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RESEARCH ARTICLE

Flavoured Betadine Gargle as A Child-Friendly Therapeutic Alternative to Conventional Gargle in Pediatric Acute Tonsillitis: A Randomized Controlled Study

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Abstract: ***Introduction***: This ground breaking prospective randomized control study compares the efficacy of flavoured betadine gargle over conventional betadine gargle in children with acute tonsillitis. ***Background***: Acute tonsillitis, most commonly caused by viral or bacterial infections is more common among paediatric patients. It often involves systemic antibiotics and analgesics however the prevalence of antibiotic resistance and side effects warrants new ways of treatment ***Objective***: To signify the efficacy of the drug in controlling local infection and to know the compliance of the usage of drug in paediatric population. ***Methods***: A prospective randomized controlled study was conducted at the Department of ENT, Saveetha Medical College and Hospital, Chennai, over six months from October 2023. 68 children with acute tonsillitis were included in this study and were divided into two groups: Group A (34 patients were given conventional betadine gargle) and Group B (34 patients were given flavoured betadine gargle) and both the groups were assessed by a questionnaire comprising of WONG BAKER FACES PAIN RATING SCALE. ***Results***: The results show that the flavoured betadine gargle is better than conventional betadine gargle in acute tonsillitis with a significant p value ($p < 0.05$) using paired t-test and unpaired t-test ***Conclusion***: This study proves that the flavoured betadine gargle offers a dual-action approach which addresses both the infectious and inflammatory nuances thus standing as a promising drug in the management of acute tonsillitis in children.

Keywords: Betadine gargle, Flavoured, Conventional, Acute tonsillitis, Development, Health care.

INTRODUCTION

Acute tonsillitis is a common condition in children characterized by inflammation of the tonsils. Most commonly caused by viral or bacterial organism, such as streptococcus bacteria Symptoms include sore throat, difficulty in swallowing, lymphadenopathy fever, and whitish patches seldom. Viral tonsillitis is mostly self-resolving with supportive care like rest, fluids, and pain relievers. Bacterial infections require antibiotics to prevent complications such as rheumatic fever or glomerulonephritis.

The inflammation of tonsils is part of the body's immune response to infection, where immune cells gather to combat pathogens entering through the mouth and nose. Frequent occurrences of acute tonsillitis or persistent symptoms may indicate chronic tonsillitis, which can lead to recurrent infections and potential complications. In refractory cases, tonsillectomy may be done. Management of acute tonsillitis focuses on alleviating symptoms, identifying the cause, and, if necessary, administering appropriate medical interventions to ensure recovery and prevent complications.

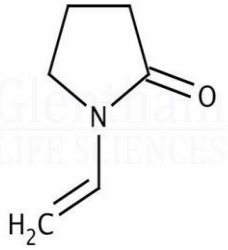
Gargling with antiseptic mouthwashes plays a vital role in maintaining oral hygiene. It acts by reducing the load of micro-organisms. Studies have shown that chlorhexidine mouthwash, inhibits plaque accumulation and reduced gingival inflammation (19). Herbal mouthwashes constituting of contents like coconut oil, castor oil have shown promising results (20). Regular use of these mouthwashes as part of daily oral care routines can help prevent oral diseases by controlling bacterial growth in the oral cavity (21). Therefore, incorporating gargles with appropriate mouthwashes can be effective in oral hygiene.

Betadine gargle is a topical antiseptic solution. When used as a gargle, Betadine helps to reduce the microbial load in the throat and mouth, making it beneficial. Clinically, Betadine gargle is often recommended for its rapid action and effectiveness in reducing the severity and duration of throat infections.

Flavoured betadine gargle is a modified version of the conventional betadine gargle providing an effective means of prevention in case of acute tonsillitis. It combines the broad-spectrum antiseptic properties of povidone-iodine with the anti-inflammatory and anti-oxidant effects, acting as a promising intervention. Research has shown its effectiveness in alleviating pain and reducing microbial burden in the oropharynx [1]. This holistic approach of this new drug paves a new path in the field of health care. Hence the development of flavoured Betadine gargle acts as a useful tool in the treatment and prevention of acute tonsillitis in paediatric population. It comprises of 2% Povidone iodine – antiseptic

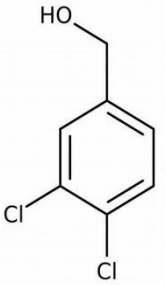
Povidone iodine acts by releasing free iodine, which affects the integrity by disrupting the microbial membranes and proteins thus inhibiting their growth and viability. It has emerged as a promising treatment for

tonsillitis due to its broad-spectrum antimicrobial properties. Studies have shown that povidone-iodine gargle significantly reduces throat pain and microbial load in acute tonsillitis cases [2]. Furthermore, it has been demonstrated to effectively prevent recurrent infections by eliminating pathogens implicated in tonsillitis [3]. The safety profile of povidone-iodine throat spray has also been well-established, making it a viable alternative to traditional antibiotics [4]. Economically, its use has been supported by health economic evaluations indicating cost-effectiveness in managing tonsillitis [5].



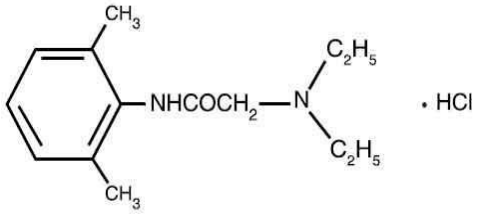
a) 2, 4 - Dichlorobenzyl alcohol – antitiseptic

Dichlorobenzyl alcohol, a most commonly used agent in lozenges and throat sprays, shows its antimicrobial effects by affecting the microbial cell membrane and inhibiting enzyme activity [8]. This mechanism helps reduce microbial colonization and prevents the progression of tonsillitis [6]. Moreover, dichlorobenzyl alcohol has shown tolerability in clinical settings, making it a viable option for tonsillitis [7].



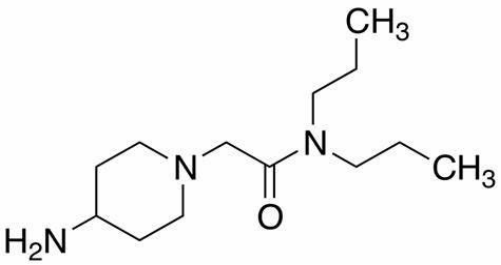
b) 4% Lignocaine – anaesthetic

Lignocaine, a local anaesthetic, acts by blocking sodium channels in nerve membranes, acts by inhibiting nerve impulses, providing temporary relief from pain [9]. This mechanism helps alleviate throat discomfort and facilitates easier swallowing [10]. Studies have confirmed lignocaine's efficacy in reducing pain intensity [11]. Additionally, its safety profile has been established through multicentre studies [12]. Lignocaine's role extends beyond symptomatic relief, making it a valuable addition in the comprehensive treatment of tonsillitis.



d) Benzydyamine – anti-inflammatory

Benzydamine, employed in throat sprays and gargles, exerts its effects through several mechanisms, including anti-inflammatory and local anesthetic properties [13]. By inhibiting prostaglandin synthesis and stabilizing cell membranes, benzydamine reduces pain and inflammation associated with acute tonsillitis [14]. Studies have demonstrated its efficacy in improving swallowing ability in patients [15]. Furthermore, its tolerability and suitability for widespread clinical use has been established [16]. Its multifaceted action makes benzydamine a valuable therapeutic option in managing symptoms of tonsillitis effectively.



e) Honey – Flavouring agent

Honey has gained recognition for its dual roles as both an anti-inflammatory and antioxidant agent in medical research. Studies have shown that honey possesses potent anti-inflammatory properties, which can aid in reducing inflammation associated with various conditions [22]. Its ability to modulate inflammatory responses is attributed to its rich composition of polyphenols and flavonoids, which exert antioxidant effects by scavenging free radicals and preventing oxidative damage to cells and tissues [23]. Moreover, honey's anti-inflammatory action is not limited to topical applications but also extends to internal use [24]. The darker honeys generally exhibit higher antioxidant levels due to their higher phenolic content [25]. As a natural remedy, honey continues to be explored for its therapeutic potential in combating oxidative stress and inflammation, offering promising avenues for integrative medicine and complementary therapies.

AIMS AND OBJECTIVES:

To study the following

1. Efficacy of the drug in controlling local infection
2. Compliance in the usage of this drug in paediatric population

METHODOLOGY:

Study design and location: This study was designed as a descriptive observational analysis and conducted in the Department of ENT at Saveetha Medical College and Hospital, Chennai. The data collection was carried out over a six-month period, beginning in October 2024 and ending in March 2025.

Study location: The research included 68 children who were clinically diagnosed with acute tonsillitis and attended the ENT outpatient services during the study duration. Participants were assigned equally into two groups (34 children each) to compare the effectiveness of two different gargle preparations.

Inclusion Criteria:

- ❖ Children aged 5 to 15 years with a confirmed diagnosis of acute tonsillitis.
- ❖ Ability and willingness to perform gargling under supervision or with parental assistance.
- ❖ No recent use (within 48 hours) of systemic antibiotics or antiseptic gargles.
- ❖ Availability for follow-up during the 7-day observation period.
- ❖ Informed consent obtained from parents or guardians.

Exclusion Criteria:

- ❖ Known allergy to iodine or any component of povidone-iodine formulations.
- ❖ Children with chronic tonsillitis or underlying systemic illnesses.
- ❖ Immunocompromised status or coexisting infections.
- ❖ Incomplete documentation or loss to follow-up.
- ❖ Requirement for antibiotic therapy during the study period.
- ❖ Group Allocation:

- ❖ Group A: 34 children administered flavoured Betadine gargle (povidone-iodine with added flavouring).
- ❖ Group B: 34 children given conventional Betadine gargle (standard povidone-iodine solution without flavouring).

Evaluation: Participants were assessed using a structured questionnaire that included the Wong-Baker FACES Pain Rating Scale to measure throat pain severity. The scale was administered to track symptom improvement. Additional questions were used to evaluate compliance, ease of use, and palatability of the gargles, with responses recorded from both the child and caregiver perspectives.

Statistics: An independent t-test was applied to compare mean pain scores between the two groups at different time points. The Chi-square test was used to analyse categorical variables such as compliance and willingness to continue treatment. A p-value <0.05 was considered statistically significant for all comparisons.

RESULTS:

Parameter	Group A (Flavoured Betadine Gargle)	Group B (Conventional Betadine Gargle)	Statistical Test	p-value	Interpretation
Sample Size (n)	34	34	—	—	—
Mean Pain Score	3.2	5.4	Independent t-test	< 0.001	Significant
Gender Distribution	18 M / 16 F	17 M / 17 F	Chi-square	0.85	Not Significant

The study involved a total of 68 children diagnosed with acute tonsillitis, evenly divided into two groups: Group A (flavoured Betadine gargle) and Group B (conventional Betadine gargle), with 34 participants in each. This equal distribution allowed for effective comparison between the two treatment approaches.

Gender Distribution:
Group A comprised 18 males and 16 females, while Group B included 17 males and 17 females. A Chi-square test was applied to assess gender distribution across both groups, yielding a p-value of 0.85. This result indicates no statistically significant difference in gender distribution, suggesting comparability in demographic characteristics.

Pain Score Comparison:
The mean pain score was significantly lower in Group A (3.2) than in Group B (5.4). An independent t-test was used to evaluate this difference, resulting in a p-value of less than 0.001. This demonstrates a statistically significant improvement in pain relief with the flavoured Betadine gargle.

Treatment Response	Group A	Group B			
- Improved	30	20	Chi-square	0.002	Significant
- No Change	4	10			
- Worsened	0	4			

Treatment Response: Among Group A, 30 children showed improvement, 4 experienced no change, and none worsened. In contrast, Group B had 20 children improve, 10 show no change, and 4 worsen. The Chi-square test revealed a p-value of 0.002, indicating a significant difference in treatment effectiveness favoring Group A.

DISCUSSION:

The present study aimed to compare the effectiveness of flavoured Betadine gargle with conventional Betadine gargle in children suffering from acute tonsillitis. The results clearly demonstrate a superior therapeutic response in the group treated with the flavoured formulation. The significant reduction in mean pain scores suggests that the flavoured gargle is not only effective but may also enhance patient comfort and acceptability, especially in pediatric populations who are often resistant to bitter-tasting medications. However there are no other studies contributing to this result.

Furthermore, treatment outcomes showed a statistically significant difference in favor of the flavoured gargle group. A higher number of children in Group A reported improvement (88.2%) compared to Group B (58.8%), while none in Group A experienced worsening symptoms. This may indicate better compliance due to improved taste and tolerability, which are critical factors in pediatric care.

Gender distribution was similar between groups, confirming that demographic differences did not influence outcomes. These findings support the use of flavoured antiseptic gargles as a child-friendly alternative in managing acute tonsillitis, potentially leading to improved adherence and faster symptom resolution.

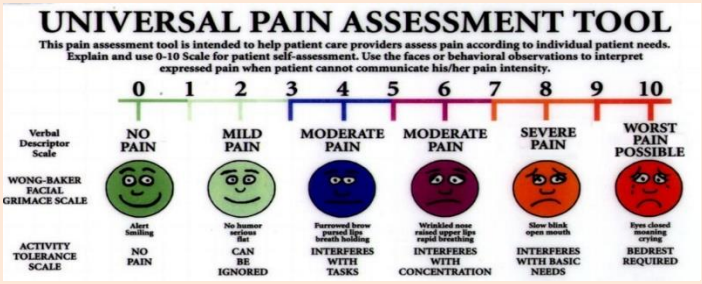
CONCLUSION:

The use of anaesthetic flavoured Betadine gargle has shown promising results in managing acute tonsillitis-related pain in children. Its enhanced taste and better tolerability may lead to improved compliance, particularly in pediatric populations that often resist bitter or unpleasant-tasting medications. This formulation not only provides effective antiseptic action but also contributes to pain relief, as reflected in the significantly lower pain scores and better treatment outcomes observed. As a result, flavoured Betadine gargle may be considered a more suitable and effective alternative to conventional formulations in clinical practice. Healthcare professionals should ensure the gargle is properly diluted and administered as per recommended guidelines. Educating caregivers and children on correct gargling techniques is essential to maximize therapeutic benefit and reduce the risk of ingestion or misuse.

For broader clinical application and policy development, further studies are necessary. Large-scale, multi-center trials with extended follow-up periods are recommended to confirm the current findings. These future studies should also explore long-term outcomes, recurrence rates, and patient satisfaction to establish a comprehensive understanding of the treatment's effectiveness and safety.In future the use of technology will be helpful in augmenting diagnostics by creating new methods like organ in chips (17) and nanoparticles (18) thus overcoming the cumbersome method of diagnosis.

ANNEXURE NAME OF THE PARTICIPANT: INFORMANT: AGE / GENDER:

S. NO.	QUESTIONS	1 POINT	2 POINTS	3 POINTS
1.	WHICH AGE GROUP DO THE PARTICIPANT BELONG TO? 5-7 8-10 11-12	OPTION (A)	OPTION (B)	OPTION (C)
2.	WHAT IS THE DURATION OF THE DISEASE? < 5 DAYS 5 -10 DAYS > 10 DAYS	OPTION (A)	OPTION (B)	OPTION (C)
3.	WHAT IS THE FREQUENCY OF THE DISEASE? ACCORDING TO PARADISE CRITERIA: ATLEAST 7 EPISODES IN THE PREVIOUS YEAR ATLEAST 5 EPISODES IN EACH OF THE PREVIOUS TWO YEARS ATLEAST 3 EPISODES IN EACH OF THE PREVIOUS THREE YEARS	OPTION (A)	OPTION (B)	OPTION (C)
4.	IS THERE ANY PREVIOUS HISTORY OF HOSPITALIZATION? WAS ON IV ANTIBIOTICS ONLY WAS ON IV ANTIBIOTICS AND BETADINE GARGLE NO	OPTION (A)	OPTION (B)	OPTION (C)
5.	FOR HOW MANY DAYS DID YOU USE THIS DRUG? INFREQUENT USE USED FOR LESS THAN THE PRESCRIBED DAYS USED FOR THE PRESCRIBED DAYS	OPTION (A)	OPTION (B)	OPTION (C)
	QUESTIONS	1	2	

S. NO		POINT	POINTS	3 POINTS
6.	HOW WOULD YOU RATE THE PAIN AFTER THE USAGE OF THIS DRUG?  SEVERE TO WORST PAIN MODERATE PAIN MILD TO NO PAIN	OPTION (A)	OPTION (B)	OPTION (C)
7.	HOW IS THE CONGESTION OF TONSILS AFTER FINISHING THE COURSE OF THIS DRUG? PERSISTENT CONGESTION MILD TO RESOLVING CONGESTION NO CONGESTION	OPTION (A)	OPTION (B)	OPTION (C)
8.	WAS THIS DRUG USED UNDER PARENT'S SUPERVISION? NO SOMETIMES YES	OPTION (A)	OPTION (B)	OPTION (C)
9.	WAS IT GIVEN ON AN OP/ IP BASES? IP OP BOTH	OPTION (A)	OPTION (B)	OPTION (C)
S. NO.	QUESTIONS	1 POINT	2 POINTS	3 POINTS
10.	HOW IS THE FEEDING HABIT OF THE PATIENT AFTER FINISHING THE COURSE OF THIS DRUG? ABLE TO TAKE ONLY LIQUID DIET ABLE TO TAKE ONLY SEMI-SOLID DIET ABLE TO TAKE BOTH SOLIDS AND LIQUIDS	OPTION (A)	OPTION (B)	OPTION (C)

OVERALL SCORING: 10 - 15 ----- AVERAGE 16 – 25 ---- GOOD 25 – 30 ---- BETTER				

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