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# **Proposal for a New Clinical Treatment of Spontaneous Cholesteatoma of the External Auditory Canal with Clobetasol Propionate**

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#### Abstract

Background: External Auditory Canal Cholesteatoma (EACC) is a disease in which the canal skin spontaneously acquires a hyperproliferative osteolytic nature leading to canal enlargement which can invade the middle ear and mastoid. The treatment of choice is generally surgical, while clinical approaches tend to be ineffective.

Objective: To assess the outcomes of clinical treatment of cholesteatoma involving the external auditory canal only using clobetasol propionate.

Material and Methods: Cases with spontaneous cholesteatoma of the EAC treated at the otologic surgery clinic of a university teaching hospital between 2011 and 2018 were assessed. The sample included only cases involving the EAC presenting no erosion into the mastoid cavity or tympanic membrane perforation.

Results: Of the 18 cases followed, disease control was achieved in 14 (77.7%), whereas no improvement was observed in 4 cases (22.2%).

### **OPEN ACCESS**

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Conclusion: Clinical treatment using Clobetasol Propionate controlled the disease in a large number of patients, precluding the need for traditional surgical procedures.

Keywords: Cholesteatoma; External auditory canal; Surgery; Clobetasol propionate

#### Introduction

Chronic diseases of the External Auditory Canal (EAC) are often confounded and classified under the same name. Consequently, studies on EAC Cholesteatoma (EACC) can include cases of keratosis obturans and benign necrotizing otitis externa, besides skin retention in malformations or traumatic stenosis of the EAC [1-3].

The focus of the present study was the assessment of treatment for spontaneous External Auditory Canal Cholesteatoma (EACC). The etiology of EACC is unknown [2].

In most case the disease presents as chronic spontaneous suppuration, sometime fetid, resembling symptoms of Acquired Middle Ear Cholesteatoma. On otoscopy, large amounts of contaminated keratin debris can be seen, which is hard to remove even through rinsing or use of forceps, and granulation tissue can also be evident (Figure 1). Otoscopy discloses significant enlargement of the EAC. In some cases, the tympanic membrane can be perforated, with migration of skin into the middle ear, making the disease further resemble acquired middle ear cholesteatoma. More advanced cases may involve erosion of the canal wall into the mastoid cavity and migration of skin into this cavity (Figure 2) [4].

All patients report a long unsuccessful history using local clinical treatment, such as cleansing, application of ear drops containing antibiotics, antifungal agents and corticoid steroids.

In spontaneous cholesteatoma of the EAC, Computed Tomography (CT) scans are usually performed, disclosing canal widening with diffuse, irregular, osseous erosion, particularly in the tympanic bone, but also in the mastoid region of the canal. At this initial stage, mass obliterating the canal lumen can be seen, with normal aeration of the middle ear and mastoid cells (Figure 2). At a later stage, the tympanic membrane can become perforated and the bone wall eroded, leading to migration of skin from the EAC into the middle ear and mastoid cavity (Figure 3) [5].

The anatomopathological test (Hematoxylin-eosin) and immunohistochemistry reaction to keratin 16 and Mib 1 reveal skin with the same characteristics as middle ear cholesteatoma (Figure 4) [6].

The clinical treatment approaches used to date and investigated in the literature, such as flushing with acid solutions (vinegar - 4% acetic acid), application of drops containing antibiotics and corticoid steroids, antifungal agents and Burow's solution, fail to promote the desired effects.

The treatment reported by all authors is normally surgical entailing removal of the aberrant skin from the whole canal and the external layers of the tympanic membrane. In the event of erosion of the wall and invasion of the mastoid canal, an open cavity tympanomastoidectomy is performed [7,8].

#### **Objective**

The objective of the present study was to assess the outcomes of clinical treatment for cholesteatoma involving the External Auditory Canal (EAC) only, using Clobetasol Propionate in patients from an otologic surgery clinic. This medication is a highly potent topical corticoid steroidal agent generally used in hyperproliferative diseases of the skin, such as psoriasis.

#### **Method**

The study was approved by the Research Ethics Committee of the Institution (Permit no. 3279616).

A longitudinal retrospective observational study was conducted.

Cases with spontaneous cholesteatoma of the EAC treated at the otologic surgery clinic (digital records archive) of a university teaching hospital between 2011 and 2018 were assessed. The sample included only cases involving the EAC presenting no erosion into the mastoid cavity or tympanic membrane perforation (where such cases are indicated for surgical management – Stage 1) [5]. The patients selected were treated using Clobetasol Propionate (cream). No other diseases of the EAC were observed or treated.

Patient histories were collected, including age, gender, otorrhea duration, bilaterality, auditory sensation, pain or pruritus.

Only cases involving the EAC, as confirmed by standard CT disclosing canal enlargement due to bone erosion without migration to mastoid cells or middle ear, were clinically treated (Figure 2) [5]. Cases exhibited enlarged EAC, partially filled by keratin debris and purulent secretion, and in some instances had granulation.

After flushing and cleansing of debris using forceps (only partial clearance possible), the canals were photographed using a fiber optic probe (Figure 1).

Clobetasol cream (0.5 mg/gr) was applied within the EAC using a cotton-coated stylus or inoculated using a syringe, and removed by flushing after 1 week. Treatment was repeated if total regression of the lesion was not achieved (normal skin appearance without debris or granulation). After the skin had attained a normal appearance, treatment was maintained using Clobetasol Propionate hair ointment (0.5 Mg/gr) once weekly. Cases non-responsive to treatment were deemed surgical. The EAC was photographed and filmed using a fiber-optic probe at each return visit.

## **Results**

A total of 31 patients with EAC cholesteatoma were assessed, 2 of which had bilateral lesions, giving a total of 33 ears studied. Regarding gender, the patient group comprised 20 females (64.5%) and 11 males (35.5%).

The mean age was 37 years, but this data was disregarded because time of disease onset reported by patients was often unclear. Otorrhea duration was also not considered due to unreliable data. All patients had chronic otorrhea, sometimes together with unpleasant odor and presence of pruritus. None of the patients reported pain.

All 33 ears were scanned using Computed Tomography (CT). All ears exhibiting typical lesions (total 18), such as enlargement of the EAC and osseous erosion without involvement of the middle ear, were included. Cases of lesions with migration of skin into the middle ear or mastoid cells were excluded and referred for surgical treatment (Figure 3).

Two ears showed no improvement in the condition, while another 2 improved initially and then relapsed during follow-up.



Figure 1: Cholesteatoma of EAC exhibiting bone erosion, large amount of contaminated keratin debris and presence of granulation.



Figure 2: Cholesteatoma of EAC in right ear involving canal only, without invasion of middle ear or mastoid cells. Shin SH et al. [5] Grade I.

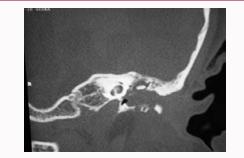
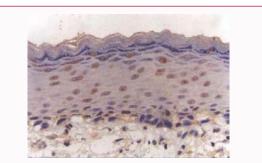


Figure 3: Cholesteatoma of EAC in left ear, invading middle ear and mastoid cells. Shin SH et al. [5] Grade III.



**Figure 4:** Immunohistochemistry of EAC cholesteatoma, resembling acquired middle ear cholesteatoma. Note large amount of keratin. Source: RIBEIRO FAQ; PEREIRA CB; ALMEIDA R- Comparative study of histological aspects and chemistries between the cholesteatoma of external acoustic meatus and spontaneous cholesteatoma acquired the middle ear (same author).



**Figure 5:** After Clobetasol Propionate treatment, revealing enlarged canal, whole tympanic ring free of debris or inflammatory process, and tympanic membrane with normal appearance.

Thus, of the 18 ears treated, 14 (77.7%) were lesion free posttreatment and, according to patients, premorbid level of hearing was retained. The first cases treated have remained symptom free after over 1 year.

#### Discussion

A sample of 33 ears with characteristic lesions of spontaneous EAC cholesteatoma was assessed, a considerable number compared to previous literature reports. The disease was confirmed by otoscopy using an optic fiber and CT. There were no candidates for radical mastoidectomy or tympanoplasty (Stages II and III) [5]. Hitherto, the surgical approach in cases involving canal only, entailed deepithelization of the EAC and tympanic membrane in order to remove skin displaying hyperproliferative characteristics. This procedure led to significant granulation of the region, often causing stenosis of the EAC. In a bid to prevent this sequela, we recommend the use of Clobetasol Propionate for its known property of controlling some proliferative diseases of the skin, such as psoriasis. Initial treatment consisted of filling the entire canal with cream and, after regression of the lesions, continuation of treatment using Clobetasol Propionate hair solution applied by the patient. Of the initial 33 ears selected,

16 discontinued treatments for specific personal reasons. Therefore, a total of 18 ears were assessed. Of this total, 2 had poor evolution and were operated on, whereas 2 relapsed after commencing treatment. Thus, the canal skin of the remaining 14 ears attained a normal appearance without scaling, keratin debris, inflammation, infection or symptoms. After treatment, the canals remained wide, facilitating visualization of the healthy tympanic membrane (Figure 5). Patients reported preserved hearing and no lesions of the middle ear or complaints during follow-up ( $\geq$  1 year in some cases). The patients continued use of the medication in the form of hair ointment applied once weekly. Therefore, 77.7% of cases of spontaneous EAC cholesteatomas were managed using clinical treatment, patients traditionally managed surgically with inherent costs and sequela.

Given the novel nature of this treatment, longer term clinical and radiographic control should be performed and a larger number of cases assessed.

#### Conclusion

Clinical treatment using Clobetasol Propionate proved effective control of EAC cholesteatoma in a large number of patients, avoiding the usual surgical procedure, in cases restricted to the auditory canal, which may be a future therapeutic option. New case-control studies could be performed to determine the effectiveness of the medication in this disease.

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