	04(08)	84.6
Globussensation	30(60)	13(26)	03(06)	90.0
Heartburn/indigestion	13(26)	05(10)	00(00)	100.0

* All the symptoms results were expressed as percentage ($p<0.05$). -Within-group: Wilcoxon signed- rank test.

TABLE 4: RSI OF BENZYDAMINE HYDROCHLORIDE (0.15% W/V) GROUP

Symptom	Visit 1 Number (%)	Visit 2 Number (%)	Visit 3 Number (%)	Reduction (%)
Hoarseness	25(50)	10(20)	02(04)	92.0
Throat clearing	14(28)	10(20)	04(08)	71.4
Excess mucus	19(38)	11(22)	02(04)	89.5
Dysphagia	09(18)	06(12)	01(02)	88.9
Postprandial cough	12(24)	05(10)	01(02)	91.7
Breathing difficulties	12(24)	04(08)	00(00)	100.0
Troublesome cough	25(50)	10(20)	02(04)	92.0
Globus sensation	32(64)	14(28)	01(02)	96.9
Heartburn/indigestion	15(30)	04(08)	00(00)	100.0

*All the symptoms results were expressed as percentage ($p<0.05$). -Within-group: Wilcoxon signed-rank test.



GRAPH 1: REFLUX SYMPTOM INDEX SCORE. *All the symptoms results were expressed as percentage ($p<0.05$). Between-group: Mann-Whitney U test.

To determine RSI, a questionnaire was employed to assess on the quality of life during chronic pharyngitis associated with LPRD/GERD. It served as a better tool to represent the severity of chronic pharyngitis associated with LPRD/GERD through an effective translation of the subject perception and quality of life. Bhargava A *et al.* identified throat pain (71%) as the predominant symptom, succeeded by foreign-body/lump sensation (55%), and hyperemia (72%) as the most common sign in RSI15.Anotherstudyreported that throat clearing is the most frequent symptom followed by sensation of a lump in throat [16]. In contrast, our study results indicated that with lump sensation (62%) being most common, followed by troublesome cough (56%), hoarseness of voice (52%) and excess throat mucus (36%). Both PI and BZ groups have shown substantial improvement in all RSI symptoms. The results were summarized in **Table 3** and **Table 4**.

PI group has shown 100% resolution in three symptoms (postprandial cough, breathing difficulties and heartburn/indigestion), while BZ achieved 100% improvement in breathing difficulties and heartburn/indigestion. The composite symptom burden is reduced by 85.6% in the BZ group and 82.8% in the PI group. There was no statistical significant difference between any individual symptoms between two groups ($p>0.05$) presented in Graph 1. At Visit 3, the composite symptom burden observation was 23 for PI and 13 for BZ, but no statistical significant difference found in between two groups ($p=0.095$). PI gargling can help to manage reflux associated symptoms especially those related to throat inflammation. These effects are attributed to antimicrobial effect of PI which suppresses microbial overgrowth. Treatment with BZ also has shown effective control of neurogenic symptoms such as globus sensation and hoarseness of voice due to neuromodulatory and anti-inflammatory effects. However, in chronic pharyngitis, anti-inflammatory action of BZ seems to be the main cause of improvement in neurogenic symptoms [17].

For chronic pharyngitis, BZ is often recommended as first-line therapy over PI. Its superior anti-inflammatory and analgesic properties make it particularly effective for managing chronic sore throat discomfort. PI offering a potent antiseptic effect alongside anti-inflammatory action may be better suited for specific situations requiring strong microbial control. BZ, a NSAID with local anesthetic effects, directly alleviates throat pain and inflammation. In contrast, PI primarily exerts antiseptic action, targeting bacterial and microbial growth. Clinical evidence suggests BZ is more effective than PI in reducing throat pain, particularly in chronic pharyngitis where symptom reliefiscrucial. While both agents may cause mild throat irritation, PI carries a higher risk of a burning sensation, especially with prolonged use. Most of our patients responded favorably to a combination of Omeprazole (20mg) and Cinitapride (3mg) orally for 4 weeks.

CONCLUSION: This study concludes that both PI (2%w/v) and BZ (0.15% w/v), when combined with Omeprazole and Cinitapride, effectively control chronic pharyngitis symptoms associated with LPRD/GERD. The PI group exhibited marginally superior symptom resolution, attributable to its dual antiseptic and anti-inflammatory actions. While BZ remains a preferred first-line option for its analgesic and anti-inflammatory properties, these findings suggests PI as an effective alternative in cases requiring enhanced antimicrobial action. Ultimately, individualized selection of treatment guided by symptom profile and patient response remains important for optimal management of this condition.

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CONFLICT OF INTEREST: Nil

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