Phenol:

Primary:

Valle-Jones JC. Chloraseptic liquid in sore throat. *The Practitioner*. 1983; 227: 1037-1040.

Study Objective: Determine whether a group of patients given Chloraseptic spray (active ingredient 1.4% Phenol w/v) would have relief from pain of sore throat and whether the course of the disease would be shortened compared to a control group who were given a placebo spray (same colour as Chloraspetic).

Methods

Design: Intervention Study

Allocation: 100 patients with painful sore throats were intended to be treated. No mention of randomization.

Follow-up period: Patients were assessed again after 48 hours of treatment (at day 3), to find out if they should continue to take part in the study and to see whether using the throat spray provided symptomatic relief. They were asked if they had headaches, pyrexia; and sore throat pain was graded as mild, moderate or severe. Symptoms were rated from worse to greatly improved. If they used other analgesics, this was noted. If patients continued in the study after 48 hours, they were told to keep spraying their throats every 2 hours and return for another follow-up within 5 days, making a total of 7 days worth of medication. The second follow-up (day 7) measured symptom improvement again as worse, unchanged, improved or completely better.

Setting: Surgery clinic

Participants: 100 patients with painful sore throats; 50 were treated with Chloraseptic liquid. 50 were treated with placebo (Chloraseptic liquid without phenol). A total of 96 patients (56 females, 38 males) took part in the whole study. 47 were given Chloraseptic liquid, 49 were given placebo. There were no significant differences between the groups (age, sex, previous history of sore throat, and no previous history of sore throat). Their ages ranged from 7-85 years and 20 of the participants had a history of sore throats in the past. The severity of sore throats in both of the groups was compared, and there was no statistical significant differences (Presence/absence of pyrexia, headache, type of pain, duration of symptoms).

Exclusion criteria: patients who had sore throats and needed antibiotic therapy, or had earache associated with sore throat, children less than 7 years old, and any patient with a history of rheumatic heart disease, sub-acute bacterial endocarditis, valvular disease or nephritis.

Intervention: adults were told to spray their throats 5 times initially, and then repeat every 2 hours. Children from ages 7-12 years were instructed to have their throat sprayed three times at the start, repeating the dose every 2 hours. Before treatment a subjective assessment of the severity of the sore

throat pain was made; either mild, moderate or severe. Presence or absence of headache or pyrexia was recorded. The duration of symptoms at the time of presentation was also noted.

Outcomes: The primary outcomes was the efficacy of Chloraseptic throat spray, to see if it resulted in a change in symptoms (improvement, greatly improved and in the second follow-up at 7 days, completely better)

Patient Follow-up: All 96 patients provided information for both follow-ups on days 3 and 7.

Main Results

At follow-up on day 3, Chloraseptic liquid caused a much greater decrease in the incidence of pyrexia, headaches and pain in patients who have sore throats, compared to placebo. Improved: 24 vs 20, and greatly improved 22 vs 2; no change 1 vs 27, respectively. $P < 0.0001$

Furthermore, Chloraseptic liquid made a greater improvement in the patient's overall condition.

At follow-up on day 7: 90% of patients who used Chloraseptic liquid were completely better compared to 43% of the control group. $P<0.0001$

Conclusions Study showed Chloraseptic to be effective and superior to placebo for relief of sore throat pain.

Chloraseptic Throat Spray, with the phenol as the active ingredient at 1.4%w/v is superior to placebo for improvement of symptoms (pyrexia, headaches and pain in patients with sore throats), as well as complete cure after 7 days of use compared to placebo.

Comments/Critical Appraisal

Strengths: Study and control groups were similar in terms of their severity of sore throats and patient characteristics. All 96 patients participated in follow-up at both 3 and 7 days. Results were statistically significant ($p<0.0001$). 100 patients were intended to be treated, and only 4 were excluded. Exclusion criteria were appropriate. Could apply the results of this study to anyone in the population over 6 years old. Statistical tests used (t test, Mann-Whitney u test, Chi-squared test).

Limitations: No indication as to whether the patients were randomized. Subjective assessments for throat pain were used, as well as for improvement of symptoms. The use of other analgesics were noted for both groups, and were reported as non significant, though we don't know how they made this conclusion. We don't know if the patients' sprayed their throats as they were told (every 2 hours) since they were at home.

Patients did not know which throat spray they were getting, since the placebo spray was the same colour as the Chloraseptic liquid that had phenol in it. One would imagine that the Chloraseptic spray had a smell to it, so the patients could probably tell what they were getting. Also, the Chloraseptic spray

would probably feel different on the patients' throat, giving away which group the patient was assigned to. This makes for a poor blinding design.

The study size was small; only 96 patients.

Novick, JM. Sodhi, GS. Evaluation of Chloraseptic. *Med Ann Dist Columbia*. 1960; 24(8): 427-429.

Study Objective:

To compare Chloraseptic to penicillin 600,000 Units IM injection and to placebo in terms of reducing bacterial count and relieving sore throat.

Methods

Design: Comparative intervention study.

Allocation: Patients were divided into 3 groups of 50, 25, and 25. The group with 50 patients were given chloraseptic, and the other 2 groups were given either placebo (same colour as Chloraseptic), or pencillin injection.

Blinding: Between placebo and Chloraseptic, the sprays were blinded because they were both the same colour. The penicillin injection IM could not be blinded, as it is obvious to a patient that they are receiving an injection. The article did not comment on whether patients knew that the injection had a medical ingredient or not.

Follow-up Period: 24 hours, 72 hours, and 5 days were the periods in which bacterial cultures were analyzed.

Setting: Hospital

Participants: a group of 100 hospital patients being treated for streptococcal pharyngeal infections were split into the 3 groups stated above. All the patients had throat cultures taken before they started therapy, and colony counts were done in each case for *Streptococcus hemolyticus*. The article did not discuss patient characteristics, whether they were similar in each of the groups nor did it discuss exclusion criteria.

Intervention: Group 1 (50 patients): Use Chloraseptic spray, 5 times in the throat, swallow, then repeat every 2 hours. Group 2(25 patients): Placebo with same instructions as group 1. Group 3(25 patients): 600,000 U of penicillin IM daily.

Outcomes: Primary Outcome: Reduction in Bacterial count in 24 hours, completely negative cultures at 24hours, 72 hours, 5 days. Secondary Outcome: relief of sore throat.

Patient Follow-up: 100 patients.

Main Results

Chloraseptic spray relieved soreness of the pharyngeal tissues within 3 minutes, and lasted 2-3 hours. Chloraseptic decreased the bacteria count of *S. Hemolyticus* 40 to 70% in 24 hours. In 84% of cases, completely negative cultures were present at 72 hours. No toxic or sensitizing effects were found, meaning that the product is safe as well. Chloraseptic was more effective than penicillin. In the first 24 hours, it was 3 times better than injectable penicillin in decreasing the bacteria count. With penicillin there were only 4% of negative cases at 5 days, where chloraseptic's was 94%.

Conclusions:

Chloraseptic was superior to penicillin and placebo in reducing bacteria count. Chloraseptic was found to relieve sore throat within 15 seconds to 3 minutes and lasted between 2-3 hours in 50 patients.

Comments/Critical Appraisal:

Placebo throat spray was the same colour as Chloraseptic, but like in the previous study, Chloraseptic probably has a smell and different feel than placebo, making the blinding weak. The groups were unbalanced (50, 25, 25) instead of all the same number. There were no confidence intervals or statistical analysis done (no p values). We do not know anything about the patients, in terms of age, sex, or other characteristics. We do not know if the patients were randomized.

The study design was overall weak. Though the primary outcome was to detect bacteria count reduction, and the Chloraseptic and the penicillin and the placebo group were compared for this, there was no mention of how these three groups compared to relief of sore throat, other than "relief of pain in the throat was also carefully considered in each of the three groups. The results were favourable in group 1 and unfavourable in the other groups". It does not state what type of grading scales or assessments were done to measure sore throat relief in the three groups. The bacteria count portion of the article did not say what was done for throat swab before culturing. A lot of details were missing. Furthermore, this was a fairly old study, however, after searching through PubMed and Web of Science, this was one of the few studies that could be found.

However, it was noted that Chloraseptic provided sore throat relief within a very short period of time in 50 hospital patients with pharyngeal infections. It also reduced bacteria much more than penicillin and placebo. The sample study was also small. We could apply this study to hospital patients with *S. Hemolyticus* or other pharyngeal infections.

Other Literature Types

Source: Letter to the Editor

Halwell R. Pharyngitis Medicamentosa*. Arch Otolaryngol Head Neck Surg*. Aug 1989: 115; 995

Summary:
Author recommends using phenol spray for numbing of the pharynx for mild pharyngitis. He encourages to use Chloraseptic spray one or two times for severe throat pain of early upper respiratory tract infection-related pharyngitis. When used more often, the author states that the viral pathogen disappears, no secondary infection is present either, but patients tend to use the spray so much so that there is rebound discomfort, "pharyngitis medicamentosa": persistent sore throat from the use of strong OTC sprays or lozenges.

Comments/Critical Appraisal

Internal Validity- the results are the physician's account of his patients. This is an opinion piece based on empirical evidence/ observation. The results state to not overuse phenol sprays as it can cause pharyngitis medicamentosa. There is bias of course since it is the author's opinion.

External Validity- Applying this to your patient: Use the phenol spray only once or twice a day. Not too often otherwise persistent sore throat may arise. For relief from this, the author states to substitute with mild saline gargles and mild lozenges that contain pectin or glycerin or honey, and this should bring relief in 1 to 2 days.

Tertiary Sources

Stead W. Sore Throat in Adults. In: *UpToDate,* Aronson MD (Ed), UpToDate, Waltham, MA, 2013.

Summary: Phenol sprays are available for relief of sore throat. Sprays are not better than hard candy.

Comments: Simply a statement from this tertiary resource. Can apply this to patients, letting them know that the spray is no better than a lozenge.

Respiratory Disorders. *Handbook of Nonprescription Drugs. An Interactive Approach to Self-Care.* 17th Ed. 2012

Summary: Listed as a local anesthetic and to use every 2-4 hours
Comments: Simply a list. References at the end of the chapter do not point to phenol products.

PHENOL (Oromucosal route) - FEE-nol. Detailed Drug Information for the Consumer. In: *Micromedex* 2.0, Truven Heatlh Analytics Inc., 2013.
Summary: Phenol relieves pain and irritation from sore throat. It is a medicine available without a prescription. Spray in the mouth. Remain in mouth for at least 15 seconds, then spit out. Do not use for

more than 2 days, unless directed by a doctor. Safety and efficacy not tested in children under 3 years old.
Comments: Applying to our patients: Non-Prescription Treatment, only use for 2 days because can cause pharyngitis medicamentosa. Children under 3 should not use the product.