



Randomised Controlled Trial of Salt Solution (Sodium Chloride) Mouth Wash vs Thymol Glycerine Usage in Sore Throat with Non Bacterial Pharyngitis

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Authors' contributions

This work was carried out in collaboration between both authors. Author MAEBMS designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Author MAEBMS managed the analyses of the study. Author MZBAB managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Backgrounds: Sore throat is one of the most common reasons for visits to the hospital. While most patients with sore throat have an infectious cause (pharyngitis), either bacterial or viral infection, fewer than 20 per cent have a clear indication for antibiotic therapy.

Objective: The aim of this study is to investigate the patient's clinical outcome after using a salt solution (sodium chloride) and thymol glycerine mouth wash in the evaluation of sore throat patient with non bacterial pharyngitis.

Methods: This was a randomized clinical trial, in which 100 patients who had non-bacterial pharyngitis were divided into two groups: those who gargled a salt solution (sodium chloride 3%) and those who gargled a thymol solution. A sore throat questionnaire was filled out 1 week later.

Results: Demographically, the results showed that there were significant differences between the two groups with regard to gender. However, there was no significant difference in age of the

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patients. A significant difference was observed between the two groups in term of sore throat pain scale, difficulty swallowing scale and swollen throat scale. All p-value are <0.001.
Conclusion: Gargling a salt solution, a natural, and harmless substance, can reduce the pain and other symptom of sore throat in patients with non-bacterial pharyngitis.

Keywords: Salt solution; mouth wash; thymol glycerine; sore throat; bacterial pharyngitis.

1. INTRODUCTION

Sore throat is one of the most common reasons for visits to the hospital. While most patients with sore throat have an infectious cause (pharyngitis), either bacterial or viral infection, fewer than 20 percent have a clear indication for antibiotic therapy.

Most infectious pharyngitis has a viral cause. The use of nonsteroidal antiinflammatory agents (NSAIDs) and mouth wash gargle is advised for the treatment of pain [1].

There are few mouth wash gargle available in the market and frequently used in the hospital. Table salt are among the most frequently used as a mouth wash in the treatment of sore throat at home but not much research has been conducted comparing the efficacy of those gargle especially in Asian region.

The main purpose of this study is to investigate the patient's clinical outcome after using a salt solution (sodium chloride) and thymol glycerine mouth wash in the evaluation of sore throat patient with non bacterial pharyngitis.

So, this study will provide us a better understanding of the treatment plan especially the mouth wash usage in the disease studied.

2. METHODOLOGY

This prospective randomised controlled study was performed in 100 patients who have non-bacterial pharyngitis from February 2019 until July 2019. 100 patients are required to have a 80% chance of detecting, as significant at the 5% level, a significant difference in mean changes for sore throat pain scale, difficulty in swallowing scale and swollen throat scale between experimental group (salt solution mouth wash) and control group (thymol usage). Subjects were randomly selected from Otorhinolaryngology clinic, University Malaya Medical Centre.

Patient with sore throat of non bacterial pharyngitis (modified centor score of 0 and 1),

more than 18 years old, no recent oral surgery (more than 6 weeks), and no recent oral intubation (more than 6 weeks) were included in the study.

Inability or unwillingness to provide consent, less than 18 years old, inability or unwillingness to comply with the requirements of the protocol as determined by the investigator, patients with recent oral surgery (less than 6 weeks), recent oral intubation (less than 6 weeks) and sore throat of bacterial pharyngitis were excluded from the study.

The Sore Throat Scoring Criteria 'Modified Centor Score' is used to screen the patients of non bacterial pharyngitis. Patient is asked to gargle with sodium chloride 3% or thymol glycerine mouthwash respectively at least three times per day for 1 week. Evaluation of the patient's clinical outcome is done after 1 week using a simple sore throat questionnaire (sore throat pain scale, difficulty swallowing scale and swollen throat scale)

2.1 Sore Throat Scoring Criteria

2.1.1 Modified centor score (mcissac score)

The original Centor score uses four signs and symptoms to estimate the probability of acute streptococcal pharyngitis in adults with a sore throat. The score was later modified by adding age. The cumulative score determines the likelihood of streptococcal pharyngitis and the need for antibiotics.

Patients with a score of zero or 1 are at very low risk for streptococcal pharyngitis and do not require testing (i.e., throat culture or rapid antigen detection testing [RADT]) or antibiotic therapy.

Patients with a score of 2 or 3 should be tested using RADT or throat culture; positive results warrant antibiotic therapy.

Patients with a score of 4 or higher are at high risk of streptococcal pharyngitis, and empiric treatment may be considered.

2.1.2 Sore throat pain scale (PS)

Patients were asked to indicate the degree of sore throat pain during swallowing. A 100 mm visual analog scale where 0="not difficult" and 10="very pain".

2.1.3 Difficulty swallowing scale (DSS)

Patients were asked to indicate the degree of difficulty in swallowing. Difficulty Swallowing Scale (DSS), a 100 mm visual analog scale where 0="not difficult" and 10="very difficult".

2.1.4 Swollen throat scale (SwoTS)

They were also asked to indicate how swollen their throat felt on the Swollen Throat Scale (SwoTS), a 100 mm visual analog scale where 0="not swollen" and 10="very swollen".

the P-value for age is 0.343 which is >0.05. Hence, there is no significance difference between both groups.

The descriptive statistics for sore throat pain scale, difficulty swallowing scale, swollen throat scale by group before and after treatment are shown in Table 2.

The difference in score before and after were computed for sore throat pain scale (PS), swallowing difficulty scale (DSS) and swollen throat scale (SwoTS). The difference were compared between salt and thymol using independent samples t-test. For all tests the variances were similar. The results for the test of mean differences are shown in Table 3.

Table 1. Demographic characteristic of the respondents

Variable	Salts	Thymol	p
Gender			0.005
Female	36(72.0%)	22(44.0%)	
Male	14(28%)	28(56.0%)	
Age	44.0 ±19.7	45.9 ±19.4	0.343

3. RESULT

As shown in demographic data in Table 1, the p-values for gender are < 0.05. Hence, there are significant difference in female and male between the salt and thymol group. However,

Table 2. Descriptive statistics for PS, DSS, SwoTS by group

Group		Mean	N	Std. deviation	Std. error mean
Salt	PS before	5.22	50	1.844	.261
	PS after	1.32	50	1.151	.163
	DSS before	5.04	50	1.873	.265
	DSS after	1.12	50	1.081	.153
	SwoTS before	4.74	50	1.946	.275
	SwoTS after	.80	50	.881	.125
Thymol	PS before	6.00	50	2.090	.296
	PS after	4.46	50	1.843	.261
	DSS before	5.86	50	1.980	.280
	DSS after	4.32	50	1.823	.258
	SwoTS before	5.66	50	1.996	.282
	SwoTS after	4.08	50	1.816	.257

Table 3. Difference in mean change

	Group	N	Mean	Std. deviation	P
Change in throat pain	Salt	50	3.9000	2.47642	<0.001
	Thymol	50	1.5400	1.86493	
Change in difficulty swallowing	Salt	50	3.9200	2.45648	<0.001
	Thymol	50	1.5400	1.86493	
Change in swollen throat	Salt	50	3.9400	2.43621	<0.001
	Thymol	50	1.5800	1.81928	

As shown in Table 3, all p-values are < 0.001 . Hence, there are significant difference in mean changes for sore throat pain, difficulty in swallowing scale and swollen throat scale between salt and thymol mouth wash. For all comparisons, the mean changes in salt are more than the changes in thymol group.

4. DISCUSSION

A sore throat is a miserable thing to deal with. Most of us do not realize how many times we swallow everyday until every swallow becomes a painful undertaking.

Parent and almost all patients the world over hold the belief that gargling with warm salt water is a surefire way to soothe a sore throat. But does it actually work? Is there any scientific data to prove it?

According to the American Osteopathic Association (AOA), pharyngitis-induced sore throat is one of the most common reasons for doctor visits. Pharyngitis may be caused by bacterial or viral infections [2].

Viruses are the most common cause of sore throats. Pharyngitis is most commonly caused by viral infections such as the influenza, common cold, or mononucleosis. Viral infections do not respond to antibiotics, and treatment is only necessary to help relieve symptoms.

Furthermore, different viruses are more prevalent during certain seasons. [3] Coryza, conjunctivitis, malaise or fatigue, hoarseness, and low-grade fever suggest the presence of viral pharyngitis [4].

The optimal approach for differentiating among various causes of pharyngitis requires a problem-focused history, a physical examination, and appropriate laboratory testing. Sore throat also may be caused by other conditions, such as gastroesophageal reflux, postnasal drip secondary to rhinitis, persistent cough, thyroiditis, allergies, a foreign body, and smoking [5,6,7].

Treating gum disease and intraoral pain with saline rinses appeared in China as early as 2700 before century. [8,9]. It has long been believed that rinsing the mouth with sodium chloride (NaCl) solution can promote healthy gums and fasten oral ulcer healing [10].

Nowadays, many medical practitioners and dentists advise their patients to rinse their mouth

with salt solution as supplementary to routine oral care to maintain oral health [11]. However, up to now, there is no scientific evidence proofing the efficiency of this simple method.

In a previous study, it was shown that usage of salt solution as mouth-rinse in conjunction with routine oral care is able to promote oral wound healing. NaCl stimulates human gingival fibroblast (hGF) cell migration, alters the organization of cytoskeletal molecules (Focal adhesion kinase and F-actin), and enhances extracellular matrix gene expression in wound healing process [12].

The roles of Focal adhesion kinase (FAK) in cell migration and cytoskeletal changes upon hyperosmotic stress or NaCl treatment reported previously will help in healing process in the throat. [13,14] In a previous study also, it was shown that hypertonicity will induces rapid F-actin polymerization and subsequently fasten the healing process [15].

Therefore, rinsing the mouth with salt solution is recognized as the most preferable method for oral wound care. It is an economic and nontoxic way to provide a moist environment to facilitate relieving the sore throat symptoms and the healing of any oral wounds [16,17].

CONCLUSION

Gargling a salt solution, a natural, and harmless substance, can reduce the pain and other symptom of sore throat in patients of non-bacterial pharyngitis.

CONSENT

As per international standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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