Koflet Lozenges in the Treatment of Sore Throat

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ABSTRACT
Forty eight patients of either sex aged 18 – 60 years entered the study to test the efficacy and tolerability of a herbal preparation known as Koflet lozenges. Twenty three of them had catarrhal pharyngitis, sixteen had catarrhal tonsillitis and nine of them had both. The dosage was 3 lozenges every 8 hours for 3 days in patients with sore throat and related signs and symptoms. The patients were evaluated every day for three days. At the end of the 3 day treatment, they were evaluated for the efficacy and tolerability of Koflet lozenges. Results showed that it was found to be effective moderately in 16.66%, good in 70.83% and excellent in 10.41%, while in one patient (2.08%) there was no response. There was no untoward incident in any of the patients.

INTRODUCTION
‘Sore throat’ is a term that includes any painful condition in the oropharynx. It has been associated with chronic tonsillitis over the years and also with various other pathologies within the head and neck area, such as sinusitis and malignancy. There are many causes of acute or chronic inflammation of the throat that lead to various clinical situations and may lead to many disorders. Sore throat is usually caused by bacteria or a virus or due to some allergies. Smoking and air pollution can cause sore throat. Shouting or speaking loudly can also cause a milder variety of sore throat. To control these conditions, symptomatic relief may be achieved by using medicines such as mouth gargles, NSAIDs, lozenges, etc. Sometimes analgesics and antipyretic therapy are additional requirements.

Tonsillitis is an inflammation (infection) of the tonsils that causes sore throat. If there is an infection, then there might be fever, headache and vomiting. Tonsillitis usually occurs when the tonsils try to filter out the disease and the germs. On examination of the throat, the tonsils are usually swollen and bright red and may have white or yellow patches of pus visible on the surface. The roof of the mouth may also be red or contain small red spots. A distinctively bad breath odour is prevalent. Previously surgeons removed tonsils the moment they get infected. Nowadays there is less recourse to the surgical procedure, because better and more effective medicines are available.

Pharyngitis also occurs due to sore throat. Pharyngitis presents with sore throat, pain radiating to the ears and dysphagia. Sometimes there is fever. Fever is more commonly associated with group A beta-haemolytic streptococci (Streptococcus pyogenes). The proportion of pharyngitis and tonsillitis that is caused by group A streptococci is related to the patient's age. Pharyngitis caused by streptococci should be treated with caution. Other causes include Mycoplasma, Epstein-Barr virus, Adenovirus, Influenza virus,
Arcanobacterium hemolyticum, gonococcal pharyngitis and others. Noninfectious causes include mouth breathing secondary to nasal obstruction (as with a URI). A reasonable approach in adults is to treat all patients with fever, systemic symptoms and tonsillar exudate with antibiotics because they are likely to have streptococcal pharyngitis. Patients exhibiting little or no evidence suggestive of bacterial pharyngitis may be reassured and treated symptomatically with lozenges or by addressing the underlying problem (humidity, nasal congestion, etc.). Streptococcal cultures or quick streptococcal tests can be reserved for those patients in whom the diagnosis is not clear. Testing for mononucleosis can be reserved for those with appropriate adenopathy. If the throat is very sore then there is inflammation, which might lead to difficulty in swallowing.

Patients with sore throat are advised to rest the voice and take some soothing agents to help relieve the pain and irritation. Gargling with warm salt water and sucking throat lozenges can help ease sore throat. They should be advised to avoid spicy foods because it will irritate the throat further. Smoking also irritates the throat and it can be responsible for recurrent infections.

Diseases of the tonsils and palate have been given prominent consideration by ancient physicians. Hippocrates performed tonsillectomy by grasping the tonsil with a hook and excising it with a knife. Galen, another ancient surgeon, has described in detail the surgical procedures of the tonsils and uvula. Pain and postoperative bleeding were encountered in the ancient times and even today they continue to be part of the problems faced by surgeons. The complication rate due to tonsillectomy at present is also approximately the same as in the ancient times\(^1\). New techniques to aid surgery of tonsils include laser, bipolar cautery, microdebriders or microshavers, but they do not seem to have definitely affected the recuperative time necessary for full recovery or prevent the complications associated with the surgery.

Sore throat can be treated initially with local antiseptic and anti-inflammatory medications. Herbal lozenges known as Koflet are supposed to have these actions. This multi ingredient herbal formulation contains herbs such as *Acacia catechu*, *Syzygium aromaticum*, *Terminalia chebula*, *Elettaria cardamomum*, *Cinnamomum zeylanicum*, *Glycyrrhiza glabra*, *Curcuma longa* and *Vitis vinifera*.

*Acacia catechu* is known for its antimicrobial properties. Studies have shown that the antibacterial activity of *Syzygium aromaticum* was found to be active against various oral pathogens such as *Streptococcus mutans*, *Actinomyces viscosus*, *P. gingivalis* and *P. intermedia*. The flavonoids present in this plant demonstrated potent growth inhibitory activity in those pathogens, which causes periodontitis\(^2\). In a study when the extract of *Terminalia chebula* was used as a mouth rinse, it significantly reduced the total bacterial count and the total streptococcal counts in the saliva\(^3\). *Elettaria cardamomum*, which is present in Koflet lozenges is known for its anti-inflammatory activity which is equivalent in action to indomethacin\(^4\). *Cinnamomum zeylanicum* has anti-inflammatory properties\(^5\). Sore throat is also caused by viruses. *Glycyrrhiza glabra* present in the formulation acts as an antiviral agent\(^6\). *Curcuma longa*, commonly known as turmeric, plays an important role in the
enhancement of wound healing and brings down inflammation\(^7\). \textit{Vitis vinifera} has antioxidant activity and is proven to have free radical scavenging properties\(^8\).

**MATERIAL AND METHODS**

Forty eight patients with acute or chronic tonsillitis or pharyngitis or both participated in the study. The group consisted of 28 males and 20 females. The mean age was 31.30±12.60 (SD±). They received Koflet lozenges at a dose of 3 lozenges every 8 hours daily for 3 days. They were instructed to suck the lozenges till they dissolve. Concomitant medication with other throat preparations and anti-inflammatory drugs was not allowed during the study period and no local therapies were given. A thorough head and neck examination was carried out to rule out other diseases. In addition, examinations of the oropharynx, tongue, oral mucosa, teeth, nose, nasopharynx and hypopharynx were also done. A complete palpation of the neck, parotid glands and examination of the ears was performed. Patients were evaluated at base line days 0, 1, 2 and 3. The signs and symptoms evaluated were congestion, oedema, exudate, cough, hoarseness of voice, pain and inflammation. The intensity of the symptoms and signs were graded on a 4 point scale, i.e. absent-0, mild-1, moderate-2 and severe-3. At the end of the treatment both patient and the physician evaluated the efficacy of treatment on the following scale – excellent, good, moderate and nil. Statistical analysis was carried out separately for the different signs and symptoms.

**RESULTS**

Out of the 48 patients who completed the trial, 23 patients had catarrhal pharyngitis, 16 patients had catarrhal tonsillitis and 9 patients had catarrhal pharyngitis and tonsillitis (Table 1). Results showed that in patients with pharyngitis, there was an excellent response in 4, good in 16, moderate in 2, while 1 patient did not respond to the treatment. In patients who had only catarrhal tonsillitis there was moderate response in three, good response in twelve and one patient showed excellent response. Six patients who had both tonsillitis and pharyngitis showed good response while three patients showed moderate response (Table 2).

Statistical analysis was done in all the 3 groups using Wilcoxon signed rank test. In patients who had only pharyngitis, the inflammation, congestion and secretions subsided quite significantly\( (P<0.0001)\). In patients who had tonsillitis, inflammation subsided within 3 days of treatment\( (P<0.0002)\), congestion\( (P<0.0001)\) and secretions\( (P<0.0039)\). In those patients who had pharyngitis and tonsillitis, the statistical analysis showed inflammation\( (P<0.0005)\),
congestion ($P<0.0078$) and secretions ($P<0.0039$). Thus, the statistical analysis was significant in all the 3 groups.

Patients who had additional allergic type of pharyngitis or tonsillitis were given systemic analgesics. About 25 patients presented with fever and increased pulse rate. They were also given Koflet lozenges for 2 days with antipyretic agents. However, when the fever continued on the second day they were prescribed antibiotics to prevent complications due to sore throat. The patients reported that Koflet lozenges helped soothe the inflamed pharynx and were able to control the irritation.

**DISCUSSION**

The tonsils are situated at the back of the throat between the tongue and the palate. They are usually large at birth. The adenoids normally shrink during childhood and disappear by the time the child enters the teen, but the tonsils shrink to about the size of an almond in adults. However, tonsils never completely disappear unless they are removed by surgery. Tonsils act as filters to keep disease away from infecting the body. In people with diseases of the tonsils, sore throat is the most common presenting complaint. An understanding of the physiology and pathology is necessary for the correct diagnosis and treatment of these disorders based on this is necessary for their effective management.

The most active phase for the immune function of tonsils is between the ages of 3 and 10 years. Involution generally begins at this point, while some activity continues. Removal of the tonsils does not seem to result in any significant immunologic deficiency. Although measurable diminishment in responses to poliovirus have been demonstrated in patients who have undergone tonsillectomy, the overall health status of most of the individuals seems to be unaffected\textsuperscript{10}. It is clear that there are some substantial differences in the activity of tonsils of individuals who have no history of infection when compared to those who have history of recurrent infections, nasal obstruction or tonsillar hypertrophy. Those individuals with clinical symptoms have a much higher incidence of pathogenic bacteria present in core tonsillar samples as well as other abnormalities like the B cell and T cell lymphocyte ratios\textsuperscript{11}. The variable bacteria found in the tonsils may work synergistically to allow pathogenic states to develop. Bacteria with improved survival strategies such as $\beta$-lactamase resistance may allow other bacteria nearby to survive treatment with certain antibiotics.

In addition to bacterial infections, viral pathogens are a common cause of pharyngitis and tonsillitis. Coxsackie virus, herpes virus and Epstein-Barr virus may affect the tonsils and produce symptoms of exudative and nonexudative pharyngitis. This pharyngitis may result in fever, erythema and pain in the local area.

Surgical techniques have changed little over the course of the past 30 to 50 years. New techniques such as magnification, bipolar cautery, powered instrumentation and local anaesthesia may have some incremental effect on postoperative outcome\textsuperscript{12}. Despite this effect, postoperative pain, especially in children, remains a problem. Postoperative haemorrhage ranges from 0.5% to 2%. It may vary according to the patient’s age. Older children and adults have a higher rate of postoperative bleeding compared to the younger age
group. Changes in speech because of loss of tissue volume may also occur but are usually temporary. Rarely, nasopharyngeal stenosis or atlantoaxial subluxation may take place. Atlantoaxial subluxation may be induced traumatically in children with Down's syndrome, who are predisposed to this condition.

No issue involving health care for children has created more heated controversy among health professionals than surgical removal of the tonsils. One of the most common surgeries carried out on children is tonsillectomy and it continues to draw professional and legislative attention. The risks have never been adequately assessed and the indications for operation remain largely ill defined. Nonetheless, the continuing high rate of performance of tonsillectomy, despite some recent decline, attests to its strong hold on the minds of many physicians and parents as of which line of treatment should be given importance and value.

Although tonsillectomy is often thought of and carried out, it requires individual attention when considering indications for operation. As of present, convincing evidence is lacking that tonsillectomy is superior in efficacy to conservative management. Unfortunately, the few reported trials of tonsillectomy have been inadequate and inconclusive. In order to arrive at rational indications for tonsil surgery, severity of symptoms in patients must first be defined to justify tonsillectomy. An operation is clearly indicated in unusual circumstances which result in massive hypertrophy of tonsils, unquestioned dysphagia, extreme discomfort in breathing, or even more severely, in alveolar hypoventilation or cor pulmonale. Some surgeons would suggest surgery after 4 or 5 episodes of streptococcal pharyngitis in a 1-year period, or "chronic sore throat" with adenopathy for 6 months that is unresponsive to treatment. Contraindications to surgery include velopharyngeal, haematologic, immunologic and infectious conditions. A number of abnormal conditions that result in velopharyngeal insufficiency, such as overt cleft of the palate, submucous or covert cleft of the palate, neurologic or neuromuscular abnormalities leading to impaired palatal function, and an unusually capacious pharynx, are contraindications. Family or past history of unusual bleeding or bruising from certain haemostatic disorders are contraindications. Sometimes tonsillectomy might predispose to the development of Hodgkin’s disease. It is possible that removal of the immunologically active tonsils will later undermine the patient’s resistance to disease of some sort, but the likelihood appears to be small.

The data emerging from this study confirms the pharmacological properties of Koflet lozenges. In patients who used Koflet, the control of the inflammatory process of the pharynx and tonsils has been shown to be instrumental in preventing the development of complications such as chronicity of these disorders. However, antibacterial therapy should be instituted in combination with Koflet lozenges in those patients in whom the subjective and objective symptoms suggest a secondary bacterial infection.

CONCLUSION
The efficacy of Koflet lozenges was studied in patients with acute or chronic tonsillitis or pharyngitis. In this setting, Koflet lozenges was associated with relief of pain and inflammatory signs (exudates and swelling). Indeed, treatment with Koflet lozenges leads to better clinical improvement in terms of both rapidity of action and improvement of the
symptoms at the end of therapy. Koflet lozenges was well tolerated and no patients reported any adverse event.

REFERENCES


