

THE USE OF NEOMYCIN AND HYDROCORTISONE IN THE TREATMENT OF EXTERNAL OTITIS

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EXTERNAL otitis has been widely discussed in the medical literature,¹⁻⁶ but two primary questions concerning the disease have not yet been fully answered: 1) What is the causative mechanism? 2) What is the most effective treatment for resistant cases? The second question is the concern of this report, because we have encountered many severe and resistant cases of external otitis, and our current method of treatment has given uniformly satisfactory results in a series of 57 patients selected for this type of treatment. Some of the patients with recurrences of the disease previously had received most of the antibiotics and the accepted local types of therapy. We do not wish to infer, however, that the newer therapy represents a panacea for all types of otitis externa.

General Considerations

The term "external otitis" implies that there is inflammation of the external ear. Actually in most cases the inflammation is limited to the auditory canal and external meatus, but at times the conchal portion of the auricle or the entire pinna may be involved. The ear drum also may be inflamed or may be covered with granulations.

These external ear infections are universal but more common in the warmer and tropical climates. In the temperate zones, the incidence is high enough to make it one of the most common complaints seen in otologic practice. It is a disease of all ages but seldom occurs in the Negro race. The ear canals of Negroes are shorter, more straight and wider, and, therefore, less favorable circumstances exist for its development. The anatomic structure of the external ear is undoubtedly a factor in the development of infection. The small, tortuous canal offers highly favorable circumstances for the development of infection especially when we consider it terminating in a blind recess. Other contributing factors are undoubtedly the warm, moist contents of the recess which is dark and poorly ventilated.

External otitis can be clinically classified as acute, subacute, chronic, and

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recurrent; the objective variations encountered are but graded phases of the same disease.

In the *most severely acute cases*, the patient complains chiefly of intense pain that is aggravated by manipulation of the external auditory canal or by chewing. The auricle may appear uninvolved, but there is frequently periauricular edema and partial or complete obliteration of the canal lumen by the edematous skin of the canal wall. In the remaining lumen are seen purulent secretions, often of various shades of yellow or green, either of thin or of thick consistency, and mixed with exfoliated debris. The patient usually complains of itching of the canals, sometimes intense. Frequently, it is difficult to visualize the tympanic membrane because of a smooth, diffuse sagging of the superior canal wall.

In *chronic cases* there are variable degrees of thickening of the skin of the external auditory canal and of the external auditory meatus which results in reduction of the lumen of the entire canal. Often, the canal is lined with exfoliated debris, either moist or dry, which can be peeled or stripped away by gentle manipulation; or this debris may fill the canal, including the sulcus tympanicus. The drum, or the small portion of it that can be visualized, usually is dull and opaque with loss of light reflex. Usually both auditory canals are involved, but not always to the same degree. Most cases of external otitis occur during the hot summer months but many patients have perennial or recurrent exacerbations of acute infection. Furunculosis of the external auditory canal most frequently develops in patients who have a pre-existing external otitis.

Bacteriology

Bacteriologic studies were made of all our cases; the bacteria were identified and sensitivity tests were made. Previous reports have stated that gram-negative bacilli were the predominant organisms; however, we found that micrococci (both staphylococcus and streptococcus) were predominant in approximately half of our cases. The gram-negative organisms were about evenly divided between *B. coli* and *Pseudomonas aeruginosa*. Other frequent gram-negative organisms were *B. proteus* and *Alcaligenes faecalis*. In this group there were only four fungal infections and all were due to candida. Approximately one half of the patients had been treated previously with many and various topical medicaments and antibiotics; no doubt the bacterial content had been altered in this group. However, in the untreated group, the organisms were about evenly divided between gram-positive cocci and gram-negative bacilli. It was noted that the great majority of the patients in the untreated group had more than one organism present, as proven by cultures taken at the time of the patients' first visits.

Differential Diagnosis

There are many other diseases of the external auditory canal in which the

symptoms may resemble those of external otitis. Brief descriptions of the symptoms of a few of the more common of these conditions follow:

Seborrheic dermatitis. The skin is erythematous, scaly, and greasy; the scalp, eyebrows, nasolabial folds, postauricular skin folds and skin of the neck usually are the parts that are affected. The clinical picture may be obscured by coexistent traumatic excoriations, superimposed infection, crusting, and weeping of the skin, or by changes that have been brought about by overtreatment.

Herpes dermatitis (simplex and zoster). This inflammatory skin disease is characterized by the formation of multiple thin-walled vesicles that cause burning and smarting. In herpes zoster, the eruption of vesicles is unilateral and follows the course of a cutaneous nerve.

Neurodermatitis. This condition is characterized by excoriated, scaly, dry, sharply circumscribed patches with thickening of the skin and increase of skin markings. Other isolated plaques are usually present on skin of the neck, of the eyelids, and of the antecubital areas.

Allergic dermatitis. The skin is erythematous, scaly and excoriated; or it may be vesiculated, hypersensitive, and crusted, with attendant itching and formation of bullae. Skin in various portions of the body including that of the external ear may be involved. Usually the patient has a past history of other allergic diseases, and in some instances there also is a family history of these conditions. Topical medications used on the skin for infection of the external auditory canal are the most common sensitizing agents. This is particularly true of antibiotics, of mercurials, of sulfas, and of local anesthetic agents. Other sensitizing agents include cosmetics, lacquers, perfumes, and jewelry. Unfortunately, improvement does not immediately follow the removal of the offending agent.

Senile skin changes. The skin is atrophied. It frequently is dry, thin, and tan or freckled. Vitamin deficiencies are an etiologic factor, as proved by the frequently beneficial effects of administering vitamin A.

Fungi and yeasts (otomycosis). Several fungi may cause inflammatory reaction in the external auditory canal. There is usually intense itching, but occasionally blocking of the canal by the moldy debris is the only symptom. The color of the molds vary from whitish to black. The two common fungi are the *pityrosporum* and the several varieties of the *aspergillus* (*niger* and *flavus*). These fungi may cause only a superficial scaling similar to seborrheic dermatitis, or secondary bacterial invaders may be present and the inflammatory changes that develop will completely overshadow the usual appearances in the external canals produced by pure fungal infections.

In these mixed bacterial and fungal infections the fungal component may not be evident until after the bacterial infection has been cleared.

Major dermatopathies. Any of these diseases, such as lupus erythematosus, pemphigus, psoriasis, lichen planus, may involve the skin of the ear canal, but each disease also is manifested by systemic symptoms and evidences of the disease elsewhere in the body. Some of these conditions may be fatal.

Therapy

One of the chief reasons for the failure of treatment in external otitis is inadequate cleansing of the external auditory canal before applying medications. Removal of the obstructing pus and debris permits the selected agent to come into direct contact with the infected tissues. In addition, removal of accumulations from the external canal discourages the propagation of bacteria by creating conditions less favorable for their growth. The suction method, if carefully done without causing trauma, is an excellent method of removing the secretions; it is less time consuming than irrigation of the canal which must be followed by careful drying. The suction technic is best accomplished by using 17-gauge tympanomeatal aspirators bent to the proper angle for good visualization. These aspirators also are extremely effective in removing devitalized epithelium that may remain adherent to the canal walls even after attempts have been made to dislodge it with cotton applicators or by irrigation.

The selection of an appropriate drug to apply to the carefully cleansed canal has been the subject of much controversy. Pharmaceutical houses have been prolific in producing antibiotics and other preparations for topical application; physicians have been liberal in their use of these preparations. Too often the results have been disappointing, and in many instances the patient has been actually made more uncomfortable by the drug because it produced a local skin-sensitivity reaction. This sensitizing reaction frequently has been noted with the sulfa compounds, penicillin, terramycin, aureomycin and streptomycin, when they have been applied locally. The incidence of reaction was particularly high when the drug had been applied to a raw weeping surface. Because of the frequent ineffectiveness of the various recommended drugs and the not infrequent skin-sensitivity reaction, the search has persisted for a more suitable therapeutic agent or combination of agents. An antibiotic having a wide range of effectiveness is necessary for the successful treatment of external otitis. It should effectively combat both gram-positive and gram-negative bacteria; it should have a low tendency for producing bacterial resistance; and it should not cause allergic skin reactions. In the treatment of pyogenic skin infections, dermatologists have found that neomycin is the most effective agent yet produced for topical antibiotic therapy. Its clinical value is greatly enhanced since it almost never causes allergic reactions in the skin. Also it has been shown that when hydrocortisone is applied locally to the skin in cases of skin inflammation, including external otitis, it relieves the inflammation during the administration, but that relapses occur when therapy is discontinued.

The addition of neomycin to hydrocortisone has the therapeutic advantage of controlling the underlying infection due to its antibacterial action, thereby preventing the recurrences that are usually encountered when hydrocortisone alone is used. With the combination of these highly favorable therapeutic agents it seemed obvious that it should be tried in a series of controlled cases of external otitis. This form of treatment for external otitis was started on this series of patients June 18, 1953, and the 57 cases reported include only those that had

cultures and sensitivity studies determined before treatment was begun.

The commercial preparation used was NeoCortef 1.5 per cent suspension and was supplied by the Upjohn Company. NeoCortef is a sterile suspension containing 15 mg. of hydrocortisone acetate, 5 mg. of neomycin sulfate, and 0.02 mg. per cc. of Myristyl-gamma-picolinium chloride (pH₇). The following technic was employed: Cultures were taken from both ears of each patient. The external auditory canals were carefully cleansed by 17-gauge aspirator; care was taken to remove, when possible, the purulent discharge and epithelial debris from the innermost portion of the canal. The NeoCortef suspension was then instilled into the external auditory canal. The patient was instructed to repeat this procedure three times daily at home. (It is easier for the patient to apply the drops when in a reclining position, lying on the side opposite to the one being treated). The solution was allowed to remain in the canal for ten to fifteen minutes. The same procedure may be used for the opposite ear if indicated. Occasionally, the extreme pain in and swelling of the canal wall would not permit cleansing by suction on the patient's first visit; however, it usually was possible after one or two days of treatment.

The suction method of cleansing of the canal probably should be utilized only by the experienced otologist because the canal wall often is extremely sensitive and the slightest amount of manipulation is excruciatingly painful. It is recommended that those less experienced in otology perform a gentle irrigation of the canal and then carefully dry it. In the severe cases with complete or almost complete obstruction of the external ear canal, we recommend that the physician see the patient daily for two or three days, or until the canal can be adequately cleansed and inspected.

Response to Therapy

In our series, the response to this type of treatment was dramatic: patients noted relief from itching almost immediately, with diminution of pain and edema of the external auditory canal and lessening of the discharge within 12 to 24 hours. In most cases there was complete subsidence of all symptoms in five to seven days; rarely was it necessary to continue this treatment for more than seven days. In approximately one half of the cases, mild recurrences occurred in two to six weeks, but in each case there was an immediate response to a second course of the treatment, usually administered by the patient himself at home without an office visit. In the cases of circumscribed external otitis (localized to external auditory meatus), the NeoCortef 2.5 per cent ointment was immediately and uniformly effective, and usually did not require more than five to seven days of treatment. In these cases the ointment used contained 25 mg. of hydrocortisone acetate, 5 mg. of neomycin sulfate, 2 mg. of methylparaben and 1.8 mg. per Gm. of Butylp-hydroxybenzoate. In the majority of the 57 cases not more than two courses of treatment were necessary to get complete relief of symptoms.

Approximately one half of the patients had received treatment before being seen here and in some of them several of the commonly used antibiotics and topical solutions had been administered without improvement. Five of the patients who had been troubled with external otitis for many years had to use the 2.5 per cent NeoCortef ointment before they obtained complete relief without recurrences.

SUMMARY

In this series of cases, the combination of neomycin and hydrocortisone applied topically, either as a suspension or in ointment form was found to be highly effective in the treatment of acute, subacute and chronic external otitis. The incidence of recurrence was also greatly reduced. Repeated courses can be carried out with continued effectiveness and a very low incidence of eczematous contact dermatitis.

The preparations employed appear to be a valuable addition to the therapy of external otitis. They combine the highly desirable anti-inflammatory, anti-bacterial action with little or no tendency to produce allergic skin sensitivity.

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