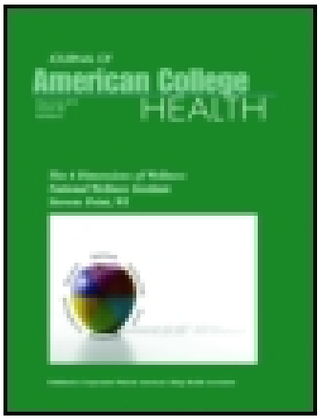

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H. Spencer Turner M.D. [a] , Walton R. Garner M.D. [b] & Richard R. Lanese Ph.D. [c d]

[a] University Health Service, The Ohio State University , 1875 Millikin Road, Columbus, Ohio, 43210, USA

[b] University Health Service, The Ohio State University , USA

[c] Department of Preventive Medicine , USA

[d] Biometrics Laboratory , University Health Service, The Ohio State University , USA

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A Comparative Study of a Phenol-Based Mouthwash as a Gargle or a Spray with a Saline Gargle

H. SPENCER TURNER, M.D.,* WALTON R. GARNER, M.D.,†
RICHARD R. LANESE, Ph.D.‡
The Ohio State University

Introduction

Treatment of sore throat pain with gargles and sprays is an established physician-recommended and consumer-accepted aid for obtaining relief, supplemented, when necessary, with oral analgesics, ice collar, heat, or any other means that may lessen the discomfort of an inflamed pharynx. Solutions used for gargling and/or spraying may contain such varied pharmacologic agents as topical anesthetics, demulcents, or astringents. Warm, salt water is frequently recommended as a gargle that would be expected to remove, to some extent at least, the exudate from the site of inflammation and to provide some local relief from the symptoms.

Studies designed to compare one agent with another for pain relief are made difficult by the subjective nature of the pain experienced for each individual. In that sense, pain is definable only as it is known to each individual by experience; thus, what may be perceived as mild pain by one individual may be perceived by another as moderate to severe. It is, therefore, necessary in studies of pain and pain relief that each individual become his/her own objective control for the subjective experience of pain. Thus, any evaluation of medication for relief of pain must allow the individual to determine the extent to which the medication is effective.

Sore throat is the fourth most common symptom seen in practice,[1] and it has been reported that over 300 million dollars per year are spent for laboatory tests and medications for the diagnosis and treatment of sore throats.[2] Further, there have been numerous reports on management strategies for sore throat,[2-4] or using sore throat management as the basis for quality assessment studies.[4,5] However, an extensive computerized search of the current medical literature revealed only a single report of the evaluation of the effectiveness of topical, nonanesthetic, preparations in the relief of sore throat pain.

Breazeale, reporting in the *Journal of the American College Health Association,* performed a study comparing the effectiveness of the relief of oropharyngeal pain by either a cationic-surfactant preparation or a phenol-based preparation.[6] Isotonic saline was used as a "placebo." On admission to the study, the degree of sore throat pain of each subject was recorded as mild, moderate, or severe. Subjects were given sprayer bottles for use at home with instructions to use the material as a spray, gargle, or rinse every two hours as necessary. Subjects were to then report back to the investigator within 24 to 48 hours, rating degree of pain relief obtained from each preparation as satisfactory or unsatisfactory.

The results of Breazeale's study indicated that ". . . an appropriate mouthwash-gargle preparation offers distinct advantage, in sore throat treatment, over the 'salt water' remedy so frequently recommended by laymen and some physicians: only 22% of the 49 placebo users reported satisfactory relief of pharyngeal discomfort while some two-thirds of the CC (cetyl-pyridinium chloride) users and nearly all of the PB (phenol-based) group reported such relief . . . a phenol-based formulation used as a mouthwash and gargle was significantly more effective than a cationic-surfactant formulation, and both were more effective than an isotonic saline placebo."[6]

Objective

The objective of this study was to compare a phenol-based preparation as a gargle or spray with a warm saline gargle to determine the degree and duration of relief afforded by each test material from sore throat pain.[7]

Selection of Subjects

A total of 150 volunteers of either sex, all of whom were students receiving care at the Ohio State University Health Service, constitute the study sample. The criteria for inclusion of a subject in the study were as follows.

First, the individual was required to be 18 years of age or older. Second, the individual had to have a sore throat described as moderate to severe, with the scale of pain being "zero" for no throat pain to "nine" for severe throat pain. Moderate sore throat pain was defined as a "six." Third, the subject had to be available for a one-hour evaluation after supervised use of the test material and was required to return to the health service three days after the initial evaluation, or as soon thereafter as possible. Fourth, the subject was required to be in general good health, excluding the current illness. Fifth, each individual was required to have a throat culture and a monospot test for mononucleosis. All individuals were required to give their informed consent for participation in the study.

Anyone who required regular use of analgesic agents, such as aspirin, was excluded from the study. Also excluded were those who were undergoing therapy for their sore throat, either with antimicrobial agents or other physician-prescribed medication or self-administered treatment, prior to the visit to the University Health Service. In addition, those who were too ill to be expected to evaluate and record treatment effects, who were sensitive to

*Director, University Health Service, The Ohio State University, 1875 Millikin Road, Columbus, Ohio 43210

†Chief of Environmental Health and Safety, University Health Service, The Ohio State University

‡Professor, Department of Preventive Medicine; Chief, Biometrics Laboratory, University Health Service, The Ohio State University

phenol, unable to gargle proficiently, or who had previously been admitted to the study were excluded.

Medication

The test materials were prepared as follows. The phenol-based gargle was provided in two seven-ounce bottles to each subject with instructions for use. The instructions were as follows: "Use full strength, gargle for 15 seconds, using approximately one capful. Expel. Repeat every two hours as necessary for pain relief."

For those assigned to the phenol-based spray, individuals were supplied two seven-ounce bottles with a sprayer, with the instructions being: "Spray five times. Expel remaining spray solution. Repeat every two hours as necessary for pain relief."

Those assigned saline gargles were given 12 packets, each containing 2.5 grams of salt, with the instructions as follows: "Dissolve each packet of salt in eight ounces of warm water. Gargle eight times using a ½-oz. solution each time, gargling for 15 seconds each time. Repeat every two hours as necessary for pain relief."

It should be noted that the instructions for use of the two phenol-based test materials are those recommended by the manufacturer. The instructions for the use of saline gargles correspond to the typical instructions given to a patient by a physician for the use of this material, that is, two minutes of gargling every two hours.

Procedure

The study was designed as an open parallel study of the three aforementioned agents. The test material to be used was assigned to the subject, as determined by a random sequence, thereby providing for three equal size groups of 50 subjects each. Antibiotics or other antimicrobial agents, if needed, were prescribed by the examining physician. Oral analgesics were limited to either aspirin or acetaminophen and were taken to supplement the use of the study gargles or spray. However, it was requested that oral analgesics not be taken until one hour after a gargle or spray period to avoid possible interference with the evaluation of the effect of the study agents. Further, it was directed that oral analgesics not be taken more frequently than every four hours.

A throat culture and a monospot test for mononucleosis were done on all participants. In addition, other laboratory work was performed as deemed necessary by the examining physician.

Study Procedure

Following evaluation and treatment by the physician, if the subject met the inclusion criteria and desired to participate in the study, he/she was referred to the study coordinator. After confirmation that the individual met all inclusion criteria previously described, the individual was assigned, on a random basis, to one of the three study groups. First, the subject was asked to determine his/her own level of sore throat pain. As previously mentioned, it was necessary, on a scale of zero (no sore throat) to nine (severe sore throat) that the individual have at least a moderate sore throat (defined as a six on the scale). The level of sore throat pain was obtained for zero time, that is, just prior to gargling or spraying. The subject was instructed to use the appropriate test material, following which he/she was to rate the severity of sore throat on the zero to nine scale at intervals of 1, 5, 10, 20, 30, 40, 50, and 60 minutes. The subject was then given the assigned gargle or spray for use at home, according to an accompanying instruction sheet, and was requested to provide an evaluation of the relief of sore throat pain obtained from the first two days of home use of the test product, recording overall evaluation of effectiveness as none, slight, moderate, or very good. In addition, each subject was asked to comment freely upon his/her preparation.

Finally, the subject was asked to revisit the University Health Service the first possible day after completing the two-day period at home. At the time of the return visit, it was ascertained that each individual had properly completed the home use card so that all subjects were observed for symptoms or signs of clinical intolerance to the study material and were asked to report any unwanted effects which they might have attributed to the study drug.

To minimize the effect of multiple observer bias in view of the subjective nature of the study, a single individual was responsible for explaining to all subjects the test procedure, supervising the immediate one-hour use of the test preparation and interviewing the subjects upon their return to the University Health Service.

Statistical Methods

To compare the effects of the phenol-based and saline preparations on sore throat pain, both analysis of covariance and log linear procedures were used.[8] The analysis of covariance examined the changes in sore throat pain over the first 60 minutes following initial treatment. Because there were within subject and between subject sources of variation, a repeated measure, mixed design, was employed. The covariance feature was introduced to adjust for possible differences in initial pain among the three groups of subjects. Since the initial pain rating could take only the values six, seven, eight, and nine, as previously described, four dichotomous ("dummy") variables were entered in this analysis as covariates. The model also includes sex, and eight time periods from one to 60 minutes as well as all interactions.

To determine the relative effects of the test preparations and the saline gargle after two days of prescribed home use, a log linear analysis was employed. This relatively new procedure was selected because the measure of subjective effectiveness used was more a categorical scale than an interval scale. In addition, it is often difficult to make statistical judgments about categorical data that are cross-tabulated when there are more than two factors to be considered simultaneously. The log linear analysis is particularly suitable in this situation. The factors in the frequency matrix of the saturated model used here were treatment group, sex, levels of initial pain, and levels of effectiveness after two days, a $3 \times 2 \times 4 \times 4$ matrix.

Results

Even though subjects were randomly assigned to the three study groups, phenol-based spray, phenol-based gargle, and saline gargle, additional statistical precautions were taken to assure the equivalence of subjects across groups. Using one-way analyses of variance and two-way cross-tabulations, the authors examined F statistics and χ^2 statistics associated with differences among the study groups on factors at entry that might have confounded the experiment. Among these factors were age, clinical diagnosis, oral temperature, white blood cell count, and throat pathogens. No statistical differences were observed among the three groups on any of these potential biasing factors. Therefore, it was concluded that the groups were random equivalents. Further statistical examination of the data indicated that there were no significant differences between the two groups of subjects treated with the phenol-based agents. Female means for the phenol-based spray and gargle were 5.91 and 5.54 respectively, while male means were 5.40 and 5.41. Accordingly, the groups receiving the phenol-based preparation were combined to form a single group which was then compared to the group receiving the saline gargle.

Table 1
ADJUSTED MEANS AND STANDARD DEVIATIONS OF THROAT PAIN RATINGS FOR MALE AND FEMALE SUBJECTS DURING HOUR FOLLOWING SALINE OR PHENOL-BASED TREATMENTS

	SALINE TREATMENT				PHENOL-BASED TREATMENT			
	Female N = 32		Male N = 18		Female N = 66		Male N = 34	
	$\bar{X}$	S.D.	$\bar{X}$	S.D.	$\bar{X}$	S.D.	$\bar{X}$	S.D.
0 minute (unadj.)	6.94	(1.05)	6.67	(0.84)	6.85	(0.95)	6.56	(0.86)
1 minute	5.09	(1.69)	5.54	(1.65)	4.97	(1.84)	4.74	(1.67)
5 minutes	5.25	(1.54)	5.54	(1.33)	5.26	(1.59)	4.83	(1.58)
10 minutes	5.28	(1.67)	5.66	(1.20)	5.47	(1.47)	5.21	(1.65)
20 minutes	5.50	(1.62)	5.77	(0.85)	5.70	(1.48)	5.27	(1.76)
30 minutes	5.65	(1.59)	5.88	(1.02)	5.82	(1.50)	5.54	(1.51)
40 minutes	5.62	(1.57)	5.99	(0.99)	6.02	(1.47)	5.68	(1.54)
50 minutes	5.75	(1.61)	6.16	(0.91)	6.21	(1.36)	5.89	(1.49)
60 minutes	6.03	(1.68)	6.32	(0.92)	6.33	(1.38)	6.04	(1.64)
Overall Mean Pain	5.52		5.86		5.72		5.40	

Table 2
ANALYSES OF COVARIANCE TESTING DIFFERENCES IN THROAT PAIN (FOR MALE AND FEMALE SUBJECTS) DURING HOUR FOLLOWING SALINE OR PHENOL-BASED TREATMENTS

Study Effects	Degrees of Freedom	Sums of Squares	Mean Square	F	Significance Level
Treatments	1	3.85	3.85	0.53	NS
Sex	1	0.01	0.01	0.00	NS
Treatment/Sex	1	26.12	26.12	3.57	NS
Covariate (init. pain)	3	1009.74	336.58	45.99	$p<.001$
Error	143	1046.55	7.32		
Time	7§	122.62	17.52	27.40	$p<.001$§
Time/Group	7	8.02	1.15	1.79	NS
Time/Sex	7	0.89	0.13	0.20	NS
Time/Group/Sex	7	0.32	0.05	0.07	NS
Error	1022§	653.28	0.64		

§The most conservative adjustment for autocorrelation with d.f. reduced to 1 and 146 yields $p<.001$.

Table 1 shows the adjusted means and overall mean for sore throat pain for the two groups of subjects during the eight time intervals following the initial saline or phenol-based treatment. Overall means for the test preparations and the saline preparation appear to be quite similar. The pain rating over the 60-minute period declines at one minute for all four subgroups and then increases steadily and consistently throughout the hour.

The analysis of covariance, Table 2, does not suggest that one may reject the treatment null hypothesis (i.e., that there is no difference in the treatments). None of the four study effects involving differences between the saline and phenol-based preparations is significant at $p < .05$. The only significant effects are time and the covariate, initial pain. The observed increase in pain for all groups over the eight time periods is, indeed, significant ($p < .001$), indicating that while all three treatments effected some lessening of pain initially from the untreated state, the relief of pain was quite transient, gradually increasing over the next hour towards baseline levels for all three treatments. Initial pain is also highly significant; the lower the pain before treatment, the lower the pain pattern following treatment, at least for the next 60 minutes.

The data for evaluating the effectiveness of the preparations after two days of home use are summarized in frequency matrix form in Table 3. In this table, the four categories of subjective evaluation were collapsed to three. The little used category of "none" was combined with the category "slight." Inspection of this table does not suggest that there are any marked effects due to the sore throat treatments. This impression is confirmed by the log linear analysis of these same data. This analysis indicates that there are no significant differences in the subjective evaluations of the saline and phenol-based preparations. None of the likelihood ratio χ^2 values associated with subjective effectiveness and the preparations even approached a probability of $< .05$. The lowest probability observed was $p < .46$ for the effects of the preparations and initial pain level on subjective effectiveness.

Comment

This study was designed to evaluate only the effectiveness in relieving sore throat pain of a phenol-based preparation, used as a gargle or a spray, or a warm saline gargle (the latter *not* considered to be a placebo). The data, as presented, indicate that the two phenol-based preparations or saline gargles, each used according to instructions, may be effective, up to an hour, for short-term relief of sore throat pain. However, none of the three treatment methods are any more effective, or less effective, than the others. It should be noted that there is no significant difference in the three treatment methods, as evaluated by the subjects during the two-day home treatment.

Thus, while it appears reasonable for the physician to rec-

Table 3
FREQUENCY DISTRIBUTION OF RATINGS OF EFFECTIVENESS ACCORDING TO INITIAL LEVEL OF PAIN BY MALE AND FEMALE SUBJECTS USING SALINE AND PHENOL-BASED TREATMENTS AT HOME

Subjective Effectiveness	Initial Pain	Sex	Saline Treatment	Phenol-Based Treatment
None and Slight	6.0	Female	3	11
		Male	2	3
	7.0	Female	1	6
		Male	1	4
	8.0	Female	2	1
		Male	0	1
	9.0	Female	1	0
		Male	1	1
Moderate	6.0	Female	4	14
		Male	4	12
	7.0	Female	2	6
		Male	4	3
	8.0	Female	2	3
		Male	1	0
	9.0	Female	2	3
		Male	0	0
Very Good	6.0	Female	8	5
		Male	3	6
	7.0	Female	4	8
		Male	2	2
	8.0	Female	3	6
		Male	0	1
	9.0	Female	0	2
		Male	0	1

ommend any of these three methods as helpful for symptomatic treatment for sore throat, the choice as to which method to use must be a joint decision between the physician and patient, based upon cost (obviously the saline gargle is less expensive) vs. the convenience of a prepackaged gargle or spray.

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