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Dolna 17, Warsaw,
Poland 00-773
+48 226 0 227 03
editorial_office@rsglobal.pl

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KETOPROFEN IN THE TREATMENT OF SORE THROAT - EFFICACY AND SAFETY OF A NONSTEROIDAL ANTI-INFLAMMATORY DRUG

Patryk Biesaga *(Corresponding Author, Email: Patryk.biesaga94@gmail.com)*
W. Orlowski Hospital in Warsaw, Poland
ORCID ID: 0009-0003-0242-9126

Konrad Kotte
St. Alexander Hospital in Kielce, Poland
ORCID ID: 0009-0008-9745-985X

Olaf Jadanowski
University of Health Sciences in Bydgoszcz, Poland
ORCID ID: 0009-0000-6279-3067

Kamil Łebek
Jan Kochanowski University, Kielce, Poland
ORCID ID: 0009-0005-4612-5022

Przemysław Piskorz
National Medical Institute of the MSWiA, Warsaw, Poland
ORCID ID: 0009-0000-9812-2230

Daria Litworska-Sójka
Provincial Combined Hospital, Kielce, Świętokrzyskie, Poland
ORCID ID: 0009-0005-4590-3777

Bartosz Komsta
Military Institute of Medicine – National Research Institute, Warsaw, Poland
ORCID ID: 0009-0003-1159-5855

Wojciech Pabis
5th Military Research Hospital and Polyclinic, Kraków, Poland
ORCID ID: 0009-0006-3455-4724

Natalia Kraciuk
Independent Public Healthcare Establishment in Wyszków, Poland
ORCID ID: 0009-0007-8319-2296

Monika Karalus
W. Orlowski Hospital in Warsaw, Poland
ORCID ID: 0009-0005-9355-4698

ABSTRACT

Introduction and objective: Sore throat is one of the most common symptoms reported during visits to the primary care physician. In most cases, its cause is a viral infection (from 90 to 95% of acute pharyngitis in adults and 70-85% in children), but there are also cases of other etiologies of infection or pain resulting from surgical procedures (including dental) or mechanical injuries.
Brief description of the state of knowledge: The results of the study indicate that ketoprofen is highly effective in treating sore throats caused by both infections and surgical procedures, including dental procedures. Studies comparing ketoprofen with benzidamine have shown better efficacy of ketoprofen, longer duration of action and fewer side effects. The efficacy of ketoprofen in the pediatric population has also been proven for both the treatment of sore throats of infectious origin and those arising from surgical procedures. Ketoprofen lysine salt is also effective in relieving pain occurring after tooth extractions, and has a good safety profile. Its efficacy is significantly higher than placebo and comparable to that of paracetamol, with no significant side effects. Thanks to its neutral pH, it also does not irritate the gastrointestinal mucosa.
Summary: The study results presented here suggest that ketoprofen may become an effective and safe alternative for the treatment of sore throat and localized oral pain in both outpatient and inpatient care. However, potential side effects should be monitored and further studies should be conducted to clearly assess the safety profile and efficacy of ketoprofen.

KEYWORDS

Ketoprofen, Sore Throat, Tonsillitis, Palatine Tonsillitis

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Introduction

Sore throat is one of the most common reasons for patients presenting to their primary care physician, especially during the infection season. Among the causes of sore throat, viral infections are the most common, accounting for about 70-85% of acute tonsillopharyngitis among children older than 3 years and between 90 and 95% in adults. [1] They are most commonly caused by rhinoviruses, coronaviruses, adenoviruses, Epstein-Barr virus, cytomegalovirus, Coxsackie, Herpes simplex, and influenza and paragrpa viruses A significant minority of sore throat cases are bacterial or fungal infections, but among bacterial infections, acute streptococcal palatine tonsillitis (streptococcal angina), caused by *S. pyogenes*, accounts for the vast majority of cases. [3, 4]

Sore throat on an infectious background is most often accompanied by symptoms of inflammation, such as mucosal swelling and congestion. In the course of bacterial and fungal infections, purulent suppositories (especially in the course of strep throat), plaques or whitish spots (for example, in the course of oral candidiasis) often appear on the mucous membrane of the throat and tonsils. In viral infections, vesicles can also be seen, usually filled with serous contents, as in foot, hand and mouth disease. An infectious sore throat often occurs along with other symptoms, such as cough, elevated temperature, runny nose or weakness. [5]

Despite the most common association with infections, sore throat can also occur in the course of gastroesophageal reflux disease, as a result of burns or mechanical injuries. In the case of gastroesophageal reflux disease, it may also be accompanied by a burning sensation in the chest, a breathlessness or coughing. In patients with burns, both chemical and thermal, the pain may involve not only the throat, but also the oral mucosa and the entire length of the esophagus. The pain experienced by patients with reflux disease can often mimic the chest pain associated with acute coronary syndromes, and requires appropriate differential diagnosis based on history, clinical symptoms and physical examination. [6]

Patients in recovery from oral and pharyngeal procedures, such as tonsillectomy or palatal plasty, also face the problem of sore throat. Another group often reporting pain and irritation of the oral and pharyngeal

mucosa are patients after dental procedures, especially surgical tooth extraction. Sore throat can also be associated with the intubation procedure itself in the course of surgical operations. [7, 8]

In GP practice, however, infections are the most common cause of sore throat. Regardless of the etiology of the infection, symptomatic treatment to relieve pain is indicated. In the case of bacterial or fungal infections, priority is given to causal treatment (e.g., antibiotic therapy in the course of strep throat or the use of antifungal drugs in cases of oral candidiasis), but preparations that reduce the severity of sore throat also find their way in. [2, 10, 11, 12] In the case of viral infections, which account for the vast majority of cases, symptomatic treatment is the main method of pharmacotherapy - supportive preparations can be used to improve immunity or shorten the duration of infection, as well as reduce other symptoms accompanying sore throat. [9, 10, 11, 12]

A wide cross-section of topical preparations for the treatment of sore throat is currently available on the market. The most important groups of drugs are substances with antiseptic, anesthetic and analgesic effects. [13]

Among the substances with antiseptic action, the most commonly used are octenidine dihydrochloride, cetylpyridinium chloride, benzydamine and colloidal silver. The principle of action of preparations containing antiseptics is a local antibacterial and antiviral effect, which allows to reduce the severity of symptoms by inactivating pathogenic microorganisms residing on the mucous membrane of the throat.

Among the available antiseptics, octenidine stands out in particular. It works by binding to negatively charged fatty acids on the outer shells of bacterial and fungal cells, leading to their damage and ultimately to the death of microorganisms. Octenidine has a very broad spectrum of activity, covering both bacterial vegetative forms and Gram-negative bacteria such as *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Acinetobacter baumannii and Pseudomonas aeruginosa*. It also acts on Gram-positive bacteria, including MRSA, ORSA, VRSA, VRE and *Enterococcus faecalis*, as well as fungi such as *Candida albicans* and *Candida parapsilosis*, and viruses and protozoa, such as *Trichomonas vaginalis.* [14-19] In addition, octenidine does not manifest toxic effects when used in the oral cavity [20]. To date, the development of resistance to this drug has also not been observed [21].

Symptomatic preparations used to treat sore throat often also contain anesthetics such as lidocaine or anesthesia, as well as analgesics and anti-inflammatories - diclofenac, choline salicylate or ketoprofen.

Ketoprofen is a drug included in the group of non-steroidal anti-inflammatory drugs (NSAIDs). Due to its chemical structure, it belongs to the group of propionic acid derivatives (similar to ibuprofen and naproxen). Ketoprofen exhibits actions characteristic of the NSAID group - it has analgesic, anti-inflammatory, antipyretic effects and inhibits platelet aggregation by inhibiting the activity of cyclooxygenase 1 and 2, involved in the synthesis of prostaglandins. [22]

Since diclofenac, also a drug belonging to the NSAID group, is successfully used in the treatment of sore throat, mainly in the form of mouth and throat rinses, the efficacy and safety of ketoprofen in the treatment of sore throat of various origins has also been studied.

The pH-neutral ketoprofen lysine salt appears to be particularly effective, as it does not cause irritation of the gastrointestinal mucosa. It comes in the form of tablets for oral use, as a solution for mouth and throat rinses, and as sachets of granules that can be applied topically, as well as in the form of a solution for oral use. [23]

The findings suggest that ketoprofen is not only an effective, but also a safe alternative to the antiseptics and analgesics used to date. It is used both in the treatment of sore throat of infectious etiology and in the relief of postoperative pain. It has been successfully used both in the pediatric population and among adults, quickly relieving pain and without significant side effects. [24-30]

Purpose of the work

The purpose of the above article is to provide an overview of pharmacotherapy of sore throat of infectious and postoperative origin in the pediatric, adolescent and adult populations. The effectiveness of substances in both outpatient and inpatient care was evaluated.

Methodology

An exhaustive review of the literature on the subject, meta-analyses on the issue described and clinical case reports were conducted.

A review of scientific articles published and indexed in PubMed, an analysis of specialized literature on the subject and clinical cases published in professional journals was conducted.

The efficacy of different forms of ketoprofen administration, different doses and comparison of its effectiveness with other analgesic, anti-inflammatory and antiseptic preparations are described. The results of the studies reviewed were carried out in a number of centers, both in Europe and around the world. The studies described were conducted on patients of adult age, as well as on representatives of the pediatric population.

Discussion

The study by Passali et al. compared the efficacy of a mouthwash solution containing benzidamine hydrochloride with a solution containing ketoprofen in the form of lysine salt. The study included 241 participants, 120 in the ketoprofen group and 121 in the benzydamine group. The effectiveness of a 15ml mouthwash solution containing benzydamine hydrochloride at 22.5mg in 15ml was compared with a 10ml solution containing ketoprofen lysine salt at 160mg in 10ml. Both solutions diluted in 100ml of water. Patients were advised to gargle with the assigned substance twice a day until pain symptoms subsided, or for a maximum of 7 days. After 3 days of treatment, a physical examination of the mouth and throat was performed, particularly focusing on the presence of mucosal swelling and congestion. For patients whose pain persisted for more than 3 days, a reexamination was performed after the symptoms had resolved.

The results proved to be statistically significant and in favor of ketoprofen - showing longer analgesic effects after the first dose and shorter duration of pain symptoms. The most commonly reported side effects of both substances were feelings of numbness and tingling of oral tissues, thirst, nausea and dry mouth. Patients in the ketoprofen group reported fewer side effects, suggesting a good safety profile for the formulation. [24]

A retrospective study by Marseglia et al. showed the efficacy of ketoprofen in acute upper respiratory tract infections in adolescents as well.

Pediatricians working as general practitioners receiving children and adolescents participated in the study. The data collected included patients with upper respiratory tract infections taking ketoprofen lysine salt for 3 days. During the study, which lasted 5 days, the presence of symptoms and fever were monitored daily using the VAS scale. Data were collected from 61 patients, both male and female, whose mean age was 13.4 years.

The formulation was shown to quickly and effectively reduce not only pain symptoms, but also contribute to lowering body temperature, which is elevated during the course of the infection. Participants in the study tolerated the treatment well and reported no side effects, indicating a good safety profile for the drug. [25]

The study by Ruperto et al. also shows that the efficacy of ketoprofen lysine salt in the treatment of sore throat in the course of acute pharyngitis in children is comparable to that of paracetamol.

The study involved 97 patients between the ages of six and twelve with a diagnosis of acute pharyngitis and palatine tonsillitis. The group was divided into three equal parts, taking placebo, paracetamol at a single dose of 12mg/kg body weight, and ketoprofen lysine salt at a dose of 40mg, respectively.

The results show significant superiority of paracetamol over placebo one hour after administration, and comparable efficacy of ketoprofen and paracetamol. All treatments were well tolerated by patients, confirming that both paracetamol and ketoprofen are effective and safe treatments for sore throat associated with infection in the outpatient setting. [26]

A study by Karpov et al. evaluated the efficacy of ketoprofen in the treatment of postoperative pain during tonsillectomy (tonsillectomy). The study included 120 patients between the ages of six and eighteen.

Patients were divided into groups of equal size, which were administered different analgesics. Members of the first group took ketoprofen lysine salt as an oral solution in cases of severe sore throat. Patients in the second group were given ketoprofen lysine salt orally three times a day during the three days following treatment. In the third group, patients were given ibuprofen orally if they reported severe sore throat. Patients in the fourth group received ketoprofen lysine salt as a topical application solution twice a day for three days after surgery.

Pain severity was assessed using the VAS scale. The study showed that patients in the second group, using ketoprofen lysine salt solution orally three times a day for three days, reported the greatest pain relief within 24 hours after treatment compared to the other groups. Differences in pain intensity between patients in groups one, three and four were not statistically significant. Patients participating in the study did not report severe adverse effects of the therapy. No participant reported bleeding that could be a consequence of NSAID drugs.

The results of the study show that the use of ketoprofen orally three times a day in the postoperative period has a measurable effect on postoperative pain relief for tonsillectomy, making it an effective and safe alternative to other NSAID drugs. [27]

The efficacy of ketoprofen in the form of lysine salt in reducing sore throat symptoms in patients after surgical procedures is also confirmed by a study by Durnovo et al. The study evaluated the efficacy of ketoprofen in the form of sachets and a topical solution in patients in the recovery period after oral procedures such as oral vestibular plastic surgery, periodontal procedures and surgical tooth extractions.

The results of the study showed that the analgesic effect of ketoprofen lysine salt in the form of sachets or topical solution appeared as early as twenty-thirty minutes after use and lasted for up to eight hours. The effect was much more noticeable in patients who had open surgical wounds. The results of the study indicate

that ketoprofen lysine salt is an effective post-operative analgesic in patients following oral and maxillofacial surgery and dental procedures. It also has a good safety profile, thanks to its neutral pH that does not irritate the gastrointestinal tract. [28]

Ketoprofen is also effective in relieving pain occurring after tooth extraction. Balzanelli at al. conducted a study evaluating the efficacy of ketoprofen lysine salt in the form of topical granule sachets.

The study involved sixty patients following third molar extraction (commonly known as wisdom teeth). The participants were divided into two equal groups, with one receiving a placebo for three days and the other receiving 80mg of ketoprofen lysine salt in the form of a sachet of topical granules. Symptoms related to inflammation (redness, warming, swelling and pain) were assessed on the first and third days of the drug. Pain severity was assessed using the VAS scale: before the first administration, thirty minutes after treatment, at the first, second, third, fourth, fifth, sixth and eighth hours after the first administration.

The study showed significantly higher efficacy of ketoprofen compared to placebo in reducing symptoms of inflammation on the first day of treatment. The analgesic effect was evident as early as thirty minutes after administration. A global analysis of the results showed that 96.6% of patients taking ketoprofen experienced a significant reduction in symptom severity, compared to only 26.7% of patients taking placebo.

Three cases of adverse reactions were reported during the study, relating to reflux symptoms. Two of these were registered in patients taking ketoprofen, and one in a pajent in the placebo group.

The results of the study confirmed the efficacy of ketoprofen lysine salt at a dose of 80mg in the treatment of post-operative pain in patients after tooth extractions. The safety profile of the drug is also not objectionable. [29]

The effects of the lysine salt of ketoprofen on the gastric mucosa were examined by Fatti at al. in a study involving healthy volunteers.

Twenty healthy volunteers were assigned to two groups, one of which received 80mg of ketoprofen lysine salt in the form of a sachet of oral granules, and the other a placebo. The patients underwent gastroscopy before the drug was administered, and then ten days after taking the substance.

The safety of the drug was assessed based on laboratory results, adverse reaction reports, investigator assessment and evaluation of gastroscopy results. No adverse reactions were reported during the study, and no significant differences were observed in laboratory results or in the final evaluation of gastroscopy results. [30]

Summary

Summarizing the results of the available studies and the literature review, ketoprofen appears to be a promising and effective alternative for the treatment of sore throats of various origins in both adults and children.

Ketoprofen lysine salt in the form of a gargle solution is characterized by a faster and longer analgesic effect compared to benzidamine chloride solution, commonly used in preparations for the symptomatic treatment of sore throat. [24]

Ketoprofen in the form of lysine salt is effective in the treatment of sore throat in the course of acute pharyngitis in the pediatric population. Study results show efficacy comparable to paracetamol and a significant advantage over placebo. In addition, it also contributes to reducing the severity of other infectious symptoms by reducing inflammation or effectively lowering body temperature. [25, 26]

Ketoprofen is also effective in treating pain symptoms during recovery from oral and throat surgery.

Pediatric patients following tonsillectomy who took oral ketoprofen three times a day reported significantly less symptom severity compared to patients taking ibuprofen or ketoprofen in another form. [27]

In patients undergoing palatal or oral vestibular plastic surgery, ketoprofen in the form of sachets of topical granules proved effective. Patients experienced pain relief as early as twenty minutes after application of the drug and reported a reduction in pain symptoms for up to eight hours after application. [28]

Similar results were obtained in a study evaluating the effectiveness of ketoprofen in relieving pain after tooth extraction. The analgesic effect appeared as early as thirty minutes after taking the drug, and a reduction in inflammatory symptoms was evident as early as the first day of treatment. [29]

Ketoprofen in the form of lysine salt also has a good safety profile. Thanks to its neutral pH, it does not irritate the gastrointestinal mucosa. In all studies analyzed, the number of side effects reported by patients using ketoprofen was comparable or less than that of the compared drugs. The most common side effects were a feeling of numbness and tingling of oral tissues, thirst, nausea and dry mouth, but they occurred as frequently with benzidamine chloride solution as with ketoprofen lysine salt solution. [24]

In a study of the efficacy of ketoprofen topical granules after tooth extraction, two cases of reflux symptoms were reported after taking the product, but a similar adverse event was also reported in the placebo group. [29]

In a study focusing on gastrointestinal complications, which assessed the condition of the gastrointestinal mucosa by gastroscopy before and after ketoprofen administration, no significant differences were noted between the drug and placebo groups. [30]

The work presented in the above paper shows that ketoprofen is an effective alternative to the preparations currently used in the treatment of sore throat. It shows high efficacy in cases of sore throat of infectious etiology, as well as in the treatment of postoperative pain. It can be used successfully both in adults and in the pediatric population.

In addition, ketoprofen in the form of lysine salt is characterized by a small number of side effects, making it not only effective but also safe.

Given the prevalence of sore throat as a symptom of numerous medical conditions, its inclusion in routine clinical practice may provide tangible benefits. Despite promising study results, further evaluation of the efficacy and safety of ketoprofen in the treatment of sore throat is indicated. Direct comparisons with other preparations may be particularly useful. Comparative analyses may facilitate the development of guidelines and recommendations that will allow an unequivocal assessment of the usefulness of ketoprofen in the clinical practice of treating pharyngitis and solidify its position in the analgesic ladder.

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